CURRICULUM VITAE

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CONTACT INFORMATION

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SUMMARY

Director, New Mexico Clinical Research & Osteoporosis Center, Albuquerque, NM
Director, Bone Health TeleECHO (Extension for Community Healthcare Outcomes), UNM Health Sciences Center, Albuquerque, NM
Clinical Assistant Professor of Medicine, University of New Mexico Health Sciences Center, Albuquerque, NM
Vice President, National Osteoporosis Foundation
President, Osteoporosis Foundation of New Mexico
Past President, International Society for Clinical Densitometry
Review Editor, Osteoporosis International
Principal investigator, numerous osteoporosis clinical trials
Author, over 280 publications in peer-reviewed journals, as well as books, book chapters, and electronic publications

EDUCATION

Residency: Internal Medicine, University of New Mexico Affiliated Hospitals, Albuquerque, New Mexico, 1973 – 1975
Internship: Rotating, University of New Mexico Affiliated Hospitals, Albuquerque, New Mexico, 1972 – 1973
Medical School: Northwestern University Medical School, MD Chicago, Illinois, 1972
Undergraduate: Amherst College, BA, Cum Laude Amherst, Massachusetts, 1968

CITIZENSHIP: USA

MILITARY

United States Air Force, 1975 – 1977

MEDICAL PRACTICE POSITIONS

New Mexico Clinical Research & Osteoporosis Center
Albuquerque, NM
1998 – Present

New Mexico Medical Group, Albuquerque, NM
1986 – 1998

Private Practice, Albuquerque, New Mexico
1977 – 1986

Military Medical Officer, Goodfellow AFB, San Angelo, Texas
1975 – 1977

TEACHING POSITIONS

University of New Mexico Health Sciences Center
Clinical Assistant Professor of Medicine

International Society for Clinical Densitometry
Faculty, Bone Densitometry Course, Vertebral Fracture Assessment Course, Osteoporosis Academy

American College of Physicians
Faculty, osteoporosis management and bone densitometry

MEDICAL EDUCATION DIRECTORSHIPS

Santa Fe Bone Symposium (annual event)
Program Director, 2000 – Present

New Mexico Bone Club (recurring events 3 to 4 times per year)
Education Director, 1997 – Present

UNM Bone Health ECHO (Extension for Community Healthcare Outcomes)
Director, 2015 – Present

MEDICAL ADMINISTRATIVE POSITIONS

President, International Society for Clinical Densitometry
2003 – 2005

President, Osteoporosis Foundation of New Mexico
2000 – Present

Medical Director, Gentiva Home Health Care, Albuquerque, New Mexico
2000 – 2004

Medical Advisor, Albuquerque Osteoporosis Support Group
1999 – Present

Osteoporosis Director, New Mexico Clinical Research & Osteoporosis Center
1998 – Present

Medical Director, Osteoporosis Center, New Mexico Medical Group
1997 – 1998

Medical Director, Horizon Specialty Hospital, Albuquerque, New Mexico

1995 – 1998
Medical Director, New Mexico Medical Group, Albuquerque, New Mexico
1994 – 1998
Medical Director, St. Francis Gardens, Albuquerque, New Mexico
1993 – 1996
Medical Director, Health South Rehab. Hospital, Albuquerque, New Mexico
1991 – 1993
President, New Mexico Medical Group, Albuquerque, New Mexico
1986 – 1994
Chairman, Dept. of Medicine, Presbyterian Hospital, Albuquerque, New Mexico
1996 – 1997
Chief of Internal Medicine, Goodfellow AFB Clinic, San Angelo, Texas
1975 – 1977

EDITORIAL POSITIONS

Senior Editor
Clinical Investigation, 2010-2015
Associate Editor
Journal of Clinical Densitometry, 2009-
Osteoporosis International, 2015-
Editorial Board
Expert Opinion on Biological Therapy, 2010-
Journal of Bone and Mineral Research, 2016-
Journal of Clinical Case Reports, 2011-
Journal of Clinical Trials, 2010-
Journal of Drug Assessment, 2010-
Journal of Osteoporosis, 2008-2012
Osteoporosis International, 2009-
Osteoporosis and Sarcopenia, 2016-
Editorial Board Advisor/Consultant
Current Medical Research & Opinion, 2008-2010
Medscape Ob/Gyn & Women's Health, 2010-
Women's Health, 2008-

REVIEWER FOR MEDICAL JOURNALS

Aging Health
American Journal of Managed Care
Annals of Internal Medicine
Archives of Internal Medicine
Archives of Medical Research
Archives of Osteoporosis
Archives of Pediatrics & Adolescent Medicine
Arthritis & Rheumatism
Bone
British Medical Journal Open
Canadian Medical Association Journal

Cleveland Clinic Journal of Medicine
Clinical Drug Investigation
Clinical Endocrinology
Clinical and Experimental Medicine
Clinical Interventions in Aging
Clinical Therapeutics
Contemporary Clinical Trials
Current Medical Literature in Rheumatology
Current Medical Research and Opinion
Drugs
Drugs & Aging
Endocrine
Endocrine Practice
Endocrine Research
EU Endocrinology
European Journal of Endocrinology
European Journal of Neurology
European Journal of Nutraceuticals & Functional Foods
European Journal of Obstetrics & Gynecology and Reproductive Biology
Expert Opinion on Drug Delivery
Expert Opinion on Drug Metabolism & Toxicology
Expert Opinion on Investigational Drugs
Expert Opinion on Pharmacotherapy
Expert Review of Clinical Pharmacology
Expert Review of Endocrinology & Metabolism
Future Rheumatology
Gender Medicine
Grand Rounds in Oral-Systemic Medicine
Indian Journal of Orthopaedics
Journal of Affective Disorders
Journal of Bone and Mineral Research
Journal of Clinical Densitometry
Journal of Clinical Endocrinology & Metabolism
Journal of Clinical Outcomes Management
Journal of Epidemiology and Global Health
Journal of General Internal Medicine
Journal of Medicine
Journal of Musculoskeletal and Neuronal Interactions
Journal of Orthopaedic Trauma
Journal of the American Geriatrics Society
Journal of the American Medical Association
Maturitas
Mayo Clinic Proceedings
Molecular and Cellular Therapies
Nature Clinical Practice Endocrinology & Metabolism
Nephrology

New England Journal of Medicine
Osteoporosis International
Pharmacy and Therapeutics
Physicians' Information and Education Research (PIER), ACP
Postgraduate Medicine
Recent Patents on Endocrine, Metabolic & Immune Drug Discovery
Seminars in Arthritis & Rheumatism
Southern Medical Journal
The Physician and Sportsmedicine
Women's Health

CLINICAL TRIAL DATA MONITORING COMMITTEES

A randomized, double-blind evaluation of the antiviral efficacy, safety, and tolerability of tenovir disoproxil fumarate versus placebo in adolescents with chronic hepatitis B infection. Gilead. GS-US-174-0115. 2008.

A randomized, double-blind evaluation of the antiviral efficacy, safety, and tolerability of tenovir disoproxil fumarate versus placebo in pediatric patients with chronic hepatitis B infection. Gilead. GS-US-174-0144. 2012.

GRANT REVIEWER

Research into Ageing, London, UK
Medical Research Council, London, UK
Health Research Council of New Zealand

EXPERT PANELS

NASA Bone Research and Clinical Advisory Panel
Ongoing advisory meetings for fracture risk mitigation with long duration spaceflight

Bone Summit II on the Risk for Early Onset Osteoporosis due to Spaceflight, National Aeronautics and Space Administration, Lyndon B. Johnson Space Center, Houston, Texas, November 4-5, 2013

Position Development Conference, International Society for Clinical Densitometry, Tampa, Florida, March 21-23, 2013

Early Onset Osteoporosis Summit, National Aeronautics and Space Administration, Lyndon B. Johnson Space Center, Houston, Texas, June 7-8, 2010

The State of the Art in the Management of Osteoporosis, The Office on Women's Health of the US Department of Health and Human Services, Washington, DC, July 28-29, 2003

Position Development Conference, International Society for Clinical Densitometry, Denver, Colorado, July 20-22, 2001

BOARD CERTIFICATION

American Board of Internal Medicine, June 1975 (No. 50061)

OTHER CERTIFICATION

International Society for Clinical Densitometry, Certified Clinical Densitomitrist, April 1997 - Present

MEDICAL LICENSE: New Mexico, November 1973 (No. 73 - 160)

AWARDS

American Society of Internal Medicine, "Young Internist of the Year", 1986
International Society for Clinical Densitometry, “ISCD Physician of the Year”, 2001
International Society for Clinical Densitometry, “Paul D. Miller ISCD Service Award”, 2006
American College of Physicians, “Laureate Award”, 2006
The Endocrine Society, “Outstanding Reviewer Recognition Award”, 2015

PROFESSIONAL ORGANIZATIONS

American College of Physicians – American Society of Internal Medicine (ACP-ASIM)
- Managed Care Committee, 1998 – 1999
- New Mexico Chapter Council Member, 1999 – 2001

American College of Physicians
- Member, 1975
- Fellow, 1986

American Association of Clinical Endocrinologists
- Member, 2002
- Fellow, 2007

American Society for Bone and Mineral Research
- Fellow, 2018
- Professional Practice Committee, 2001 – 2004
- Scientific Program Committee, Abstract Reviewer 2005 - Present

American Society of Internal Medicine
- Retirement/Investment Committee, 1986
- Group Travel Committee, 1990 – 1992
- Managed Care Committee, 1994 – 1998

Greater Albuquerque Medical Association, 1975 – Present
- Vice President, 1981

International Bone and Mineral Society

International Osteoporosis Foundation
- Council of Scientific Advisors, 2007 – Present

International Society for Clinical Densitometry
- Board of Directors, 1999 – Present
- Public Policy Committee, Chairman, 1999 – 2001
- Interspecialty Council, Chairman, 2001 – 2003
- Co-chair, 7th Annual Scientific Meeting, 2001
- Nominating Committee, Chairman, 2005 – 2006

Corporate Advisory Committee, Chairman, 2005 – Present
Marketing Committee, Chairman, 2005 – 2006
President-Elect, 2001 – 2003
President, 2003 – 2005
Scientific Advisory Committee, Chairman, 2006 – 2009
International Relations Committee, Chairman, 2009 – Present
Public Policy Committee, Chairman, 2015 – Present

National Osteoporosis Foundation
Interspecialty Medical Council, 2005 – 2013
Implementation Committee for *Clinician's Guide to Prevention and Treatment of Osteoporosis*, 2007-2008
Board of Trustees, 2012 – Present
Annual Meeting Program Committee, 2017, 2018

New Mexico Foundation for Medical Care
Board of Directors, 1980 – 1981

New Mexico Medical Society, 1975 – Present

New Mexico Osteoporosis Foundation
Founder, 1997
Program Director, Osteoporosis Continuing Education, 1997 – Present
Chairman, Scientific Advisory Committee, 1997 – Present

New Mexico Society of Internal Medicine
Council Member, 1978 – 1998
Secretary/Treasurer, 1980 – 1981
President Elect, 1982 – 1983
President, 1984 – 1985

The Endocrine Society
Special Programs Committee, 2014 – Present

United States Bone and Joint Initiative
Board of Directors, 2012 – 2013

World Health Organization
WHO Scientific Group on Assessment of Osteoporosis at the Primary Care Level, 2004

HOSPITAL CONSULTING STAFF

Presbyterian Hospitals, Albuquerque, New Mexico
Lovelace Health Systems, Albuquerque, New Mexico

COMMUNITY ACTIVITIES

Albuquerque Public Schools, Team Physician, 1985 – Present
Albuquerque Isotopes (Triple A Baseball), Team Physician, 2002 – Present
Albuquerque Dukes (Triple A Baseball), Team Physician, 1987 – 2000
Rio Grande Nature Center, Board of Trustees, 2000 – Present
Osteoporosis Foundation of New Mexico, President, 2000 – Present

PERSONAL

Married, 4 children

Resident of Albuquerque, NM, USA, since 1972

SCIENTIFIC PRESENTATIONS

Numerous invited presentations have been given at scientific meetings in North America, South America, Europe, and Asia. These have included plenary lectures, keynote presentations, meet-the-professor sessions, oral presentations of abstracts, bone clubs, grand rounds, web-conferences, symposia, workshops, seminars, "round-table" discussions, newsletters, instructional courses, and educational programs recorded for CDs. Topics have included the following:

Adherence to Osteoporosis Therapy
Alendronate for the Treatment of Osteoporosis
Anabolic Therapy for Osteoporosis
Anticonvulsant Bone Disease
Basic Bone Physiology
Bisphosphonate Therapy for Osteoporosis
BMD, Bone Turnover, and Fractures
Bone Densitometry for Gastroenterologists
Bone Densitometry for Neurologists
Bone Densitometry for Nurse Practitioners
Bone Densitometry for OB-GYNs
Bone Densitometry for Orthopedic Surgeons
Bone Densitometry for Primary Care Physicians
Bone Densitometry for Rheumatologists
Bone Densitometry for Urologists
Bone Density and Bone Quality
Bone Density Matters
Bone Density Testing in the Evaluation of Osteoporosis
Bone Health TeleECHO / Project ECHO / TeleHealth
Bone Turnover Markers
Celiac Disease and Skeletal Health
Clinical Practice Guidelines in the Management of Osteoporosis
Combination Therapy for Osteoporosis
Controversies with Osteoporosis
Cost-utility Analysis for Osteoporosis Treatment
Denosumab- An Emerging Treatment for Osteoporosis
Diagnosis of Osteoporosis
Emerging Therapy for Osteoporosis
Emerging Treatments for Osteoporosis
Fracture Intervention Programs
Fracture Risk Assessment
Glucocorticoid-induced Osteoporosis
Hip Fractures
Hyperparathyroidism
Ibandronate for the Treatment of Osteoporosis
Individualizing Osteoporosis Treatment
Low Bone Density in Premenopausal Women

Managing a Bone Densitometry Facility
Monitoring Osteoporosis Therapy
New and Emerging Treatments for Osteoporosis
NOF Guidelines and FRAX - Benefits and Limitations
Nonpharmacological Therapy for Osteoporosis
Non-responders to Osteoporosis Treatment
Nutrition and Osteoporosis
Obesity, Osteoporosis, and Bone Density Testing
Official Positions of the International Society for Clinical Densitometry
Oral Bone Health and Osteoporosis
Osteoporosis Evaluation and Treatment
Osteoporosis in Men
Osteoporosis Treatment Thresholds
Pitfalls in Bone Density Testing
Project ECHO for Osteoporosis
Raloxifene for the Treatment of Osteoporosis
RANK Ligand Inhibition and Skeletal Health
Rationale for Intermittent Bisphosphonate Dosing
Reporting Fracture Risk
Rheumatological Diseases and Osteoporosis
Risedronate for the Treatment of Osteoporosis
Risk Communication and Shared Decision Making
Safety of Long-term Bisphosphonate Therapy
Selective Estrogen Receptor Modulators
Skeletal Effects of Hyperparathyroidism
Skeletal Health in Native Americans
Telementoring for Osteoporosis (Bone Health ECHO)
Transplantation Osteoporosis
Treat-to-Target (Treat-to-Goal) for Osteoporosis
Update on FRAX
Update on Osteoporosis
Vertebral Fracture Assessment by DXA
Vertebral Fractures
Vertebroplasty and Kyphoplasty
Vitamin D Deficiency and Insufficiency
Zoledronic Acid for the Treatment of Osteoporosis

BIBLIOGRAPHY

Publications in Peer-reviewed Journals

For direct link to publications listed in PubMed, go to “My Bibliography” at:
http://www.ncbi.nlm.nih.gov/sites/myncbi/1LGocfQuRrjAo/bibliography/41045340/public/?sort=date&direction=descending

1. Lewiecki EM, Rahman F. Pruritus: A manifestation of iron deficiency anemia. JAMA. 1976;236:2319-2320.

2. Lewiecki EM. CBGC. JAMA. 1977;237:2472.

3. Lewiecki EM. Primary plague septicemia. Rocky Mountain Med J. 1978;75:201-203.

4. Lewiecki, EM, Mason W. Beeper bite: A jogging complication in physicians. West J Med. 1982;136:354.

5. Lewiecki, EM. Vertebroplasty and Kyphoplasty in 2001. J Clin Densitometry. 2001;4:185-187.

6. Khan AA, Brown JP, Kendler DL, Leslie WD, Lentle BC, Lewiecki EM, Miller PD, Nicholson RL, Olszynski WP, Watts NB. The 2002 Canadian bone densitometry recommendations: take-home messages. CMAJ. 2002;167:1141-1145.

7. Simon JA, Lewiecki EM, Smith ME, Petruschke RA, Wang L, Palmisano JJ. Patient preference for once-weekly alendronate 70 mg versus once-daily alendronate 10 mg: A multicenter, randomized, open-label, crossover study. Clin Therapeutics. 2002;24:1871-1886.

8. Lewiecki EM. Nonresponders to osteoporosis therapy. J Clin Densitom. 2003;6:307-314.

9. Leib ES, Lewiecki EM, Binkley N, Hamdy RC. Official positions of the International Society for Clinical Densitometry. J Clin Densitom. 2004;7(1):1-6.

10. Khan AA, Bachrach L, Brown JP, Hanley DA, Josse RG, Kendler DL, Leib ES, Lentle BC, Leslie WD, Lewiecki EM, Miller PD, Nicholson RL, O'Brien C, Olszynski WP, Theriault MY, Watts NB. Standards and guidelines for performing central dual-energy x-ray absorptiometry in premenopausal women, men, and children: a report from the Canadian panel of the international society of clinical densitometry. J Clin Densitom. 2004.7(1):51-64.

11. Leib ES, Lewiecki EM, Binkley N, Hamdy RC. Official positions of the International Society for Clinical Densitometry. South Med J. 2004;97(1):107-110.

12. Kiebzak GM, Lewiecki, EM, Petak SM. Impact of using the ultradistal radius region of interest on diagnostic classification. J Clin Densitom. 2004;7:143-152.

13. Lewiecki EM. Bone density testing in the management of postmenopausal osteoporosis. Women's Health Primary Care. 2004;7:84-95.

14. Lewiecki EM. Low bone mineral density in premenopausal women. South Med J. 2004;97:544-550.

15. Lewiecki EM. Management of osteoporosis. Clin Mol Allergy. 2004;2:9.

16. Lewiecki EM, Kendler DL, Kiebzak GM, Schmeer P, Prince RL, El-Hajj Fuleihan G, Hans D. Special report on the official positions of the International Society for Clinical Densitometry. Osteoporos Int. 2004;15:779-784.

17. Lewiecki EM, Watts NB, McClung MR, Petak SM, Bachrach LK, Shepherd JA, Downs RW Jr. Official positions of the International Society for Clinical Densitometry. J Clin Endocrinol Metab. 2004;89(8):3651-3655.

18. Gluck OS, Maricic MJ, Leib ES, Lewiecki EM. Recommendations regarding individuals in whom bone densitometry should be performed: comment on the article by van Staa et al. Arthritis Rheum. 2004;50(8):2715-2716.

19. Binkley N, Kiebzak GM, Lewiecki EM, Krueger D, Gangnon RE, Miller PD, Shepherd JA, Drezner MK. Recalculation of the NHANES database standard deviation improves T-score agreement and reduces osteoporosis prevalence. J Bone Miner Res. 2005;20:195-201. Epub. Nov 16, 2004.

20. Lewiecki EM. Premenopausal bone health assessment. Curr Rheumatol Rep. 2005;7(1):46-52.

21. Lewiecki EM, Miller PD, Leib ES, Bielzikian JP. Response to "The perspective of the International Osteoporosis Foundation on the official positions of the International Society for Clinical Densitometry" by John A. Kanis et al. Osteoporos Int. 2005;16(5):579-580. Epub Mar 16, 2005.

22. Binkley N, Lewiecki EM. Vitamin D and common sense. J Clin Densitom. 2011 Apr-Jun;14(2):95-9.

23. Chen P, Satterwhite JH, Licata AA, Lewiecki EM, Sipos AA, Misurski DM, Wagman RB. Early changes in biochemical markers of bone formation predict BMD response to teriparatide in postmenopausal women with osteoporosis. J Bone Miner Res. 2005;20(6):962-970. Epub 2005 Jan 18.

24. Lewiecki EM, Miller PD, Leib ES, Bilezikian JP. Response to "The perspective of the International Osteoporosis Foundation on the official positions of the International Society for Clinical Densitometry," by John A. Kanis et al. J Clin Densitom. 2005;8(2):143-144.

25. Lewiecki EM. Clinical applications of bone density testing for osteoporosis. Minerva Med. 2005;96(5):317-330.

26. Baim S, Wilson CR, Lewiecki EM, Luckey MM, Downs RW Jr, Lentle BC. Precision assessment and radiation safety for dual-energy X-ray absorptiometry: position paper of the International Society for Clinical Densitometry. J Clin Densitom. 2005;8(4):371-378.

27. Lewiecki EM. Review of guidelines for bone mineral density testing and treatment of osteoporosis. Curr Osteoporos Rep. 2005;3(3):75-83.

28. Lewiecki EM. Update on bone density testing. Curr Osteoporos Rep. 2005;3(4):136-142. Reprinted in Curr Prim Care Rep. 2006;1:255-261.

29. Srivastava AK, Vliet EL, MD, Lewiecki EM, Maricic M, Abdelmalek A, Gluck O, Baylink DJ. Clinical use of serum and urine bone markers in the management of osteoporosis. Curr Med Res Opin. 2005;21(4):1015-1026.

30. Cryer B, Binkley N, Simonelli C, Lewiecki EM, Lanza F, Chen E, Petruschke RA, Mullen C, de Papp AE. A randomized, placebo-controlled, 6-month study of once-weekly alendronate oral solution for postmenopausal osteoporosis. Am J Geriatr Pharmacother. 2005;3:127-136.

31. Hamdy RC, Chesnut CH III, Gass ML, Holick MF, Leib ES, Lewiecki EM, Maricic M, Watts NB. Review of treatment modalities for postmenopausal osteoporosis. South Med J. 2005;98:1000-1014.

32. Lewiecki EM. Is alendronate therapy cost-effective for postmenopausal osteopenia? Nature Clin Pract Endocrinol Metab. 2005;1(2):74-75.

33. Lewiecki EM. Skeletal health prognostications. South Med J. 2006;99(2):105-106.

34. Lewiecki EM, Rudolph LA, Kiebzak GM, Chavez JR, Thorpe BM. Assessment of osteoporosis website quality. Osteoporos Int. 2006 May;17(5):741-52. Epub 2006 Jan 31.

35. McClung MR, Lewiecki EM, Cohen SB, Bolognese MA, Woodson GC, Moffett AH, Peacock M, Miller PD, Lederman SN, Chesnut CH, Lain CD, Kivitz AJ, Holloway DL, Zhang C, Peterson MC, Bekker PJ, for the AMG 162 Bone Loss Study Group.

Denosumab in postmenopausal women with low bone mineral density. N Engl J Med. 2006;354:821-831.

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37. Lewiecki EM. Augmentation procedures for osteoporotic vertebral fractures- An ongoing experiment or emerging standard of care? South Med J. 2006 May;99(5):449-50.

38. Vokes T, Bachman D, Baim S, Binkley N, Broy S, Ferrar L, Lewiecki EM, Richmond B, Schousboe J. Vertebral fracture assessment: The 2005 ISCD official positions. J Clin Densitom. 2006 Jan-Mar;9(1):37-46. Epub 2006 May 12.

39. Binkley N, Bilezikian J, Kendler D, Leib E, Lewiecki EM, Petak S. Official positions of the International Society for Clinical Densitometry and executive summary of the 2005 Position Development Conference. The 2005 ISCD official positions. J Clin Densitom. 2006 Jan-Mar;9(1):4-14. Epub 2006 May 12.

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49. Lewiecki EM. Denosumab: a promising drug for the prevention and treatment of osteoporosis. Women's Health. 2006;2(4):517-525.

50. Lewiecki EM, Binkley N, Petak SM. DXA quality matters. J Clin Densitom. 2006; 9(4):388-392.

51. Lewiecki EM, Silverman SL. Redefining osteoporosis: when to treat and how long to treat. Arq Bras Endocrinol Metabol. 2006;50(4):694-704.

52. Lewiecki EM, Borges JLC. Bone density testing in clinical practice. Arq Bras Endocrinol Metabol. 2006;50(4):586-595.

53. Ragi Eis S, Lewiecki EM. Peripheral bone densitometry- clinical applications. Arq Bras Endocrinol Metabol. 2006;50(4):596-602.

54. Lewiecki EM. Proceedings of the Santa Fe Bone Symposium 2006. Women's Health. 2006;2(6):825-828.

55. Recker RR, Kendler D, Recknor CP, Rooney TW, Lewiecki EM, Utian WH, J Cauley JA, Lorraine J, Qu Y, Kulkarni PM, Gaich CL, Wong M, Plouffe L, Jr, Stock JL. Comparative effects of raloxifene and alendronate on fracture outcomes in postmenopausal women with low bone mass. Bone. 2007;40(4):843-851. Epub 2006 Dec 19.

56. Leib ES, Binkley N, Bilezikian JP, Kendler DL, Lewiecki EM, Petak SM. Position Development Conference of the International Society for Clinical Densitometry. Vancouver, BC, July 15-17, 2005. J Rheumatol. 2006 Nov;33(11):2319-21.

57. Cramer JA, Gold DT, Silverman SL, Lewiecki EM. A systematic review of persistence and compliance with bisphosphonates for osteoporosis. Osteoporos Int. 2007;18:1023-1031. Epub 2007 Feb 17.

58. Blake GM, Lewiecki EM, Kendler DL, Fogelman I. A review of strontium ranelate and its effect on DXA scans. J Clin Densitom. 2007;10(2):113-119. Epub 2007 Feb 28.

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62. Kiebzak GM, Binkley N, Lewiecki EM, Miller PD. Diagnostic agreement at the total hip using different DXA systems and the NHANES III database. J Clin Densitom. 2007;10(2):132-137. Epub 2007 April 9.

63. Laster AJ, Lewiecki EM, for the ISCD Board of Directors. J Clin Densitom. Vertebral fracture assessment by dual-energy X-ray absorptiometry: insurance coverage issues in the United States. A White Paper of the International Society for Clinical Densitometry. 2007;10(3):227-238. Jun 27, 2007 [Epub ahead of print]

64. Lewiecki EM, Simon JA. Clinical use of bone density testing. The Female Patient. 2007;32:35-38.

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68. Lewiecki EM. Long dosing intervals in the treatment of postmenopausal osteoporosis. Curr Med Res Opin. 2007;23(11):2617-2625.

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CLINICAL TRIALS

Osteoporosis and SarcopeniaTrials
(Principal Investigator, Unless Otherwise Noted)

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2. A Double-Blind, Randomized, Placebo-Controlled, Multicenter Study to Assess the Safety, Tolerability and Clinical Effects of Twice-Daily Doses of an Oral Calcimimetic Agent (AMG-073) in Subjects With Primary Hyperparathyroidism (PHPT). Amgen 990160 AMG-073. Closed 2001.

3. The Effect of Ortho Tri-Cyclen® on Bone Mineral Density in Pediatric Subjects with Anorexia Nervosa: A Double-Blind, Placebo-Controlled Study. Ortho-McNeil CAPPS-169. Phase 2. Closed 2003.

4. A Prospective and Randomized Controlled Study to Evaluate the Performance of Inflatable Bone Tamps in the Percutaneous Treatment of Painful Osteopenic Vertebral Body Compression Fractures. Kyphon 2000-1. Closed 2001.

5. Safety and efficacy of droloxifene for preventing bone loss in normal early postmenopausal women. Pfizer. 1998-2000. Closed.

6. Osteoporosis prevalence with community-based referral for bone densitometry. Investigator-initiated study. 1998.

7. Loss of bone density with bisphosphonate therapy for osteoporosis. Investigator-initiated study. 2002.

8. Bisphosphonate treatment of osteoporosis in patients with impaired renal function. Investigator-initiated study. 2002.

9. A Multicenter, Randomized, Double-Blind, Placebo-Controlled, 12-Month Study to Evaluate the Efficacy and Safety of Oral Alendronate Sodium Once Weekly for the Prevention and Treatment of Glucocorticoid-Induced Bone Loss. Merck 193. Closed 2003.

10. A Study of the Safety & Efficacy of Lasofoxifene for the Prevention of Bone Loss and for Lipid Lowering in Postmenopausal Women at Risk for Osteoporosis. (OPAL). Pfizer A2181003. Closed 2003. [Subinvestigator]

11. Double-Blind, Placebo-Controlled, Dose Ranging Trial to Evaluate the Efficacy of Atorvastatin on Bone Mineral Density and Markers for Bone Turnover in

Postmenopausal Women with Dyslipidemia and at Risk for Osteoporosis. (BONES). Pfizer A2581049. Closed 2003. [Subinvestigator]

12. Impact of using the ultradistal radius region of interest on the diagnosis of osteoporosis. Investigator-initiated study. 2003. [Subinvestigator]

13. Changes in patient perceptions of estrogen therapy for the management of osteoporosis. Investigator-initiated study. 2003.

14. A Randomized, Double-Blind, Double-Dummy, Parallel-Group, Multicenter Study to Evaluate and Compare the Effects of Alendronate and Raloxifene on Bone Mineral Density in Postmenopausal Women with Osteoporosis (EFFECT Study – Efficacy of Fosamax® vs. Evista® Comparison Trial. (EFFECT). Merck 189. Closed 2004.

15. An 18-Month, Double-Blind, Placebo-Controlled, Phase III, Trial with a 12-Month Interim Analysis of the Effect of Recombinant Human Parathyroid Hormone (ALX1-11) on Fracture Incidence in Women with Postmenopausal Osteoporosis. (TOP). NPS Allelix ALX1-11-93001. Closed 2004.

16. Evaluation of osteoporosis website quality. Investigator-initiated study. 2004.

17. Evaluation of precision and correlation of bone density measurements using the GE Lunar Prodigy and Hologic Delphi. GE Healthcare. Closed 2003.

18. A randomized, double-blind, multicenter, placebo-controlled study to compare the safety and tolerability of an oral buffered solution of Alendronate Sodium 70mg once weekly versus placebo for the treatment of osteoporosis in postmenopausal women. (OASIS). Merck 219-00. Closed 2004.

19. A Multi-Center, Double Blind, Randomized, Placebo and Raloxifene Controlled Study to Assess Safety and Efficacy Of TSE-424 in the Prevention Of Postmenopausal Osteoporosis. Wyeth 3068A-1. Closed 2004.

20. Comparison of Raloxifene to Alendronate in Postmenopausal Women with Osteoporosis. (EVA). Lilly H3S-US-GGKO. Phase 4. Closed 2004.

21. A multinational Multicenter, Randomized, Double-Blind, Parallel Group, Placebo-Controlled Clinical Trial of the Effects of Tibolone on the incidence of New Vertebral Fractures in Osteoporotic Postmenopausal Women. (LIFT). Organon 32962. Closed 2004.

22. Diagnostic capabilities using T-scores are comparable between Delphi and Prodigy. Investigator-initiated study. 2004. [Subinvestigator]

23. An 18-Month Open Label Extension Study (OLES) of the Safety and Efficacy of Recombinant Human Parathyroid Hormone, fhPTH(1-84), ALX1-11, in Women with

Postmenopausal Osteoporosis Who Participated in Protocol ALX1-11-93001. (OLES). NPS Allelix CL1-11-002. Phase 3.

24. Fracture Incidence Reduction and Safety of TSE-424 Compared to Placebo and Raloxifene in Osteoporotic Postmenopausal Women. Wyeth-Ayerst 3068A1-300-US.

25. A study of the safety and efficacy of lasofoxifene for prevention of bone loss & for lipid lowering in postmenopausal women at risk for osteoporosis. (OPAL). Pfizer A218-1003-5042. Phase 3. Closed 2003.

26. Postmenopausal evaluation and risk-reduction with lasofoxifene. (PEARL). Pfizer A2181002. Phase 3. 2001-2006.

27. A double-blind placebo-controlled trial of the safety, toleration and efficacy of lasofoxifene 0.25 mg/d and raloxifene 60 mg/d for the prevention of bone loss in postmenopausal women. (CORAL). Pfizer A2181030. Phase 3. 2003-xxxx. [Subinvestigator]

28. A multi-center, double-blind, randomized, placebo-controlled study to evaluate the safety and efficacy of zoledronic acid in the treatment of osteoporosis in postmenopausal women taking calcium and vitamin D. (HORIZON-PFT: Pivotal Fracture Trial). Novartis CZOL446H2301. Phase 3. 2001-2006.

29. Skeletal site selection for bone density testing in elderly women. Investigator-initiated study. Self-funded. 2001.

30. A randomized, double-blind, placebo controlled, multi-dose phase 2 study to determine the efficacy, safety and tolerability of AMG 162 in the treatment of postmenopausal women with low bone mineral density. Amgen AMG 162 – 20010223. Phase 2.

31. Randomized, double-blind, parallel groups, multi-center study to compare the efficacy and safety of monthly oral administration of 100 mg and 150 mg ibandronate with 2.5 mg daily oral ibandronate in postmenopausal osteoporosis. (MOBILE). Hoffman La Roche BM16549. Phase 3. 2002-2005.

32. Randomized, double-blind, parallel groups, multicenter study to compare the efficacy and safety of two IV ibandronate dose regimens (2 mg q 2 mo, 3 mg 2 q 3 mo) with 2.5 mg daily oral ibandronate in postmenopausal osteoporosis. (DIVA). Hoffman La Roche BM16550. Phase 3. 2002-2005.

33. Randomized, double-blind, double-dummy, parallel group, multi-center study to compare the efficacy and safety of once monthly oral administration of 150 mg ibandronate with once-weekly oral administration of 70 mg alendronate in

postmenopausal osteoporosis – non-inferiority trial. (MOTION). Hoffman La-Roche MM17385A.

34. Clinical Investigation for Using Pulsed Electromagnetic Fields to Slow or Reverse Progression of Bone Mineral Density Loss in Osteoporotic Patients. Orthofix U10P.

35. A study to evaluate the effects of calcium supplementation on the efficacy and safety of recombinant human parathyroid (ALX1-11) in postmenopausal women with osteoporosis (CAP study). NPS Allelix CL1-11-008. Phase 3. 2003-2005.

36. An open label study of the effect of teriparatide (PTH[1-34]) on bone turnover markers in postmenopausal women with osteoporosis treated previously with risedronate or alendronate. (OPTAMISE). Aventis HMR4003B/4034. Phase 4. 2003-

37. Effects of Arzoxifene on Vertebral Fracture Incidence and on Invasive Breast cancer Incidence in Postmenopausal Women with Osteoporosis or with Low Bone Density. (GENERATION). Lilly H4Z-MC-GJAD.

38. A study to evaluate AMG 162 in the treatment of postmenopausal osteoporosis. (FIRST). Amgen AMG 162 – 20030216. Phase 3. 2004-

39. A 2-year, randomized, multi-center, double-blind, placebo controlled study to determine the efficacy and safety of intravenous zoledronic acid 5mg administered either annually at randomization and 12 months, or administered at randomization only in the prevention of bone loss in postmenopausal women with osteopenia. Novartis CZOL446N2312.

40. Study to Evaluate AMG 162 in the Prevention of Postmenopausal Osteoporosis. Amgen AMG 162 – 20040132. Phase 3.

41. A randomized, placebo-controlled, parallel-groups study to evaluate the effects of 1-year administration of 2MD with or without calcium and vitamin D supplements on bone mineral density, bone biomarkers and calcium metabolism in postmenopausal women with osteopenia. (ROSE). Pfizer A5771001. Phase 2a. 2004-2006.

42. A Long-Term Prospective Observational Study of the Effectiveness, Safety and Tolerability of FORTEO Therapy in the Community Setting. (DANCE). Eli Lilly B3D-US-GHCQ. Phase 4.

43. An open label, multi-center study to determine level of adherence to monthly oral or every 3 month intravenous ibandronate treatment in postmenopausal women with osteoporosis or osteopenia, who are GI intolerant of daily and/or weekly alendronate or risedronate. (PRIOR). Roche ML-18058 A. Phase 3b.

44. Randomized, multicenter, double-blind, double-dummy, parallel group study to determine the efficacy and safety of intravenous zoledronic acid 5 mg annually compared to oral alendronate 70 mg weekly for the treatment of osteoporosis in men. Novartis CZOL446M2308. Phase 3.

45. A 3-year, double-blind extension to CZOL446H2301 to evaluate the long term safety and efficacy of zoledronic acid in the treatment of osteoporosis in postmenopausal women taking calcium and vitamin D. Novartis CZOL446H2301E1. 2005 –

46. A one year, parallel, placebo-controlled, double-blind, randomized study to assess the effect of monthly 150 mg oral ibandronate dosing versus placebo on bone quality and strength at the proximal femur in women with osteoporosis (IQ Study). GSK BON103593. 2005 –

47. Double-blind, placebo-controlled, randomized, multicenter study to assess the efficacy and safety of oral ibandronate 150 mg once monthly in postmenopausal women with osteopenia. (PREVENTION). Hoffmann-La Roche BA18492. 2005 -

48. A pilot study to assess the adjunctive use of Physio-Stim® to slow or reverse progression of bone mineral density loss in osteoporotic subjects. Orthofix Inc. U2OP. 2005.

49. A double-blind, randomized, placebo- and active-controlled efficacy and safety study of bazedoxifene/conjugated estrogens combinations for prevention of endometrial hyperplasia and prevention of osteoporosis in postmenopausal women. Wyeth Research. 3115A1-304-WW.

50. A one-year, parallel, placebo-controlled, randomized (2:1) double-blind study of one year duration to assess the effect of oral ibandronate 150 mg. once-monthly versus placebo on LS BMD in men with osteoporosis. GSK. BAN105960. 2006.

51. A randomized, double blind, placebo-controlled study to evaluate the effects of alendronate on bone mineral density in perimenopausal women with low bone mineral density. Merck Frosst Canada & Co. Protocol 17841. 2006.

52. A phase 2, double-blind, randomized, placebo-controlled, daily-dose, proof-of-concept study of a vitamin D compound (DP001 soft gel capsules) in postmenopausal women with osteopenia. Deltanoid Pharmaceuticals. 2MD-3H-2B. 2006.

53. A one-year partial double-blinded, randomized, multi-center, multi-national study to assess the effects of combination therapy of annual zoledronic acid (5 mg) and daily subcutaneous teriparatide (20 mcg) on postmenopausal women with severe osteoporosis. Novartis. CZOL446H2409. 2006.

54. An open-label, single-arm extension study to evaluate the long-term safety of denosumab administration in postmenopausal women with low bone mineral density. Amgen. AMG20050233. 2006.

55. A randomized study evaluating the effect on renal function of ibandronate administered as an i.v. bolus injection compared to an i.v. infusion, and alendronate oral administered once weekly, in postmenopausal women with osteoporosis at high risk for renal disease (DIVINE). Roche. BA20341, 2007.

56. An open label, single arm, extension study to evaluate the long term safety and sustained efficacy of Denosumab (AMG 162) in the treatment of postmenopausal osteoporosis. Amgen. AMG200602289. 2007.

57. A Phase III Randomized, Placebo-Controlled Clinical Trial to Assess the Safety and Efficacy of Odanacatib (MK-0822) to Reduce the Risk of Fracture in Osteoporotic Postmenopausal Women Treated With Vitamin D and Calcium. Merck. MK018-0822, 2007.

58. The effects of teriparatide on bone microarchitecture as determined by high resolution magnetic resonance imaging topological analysis. Lilly. B3D-US GDHJ. 2007.

59. A 52-week randomized, double-blind, multicenter, mechanistic study with a 24 week open-label follow-up to evaluate the effect of Avandia™ on bone in postmenopausal women with type 2 diabetes mellitus. GSK. AVD111179. 2008.

60. A phase 4, randomized, double-blind, placebo-controlled study of evaluate the effect of pioglitazone compared to placebo on bone metabolism in impaired fasting glucose, postmenopausal women for 1 year of treatment. Takeda. AD4833_402. 2008.

61. A randomized, double-blind, multiple dose, placebo-controlled, parallel group, 48-week, study of oral recombinant salmon calcitonin compared to calcitonin nasal spray in postmenopausal osteoporotic women. Unigene Laboratories. UGL-OR0801. 2008.

62. A double-blind, randomized, placebo- and active-controlled efficacy and safety study of the effects of bazedoxifene/conjugated estrogens combinations on endometrial hyperplasia and prevention of osteoporosis in postmenopausal women. Wyeth. Phase 3. 3115A1-3307-WW.

63. A randomized, placebo-controlled, multi-dose phase 2 study to determine the efficacy, safety and tolerability of AMG 785 in the treatment of postmenopausal women with low bone mineral density. Amgen. AMG785 20060326. 2009.

64. Skeletal Histomorphometry In Patients On Teriparatide Or Zoledronic Acid Therapy (SHOTZ). Lilly. B3D-US-GHDL. 2009.

65. A Sub-Study To Explore Biomarkers Of Physical Function In The Phase III Randomized, Placebo-Controlled Clinical Trial To Assess The Safety And Efficacy Of Odanacatib (MK-0822) To Reduce The Risk Of Francture In Osteoporotic Postmenopausal Women Treated With Vitamin D And Calcium. Merck. 0822 Protocol 035-00. 2009.

66. A multi-center, randomized, double-blind, placebo-controlled study to compare the efficacy and safety of denosumab versus placebo in males with low bone mineral density (ADAMO). Amgen. 20080098. 2009.

67. A phase III randomized, placebo-controlled clinical trial to assess the safety and efficacy of odanacatib (MK-0822) in the treatment of men with osteoporosis treated with vitamin D and calcium. Merck. 053-00. 2010.

68. Phase I, randomized, double-blind, placebo-controlled study to evaluate the effect of dexlansoprazole 60 mg delayed release capsules and esomeprazole 40 mg delayed release capsules on bone homeostasis in healthy postmenopausal female subjects. Takeda. TAK-390MR_104. 2010.

69. Prospective observational study to evaluate persistence with Prolia® (denosumab) in postmenopausal women with osteoporosis in routine clinical practice. Amgen. 20101218. 2011.

70. Psychometric validation of the modified Osteoporosis Assessment Questionnaire (OPAQ) and a short battery of performance measures. Oxford Outcomes. 2011.

71. An open-label, randomized study to estimate the percent change from baseline in lumbar spine bone mineral density after 3 months of AMG 785 administration in postmenopausal women with low bone mineral density previously treated with alendronate. Amgen. 20110253. 2012.

72. A multicenter, international, randomized, double-blind, placebo-controlled, parallel-group study to assess the efficacy and safety of AMG 785 treatment in postmenopausal women with osteoporosis (FRAME). Amgen. 20070337. 2012.

73. A blinded extension to 5 years of a phase 3 randomized, placebo-controlled clinical trial to assess the safety and efficacy of odanacatib (MK-0822) to reduce the risk of fracture in osteoporotic postmenopausal women treated with vitamin D and calcium. Merck. 018-10. 2012.

74. Teriparatide and risedronate in the treatment of patients with severe postmenopausal osteoporosis: comparative effects on vertebral fractures (VERO). Lilly. B3D-EW-GHDW. 2012.

75. Anabolism versus antiresorption: a quadruple-labeling histomorphometry study to compare the mechanism of action of teriparatide and denosumab in postmenopausal women with osteoporosis (AVA). Lilly. B3D-US-GHDV. 2012.

76. A phase 3 randomized, double-blind, placebo-controlled study to evaluate the effects of odanacatib (MK-0822) on bone mineral density (BMD) and overall safety in the treatment of osteoporosis in posmenopausal women previously treated with an oral bisphosphonate. Merck. MK-0822-076-01. 2013.

77. A randomized, double-blind, parallel group, multicenter study of the safety and efficacy of 3 month subcutaneous REG1033 treatment in patients with sarcopenia. Regeneron. 2013.

78. A Multicenter, Double-blind, Randomized Study to Assess the Efficacy and Safety of Denosumab Produced by Two Different Processes in Postmenopausal Women With Osteoporosis. Amgen. Protocol 20120187. 2013.

79. A phase 1, randomizd, open-label parallel group study comparing two types of self-injected romosozumab. Amgen. Protocol 20120279. 2014.

80. Effectiveness of DiscontinuinG bisphosphonatEs Study: R21 Pilot Study (EDGE). University of Alabama at Birmingham. 2015.

81. Changes in Biochemical Markers of Bone Turnover (serum CTX and P1NP) after initiation of a “Drug Holiday” from Bisphosphonates. National Bone Health Alliance. 2015.

82. A randomized study comparing the effects of PF708 and Forteo in patients with osteoporosis. Pfenex Inc. PF708-301. 2016.

83. A phase 3b, multicenter, placebo-controlled, double-blind, dose-finding study in adult patients with type I, III or IV osteogenesis imkperfecta treated with BPS804. Mereo BioPharma. MBPS205. 2017.

84. A Randomized, Double-blind, Placebo-controlled, Phase 3 Multicenter Study to Evaluate the Safety and Efficacy of Abaloparatide-SC for the Treatment of Men with Osteoporosis. BA058-05-019. Radius. 2017.

Other Clinical Trials
(Co-investigator or Subinvestigator)

1. A 26-Week Randomized, Double-Blind, Multi-Center, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Tolerability7 of BRL49653C when Administered Once Daily to Patients with Non-Insulin Dependent Diabetes Mellitus (NIDDM) who are Inadequately Controlled on at Least ½-Maximal Dose (≥10 mg/day) of Glyburide. SmithKlineBeecham 49653C/096. Closed 1998.

2. A Placebo and Active Comparator-Controlled, Parallel-Group, 6-Week, Double-Blind Study, Conducted Under In-House Blinding Conditions to Assess the Safety and Efficacy of MK-0966 Versus Ibuprofen in Patients with Osteoarthritis of the Knee or Hip. Merck 033. Closed 1996.

3. A Study to Evaluate the Effect of Lansoprazole 30 mg QD versus Omeprazole 20 mg QD on Relief of Symptoms in Patients with Erosive Reflux Esophagitis.TAP M98-890. Closed 2000.

4. A Second, Double-Blind, Active Comparator-Controlled Extension of a Placebo-Controlled, Double-Blind Study to Assess Safety and Further Define the Clinically Effective Dose Range of Mk-0966 (L-748,731) in Patients with Osteoarthritis of the Knee or Hip. Merck 029. Closed 1996.

5. A Randomized, Double-Blind, Active-Controlled Evaluation of the Antihypertensive Response to Omapatrilat in Subjects Uncontrolled on Calcium-Channel Blocker Therapy. Bristol Myers Squibb CV 137-072. Phase 3b. Closed 2003.

6. A Randomized, Double-Blind, Active-Controlled Evaluation of the Antihypertensive Response to Omapatrilat in Subjects Uncontrolled on Ace Inhibitor Therapy. Bristol Myers Squibb CV 137-073. Phase 3b. Closed 2003.

7. A Study to Compare Lansoprazole to Ranitidine in Patients with Heartburn. TAP M96-548. Closed 1997.

8. A Study to Evaluate the Effects of Lansoprazole 30 mg or 15 mg QD Versus Placebo in Patients with Non-Ulcer Dyspepsia. TAP M97-671. Closed 1999.

9. Study to Evaluate the Effect of EM574 5 mg QID, 10 mg TID, 20 mg BID Versus Placebo in Females with Non-Erosive Gastroesophageal Reflux Disease. TAP M97-032. Closed 1999.

10. A Phase IV, Parallel, Randomized, Double-Blind Study Comparing the Analgesic Efficacy and Safety of Acetaminophen, Naproxen Sodium, Ibuprofen, and Aspirin in Patients with Osteoarthritis. McNeil 93-320. Closed 1996.

11. A Double-Blind, Randomized, Placebo-Controlled, Parallel-Group, Multicenter Study to Investigate the Efficacy and Safety of Inhaled Zanamivir 1- mg Administered Once a Day for 28 Days in the Prevention of Symptomatic Influenza A & B Viral Infections in Community Dwelling High Risk Subjects Aged ≥ 12 Years. GlaxoWellcome NAI 30034. Closed.

12. A Randomized, Double-Blind, Multicenter Trial Comparing 10 Days of Oral Therapy With CP-99,219 (200 mg Daily) and 14 Days of Oral Clarithromycin (500 mg BID) for the Treatment of Acute Sinusitis #154-115-5101. Pfizer CP-99,219 and CP-116,517. Closed 1996.

13. A Randomized, Double-Blind, Parallel Trial Comparing Lotrel 5/10 mg Once Daily, Lotrel 5/20 mg Once Daily Amlodipine 5 mg Once Daily, and Amlodipine 10 mg Once Daily in Patients Age 18 – 80 Years With Essential Hypertension Inadequately Controlled With Amlodipine 5 mg Once Daily Followed by a Single-Blind Extension of Lotrel 5/20 mg Once Daily. Novartis 103 M0574V. Closed 1997.

14. Long Term Safety Study of Zileuton Controlled-Release Plus Usual Care Versus Placebo Plus Usual Care in Patient With Asthma. Abbott M96-464. Closed 1997.

15. A Parallel, Double-Blind, Randomized, Single Dose Study, Comparing the Analgesic Efficacy & Safety of Acetaminophen 1000 mg, Naproxen 375 mg, and Placebo in the Treatment of Tension Headache. McNeill 92-206. Closed.

16. A Multi-Center, Randomized Study to Compare the Safety & Efficacy of Oral Levoflaxacin with Amoxicillin / Clavulanate Potassium in the Treatment of Acute Sinusitis in Adults. RW Johnson M92-040. Closed.

17. A Double-Blind, Double-Dummy, Multi-Center, Parallel Group Study to Compare the Efficacy & Safety of FACTIVE Given Either as a Single Oral Dose of 640 mg or as 320 mg Once Daily for Three Days Versus Oral Ciprofloxacin 250 mg Twice a Day for Three Days in the Treatment of Uncomplicated Urinary Tract Infections (UTI) in Female Patients. SmikthKlineBeecham SB-265805/053. Closed 1999.

18. A Triple-Blind, Randomized, Parallel, Efficacy Study of Losartan versus Irbesartan in Patients with Mild to Moderate Essential Hypertension. Merck 183-00. Closed 1999.

19. Chronic Asthma and Quality of Life: Comparative Study of Salmeterol versus Current Treatments. BlaxoWellcome SLG-400. Closed.

20. A Phase IV, Parallel, Double-Blind, Randomized, Single Dose Study Comparing the Analgesic Efficacy & Safety of Acetaminophen 1000 mg, Naproxen Sodium 440 mg & Placebo in the Treatment of Tension Headaches. McNeill 93-318. Closed.

21. A 24-Week, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy, Safety, and Tolerability of Ariflo (15 mg bid) in Patients with Chronic Obstructive Pulmonary Disease (COPD). SmithKlineBeecham SB 207499/156. Closed 2001.

22. A Randomized, Double-Blind, Placebo-Controlled Study to Compare the Effects of Nabametone 2 G, Celecoxib 400 mg and Ibuprofen 2400 mg Per Day on Blood Pressure Control in Patients with Hypertension Stabilized on Anti-hypertension Therapy. SmithKlineBeecham 14777/259. Closed 2001.

23. A Cost Minimization Comparison of Mibefradil (Posicor) Versus Amlodipine (Norvasc®) For The Treatment of Mild-To-Moderate Hypertension in Actual Practice Settings. Hoffman La-Roche OM 074-002. Closed 1997.

24. A Randomized, Double-Blind, Double-Dummy, Placebo-Controlled, Parallel Evaluation of Ranitidine for the Reduction of Severity or Prevention of Meal-Induced Heartburn. GlaxoWellcome RANA 4006. Closed 1997.

25. A Double-Blind, Randomized, Placebo-Controlled Study to Determine the Effectiveness and Safety of MigramistÔ (Dihydroergotamine Mesylate Nasal Spray) 2 mg for the Acute Treatment of Migraine Headache With or Without Aura in Migraineur Families. Sandoz DHE-454. Closed.

26. A Randomized Double-Blind, Double-Dummy, Multicenter, Parallel-Group Study to Assess the Efficacy & Safety of Oral SB-265805 320 mg Once Daily for 7 Days versus Oral Levofloxacin 500 mg Once Daily for 7 Days for the Treatment of Acute Exacerbation of Chronic Bronchitis. SmithKlineBeecham 265805/008. Closed 1999.

27. A Randomized Double-Blind, Double-Dummy, Multicenter, Parallel-Group Study to Assess the Efficacy & Safety of SB-265805 320 mg Once Daily versus Cefuroxime 500 mg Plus Clarithromycin for 7 or 14 Days in the Treatment of Bacterial Community Acquired Pneumonia in Adults. SmithKlineBeecham 265805/012. Closed 1999.

28. Comparative Safety and Efficacy of Cefditoren Pivoxil and Clarithromycin in the Treatment of Acute Bacterial Exacerbation of Chronic Bronchitis. TAP CEF-97-005. Closed 1999.

29. A 12-Week, Double-Blind, Placebo-Controlled, Randomized Trial of Naprelan 1000 mg QAM and Naprosyn® 500 mg BID in Patients With RA, Continuing to a Nine Month Open Label Trial of Naprelan 1000 mg QAM. Elan 1091002RA. Closed.

30. A Double-Blind 12-Week Study to Compare the Safety and Tolerability of the (st) Enantiomer of Ibuprofen in the Treatment of Pain Due to OA. Sterling Winthrop CHP 94-4. Closed.

31. A Prospective, Double-Blind, Randomized Comparison of Two Treatment Regimens: Losartan Potassium & Losartan / Hydrochlorothiazide versus Amlodipine and Amlodipine / Hydrochlorothiazide in the Treatment of Patients with Mild to Moderate Hypertension. Merck 136-00. Closed.

32. A Study to valuate the Efficacy of Rosiglitazone (BRL 49653C) on Reduction of Microalbuminuria in Patients With Type 2 Diabetes Mellitus. SmithKlineBeecham BRL49653C. Closed 2002.

33. A Randomized, Double-Blind, Double-Dummy, Multicenter, Parallel-Group Study to Assess the Efficacy and Safety of Oral Gemifloxacin (FactiveÔ) 320 mg Once Daily for 5 Days versus Oral Levofloxacin 500 mg Once Daily for 7 Days for the Treatment of Acute Exacerbations of Chronic Bronchitis. SmithKlineBeecham 265805/212. Closed 2000.

34. Fosfomycin Tromethamine Versus Nitrofurantoin Monohydrate / Macrocrystals in Uncomplicated Urinary Tract Infections – A Double-Blind Randomized Study. Forest MON-US-03. Closed.

35. A Multi-National, Randomized, Double-Blind, Active-Controlled Study for Evaluation of the Efficacy and Safety of Oral HMR 3647 800 mg Once a Day for 5 Days versus Cefuroxime Axetil 250 mg Twice a Day for 10 Days in the Treatment of Acute Maxillary Sinusitis in Adults. Aventis HMR 3647A/3011. Closed 2000.

36. A Multicenter, Randomized, Double-Blind, Active-Controlled, Comparative Three-Arm Study Evaluation of the Efficacy and Safety of Oral HMR 3647 800 mg Once a Day for 5 Days versus HMR 3647 800 mg Once a Day for 10 Days versus Amoxicillin / Clavulanic Acid 500 / 125 mg Three Times a Day for 10 Days in the Treatment of Acute Maxillary Sinusitis in Adults. Hoechst Marion Roussel HMR 3647A/3005. Closed 1999.

37. A Multicenter, Double-Blind, Active-Controlled, Two-Arm Parallel-Group Study of the Efficacy and Safety of Oral HMR 3647 800 mg Once a Day for 5 Days versus Oral Clarithromycin 250 mg Twice a Day for 10 Days in Subjects with Group A Beta-Hemolytic Streptococcal Pharyngitis/Tonsillitis. Hoechst Marion Roussel HMR 3647A/3008. Closed 1999.

38. A Double-Blind, Randomized, Placebo-Controlled Trial of a Tablet Formulation of Pleconaril in the Treatment of Viral Respiratory Infection in Adults. Viro Pharma 843-043. Closed 2001.

39. An Open-Label Extension Study to Assess the Long-Term Safety, Tolerability and Efficacy of BRL49653C When Administered Once or Twice Daily in Combination with Glyburide to Patients With Non-Insulin Dependent Diabetes Mellitus

(NIDDUM) “SU Open Label Ext. Study”. SmithKlineBeecham 49653/112. Closed 1999.

40. A Prospective, Open-Label, Randomized Comparison of Two Treatment Regimens; Losartan Potassium or Losartan / Hydrochlorothiazide versus Usual Care in Patients Being Treated for Mild to Moderate Hypertension Who Need to Switch Drug Therapy. (LET). Merck C02 355. Closed.

41. A Randomized, Double-Blind, Double-Dummy, Parallel-Group, Placebo-Controlled, Six-Month Clinical Trial to Examine the Efficacy and Safety of Salmeterol Xinafoate 42 MCG BID, Beclomethasone Dipropionate 84 MCG QID and Placebo in Adolescent and Adult Subjects with Mild to Moderate Asthma. GlaxoWellcome SLGA 5015/5016. Closed.

42. A Multiple Dose-Response Study of Oral TAK-603 / A-165646 in Rheumatoid Arthritis Patients. TAP M96-598 (TAK-603). Closed.

43. Double-Blind, Randomized, Comparative, Multicenter Study of RP64206 (Sparfloxacin) versus Cefaclor in the Treatment of Community-Acquired Pneumonia. Rhone-Poulenc Rorer RP 64206-352. Closed.

44. A Double-Blind, Randomized, Placebo and Active-Controlled, Parallel-Group, Dose-Finding Study to Evaluate the Efficacy and Safety of Once Daily Oral Administrator of 5 mg, 10 mg, 25 mg, and 50 mg of M100240 for 8 Weeks in Subjects with Mild to Moderate Essential Hypertension. Aventis M100240 / 2004 / 0210 & LT Extension. Closed.

45. A Double-Blind, Randomized, Multicenter, Parallel Dose Study to Evaluate the Safety and Efficacy of Zonisamide 150 mg and 300 mg Per Day and Placebo in Subjects with Migraine Headache. Elan AN46046-228. Closed.

46. Flexibility of Biphasic Insulin Aspart 70 / 30 (BIAsp 30) Dosing. A Comparison of Safety and Efficacy of BIAsp 30 BID Injected Before versus After Meals: A Multicenter, Randomized, Open-Label, Cross-Over Design Study in Elderly Insulin-Treated Subjects with Type 2 Diabetes. Novo Nordisk BIAsp-1239. Closed.

47. Multicenter, Double-Blind, Randomized, Placebo-Controlled, Parallel-Group Study to Evaluate the Safety and Efficacy of Trileptal® in Patients with Neuropathic Pain Due to Diabetic Neuropathy. Novartis CTRI476G2301. Closed.

48. Clinical Protocol for a Randomized, Double-Blind, Placebo-Controlled Study of SD-5613 as Monotherapy in Patients with Primary Hypercholesterolemia (MONotherapy Assessment of Reducing CHolesterol [MONARCH]). GD Searle NB4-00-02-009. Closed.

49. A Multicenter, Double-Blind, Randomized Study to Compare the Safety and Efficacy of Nizatidine Extended Release (ER) 150 mg Twice Daily (BID), Nizatidine ER 300 mg Daily (QD) and Placebo in the Treatment of Subjects with Symptomatic, Endoscopically Confirmed Erosive Gastroesophageal Reflux Disease (GERD). Reliant. Rel-AX-002. Closed.

50. An Open-Label, Randomized, Multicenter, Clinical Trial to Assess the Long-Term Safety of Nizatidine Extended Release (ER) 150 mg Twice Daily, and Nizatidine ER 300 mg Once Daily in Subjects with Erosive Gastroesophageal Reflux Disease. Reliant Rel-AX-012. Closed.

51. A Randomized, Double-Blind, Long Term Comparative Study Evaluating the Safety and Efficacy of Acetaminophen (4000 mg/day) and Naproxen (750 mg/day) in the Treatment of OA of the Hip or Knee. McNeil 98-055. Closed.

52. A Multicenter, Blinded, Randomized, Placebo-Controlled Trial to Study the Ability of IL-1ra (anakinra) to Retard Joint Destruction, and Evaluate the Long-Term Safety of IL-1ra, in Subjects with Rheumatoid Arthritis. Amgen IL-1ra 990145. Closed.

53. A Randomized, Double-Blind, Parallel-Group, Placebo-Controlled 12-Week Trial of Inhaled Fluticasone Propionate 88 mg BID, 220 mcg BID, and 440 mcg BID versus Placebo in Propellant GR106642X in Adolescent and Adult Subjects with Asthma Who Are Maintained on Inhaled Corticosteroid Therapy. GlaxoWellcome FAP30007. Closed.

54. A Randomized, Double-Blind, Parallel-Group, Placebo-Controlled 12-Week Trial of Inhaled Fluticasone Propionate 88 mg BID, 220 mcg BID, and 440 mcg BID versus Placebo in Propellant GR106642X in Adolescent and Adult Subjects with Asthma Who Are Maintained on Bronchodilator Therapy. GlaxoWellcome FAP30008. Closed.

55. Safety and Efficacy of Clarithromycin Extended Release (ER) Tablets (500 mg QD or 1000 mg QD) for the Treatment of Penicillin-Resistant S. pneumonia / Macrolide-Resistant S. pneumoniae (PRSP / MRSP) in Community-Acquired Pneumonia. Abbott M98-935. Closed.

56. A Randomized, Double-Blind, Multicenter Study to Evaluate the Tolerability and Effectiveness of Etorcoxib 90 mg QD versus Diclofenac Sodium 50 mg TID in Patients with Osteoarthritis. Etorcoxib versus Diclofenac Sodium Gastrointestinal Tolerability and Effectiveness (EDGE Trial). Merck 061. Closed.

57. A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel Design Study of the Safety and Effectiveness of Cerivastatin in Combo with Fenofibrate Alone, and Placebo in a Population of Type 2 Diabetic Men and Women.

Fenofibrate And Cerivastatin Trial Optimizing Response. (FACTOR). Bayer 100311. Closed.

58. Efficacy and Safety of Phlogenzym® in Patients with Active Painful Gonarthritis. MUCOS Pharma MU-699401. Closed.

59. A Phase II Pivotal Trial of Oxypurinol for the Treatment of Symptomatic Hyperuricemic Patients Who Are Unable to Tolerate Allopurinol. ILEX OXPL213-A4. Closed.

60. The Safety and Efficacy of PNU-182716 versus Rosiglitazone: A One-Year Randomized, Double-Blind, Parallel-Group, Active Comparator Study. Pharmacia & Upjohn 716-MET-0096-015. Closed.

61. One-Year Safety-In-Use Study of Ipratropium Bromide HFA-134a in Adults with Chronic Obstructive Pulmonary Disease (COPD). Boehringer Ingelheim 244.2453. Closed.

62. A Randomized, Double-Blind, Double-Dummy, Multicenter, Parallel-Group Study to Assess the Efficacy and Safety of Oral Augmentin SR2000 / 125 mg Twice Daily versus Oral Augmentin 875 / 125 mg Twice Daily for 7 Days in the Treatment of Adults with Bacterial Community Acquired Pneumonia. SmithKlineBeecham BRL-025000/600. Closed.

63. A Prospective, Randomized, Open-Label, Blinded-Endpoint, Parallel-Group 6-week Treatment Study Comparing Telmisartan combined with Hydrochlorothiazide (40 mg/12.5 mg or 80 mg/12.5 mg) Tablets with Losartan combined with Hydrochlorothiazide (50 mg / 12.5 mg) Tablets using Ambulatory Blood Pressure Monitoring in Patients with Mild-to-Moderate Hypertension. (MICARDIS). Boehringer Ingelheim 502.387. Closed.

64. Phase II Randomized, Double-Blind, Placebo-Controlled Dose-Ranging Study to Determine the Efficacy, Safety, Tolerability and Pharmacokinetics of Ro 205-2349 in Patients with Type 2 Diabetes Mellitus. Roche WM16177. Closed.

65. Phase II Dose – Ranging Study of OROS (Oxycodone HC1) in Patients with Chronic Pain Due to Osteoarthritis. ALZA C-2001-035. Closed.

66. A 16-Week, Randomized, Double-Blind, Placebo-Controlled, Flexible-Dose, Parallel Group, Multicenter Study with a Withdrawal Phase to Investigate the Safety and Efficacy of Dexloxiglumide 200 MG T.I.D. or 200 MG B.I.D. in Female Patients with Constipation-Predominant Irritable Bowel Syndrome. Forest DEX-MD-02A. Closed.

67. A 16-Week, Randomized, Double-Blind, Placebo-Controlled, Flexible-Dose, Parallel Group, Multicenter Study with a Withdrawal Phase to Investigate the

Safety and Efficacy of Dexloxiglumide 200 MG T.I.D. or 200 MG B.I.D. in Female Patients with Constipation-Predominant Irritable Bowel Syndrome. Forest DEX-MD-02B. Closed.

68. A 16-Week, Randomized, Double-Blind, Placebo-Controlled, Flexible-Dose, Parallel Group, Multicenter Study with a Withdrawal Phase to Investigate the Safety and Efficacy of Dexloxiglumide 200 MG T.I.D. or 200 MG B.I.D. in Female Patients with Constipation-Predominant Irritable Bowel Syndrome. Forest DEX-MD-03. Closed.

69. A 16-Week, Randomized, Double-Blind, Placebo-Controlled, Flexible-Dose, Parallel Group, Multicenter Study with a Withdrawal Phase to Investigate the Safety and Efficacy of Dexloxiglumide 200 MG T.I.D. or 200 MG B.I.D. in Female Patients with Constipation-Predominant Irritable Bowel Syndrome. Forest DEX-MD-10. Closed.

70. A Randomized, Double-Blind, Multicenter Study to Evaluate the Tolerability and Effectiveness of Etoricoxib 90 mg q.d. vs. Diclofenac Sodium 50 mg t.i.d. in Patients with Osteoarthritis. (EDGE). Merck 061-00. Closed.

71. A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Fixed-dose, Multicenter Study of Weight-Reducing Effect and Safety of SR141715 in Obese Patients with Untreated Dyslipidemias. Sanofi-Synthelabo EFC4735. Closed.

72. A Phase III, Randomized, Double-Blind, Placebo-Controlled, Outpatient Study to Assess the Long-Term Safety and Efficacy of Two Dose Levels of a Modified Release Formulation of NBI-34060 in Adult Patients with Primary Insomnia. Neurocrine Biosciences NBI-34060-MR-0211. Closed.

73. A Phase III, Open-Label, Outpatient Extension Study to Assess the Long-Term Safety of a Modified Release Formulation of NBI-34060 in Adult Primary Insomnia Patients with Sleep Maintenance Difficulties. Neurocrine Biosciences NBI-34060-MR-0220. Closed.

74. A Randomized, Double-Blind, Placebo-Controlled Trial of 4-Hydroxy Tamoxifen Gel in Premenopausal Women with 50% to 80% Density in Breast Tissue Based on Digitized Analysis of Screening Mammography. Besins 01-4-OHT-01. Closed.

75. A 12-Week, Randomized, Placebo- and Active-Comparator-Controlled, Parallel-Group, Double-Blind Study to Assess the Safety and Efficacy of Etoricoxib 30 mg versus Ibuprofen 2400 mg in Patients with Osteoarthritis (Study 2). Merck 073. Closed.

76. A prospective, multinational, multicenter, double-blind, randomized, active-controlled trial in patients with essential hypertension to compare the effect of Valsartan 80 and 160 mg, with or without the addition of hydrochlorothiazide, once

daily to that of amlodipine 5 and 10 mg once daily, with or without the addition of hydrochlorothiazide, on cardiovascular morbidity and mortality. (VALUE). Novartis 48 933 01 405. Closed 2004.

77. Twelve-week, randomized, double-blind, placebo-controlled study with PRN BID and fixed dosing of Alosetron in female subjects with severe diarrhea-predominant IBS who have failed conventional therapy. GlaxoSmithKline S3B30048. Closed 2004.

78. A double-blind, Randomized placebo-controlled study of R-Tofisopam in outpatients with irritable bowel syndrome. Vela IBS VPI TFP-201. Closed 2004.

79. A randomized, double-blind study to compare the durability of glucose lowering and preservation of pancreatic Beta-Cell Function of Rosiglitazone Monotherapy compared to Metaformin or Glyburide/Glibebclamide in patients with drug-naïve, recently diagnosed Type 2 Diabetes Mellitus.NIDDM. (ADOPT). SmithKlineBeecham 0496553/048.

80. A 12-week, randomized, open label 3-Arm parallel-group, multi-center, phase IIIb study comparing the efficacy and safety of Rosurastin with Atorvastatin a Simvastatin achieving NCEP ATP III LDL-C goals in high-risk subjects with Hypercholesterolemia in the managed care setting. Astra Zeneca 4522US/0003.

81. A randomized, double-blind, active-comparator-controlled, parallel-group study to evaluate the safety of Etoricoxib in patients with Osteoarthritis or Rheumatoid Arthritis. (MEDAL). Merck 066.

82. A multi-center, randomized, double-blind, double-dummy study evaluating the safety and efficacy of the addition of Amlodipine to Quinapril or Losartan in the treatment of Diabetic Hypertensive subjects. Pfizer A0531063.

83. A double-blind, randomized, placebo-controlled study of R-TOFISOPAM in outpatients with irritable bowel syndrome. Vela VPI-TOFP-201.

84. A double-blind, randomized, controlled, parallel-group, multi-center study evaluating the safety and efficacy of Civamide Cream 0.075% as a treatment in subjects with Osteoarthritis of the knee. Winston WL-1001-05-01.

85. A double-blind, randomized, placebo-controlled, Phase III safety study of Tramadol ER 300mg, taken once-daily for the relief of signs and symptoms of Osteoarthritis of the hip and knee. Cipher TRAMCT.02.04.

86. A 4-week, randomized, double-blind, placebo- and positive-controlled, parallel-group, multi-center study of SD-6010 in subjects with symptomatic Osteoarthritis of the knee. Pfizer A6171009.

87. An open label multi-center study evaluating the safety and efficacy of Civamide Cream 0.075% as a treatment in subjects with Osteoarthritis of the knee(s). Winston WL-1001-05-04 Open Label Extension.

88. A multi-center, double-blind, randomized, parallel-group study to compare the effect of 24 weeks treatment with LAF237 (50mg qd or bid) to placebo as add-on therapy to Glimepride in patients with Type 2 Diabetes inadequately controlled with Sulfonylurea Monotherapy. Novartis CLAF237A2305.

89. A 28-week extension to a multi-center, double-blind, randomized, parallel-group study to compare the effect of 24 weeks treatment with LAF237 (50mg qd or bid) to placebo as add-on therapy to Glimepride in patients with Type 2 Diabetes inadequately controlled with Sulfonylurea Monotherapy. Novartis CLAF237A2305E1.

90. A randomized, double-blind, parallel-filter study to evaluate the Antihypertensive efficacy and safety of Losartan-HCTZ combination as compared to Losartan Monotherapy in patients with Essential Hypertension. Merck MK0954A-264-00

91. A twelve-week, double-blind, placebo controlled study to assess the tolerability, efficacy, and safety of Ropinirole dosed PRN in subjects with Restless Legs Syndrome (RLS) who respond to open-label treatment with Roprinole. (Treat RLS PRN). GSK GSK-100310.

92. A multi-center, standard of care-controlled study to evaluate the long-term safety of bicifadine for the treatment of chronic low back pain. DOV. DOV-075-022-US. 2005.

93. A multi-center, double-blind, placebo-controlled randomized study of bicifadine 200 mg BID, bificadine 300 mg BID, and bificadine 400 mg BID in the treatment of chronic low back pain. DOV. DOV-075-020-US. 2005.

94. A 4-week, randomized, double-blind, placebo-controlled study to assess the safety and efficacy of L-000904218 in patients with osteoarthritis of the knee or hip. Merck 006-00. 2005.

95. Pulmonary outcomes within a 2-year period in subjects with diabetes mellitus treated with Technosphere®/Insulin or usual antidiabetic treatment and in subjects without abnormalities in glucose control. Mannkind Corporation. MKC-TI-030. Phase 3a. 2005.

96. A phase 3 study to evaluate the efficacy and safety of TAK-390MR (60 mg QD and 90 mg QD) compared to placebo on symptom relief in subjects with symptomatic non-erosive gastroesophageal reflux disease (GERD).TAP Pharmaceuticals. T-GD04-083. 2005.

97. A phase 3 study to evaluate the efficacy and safety of TAK-390MR (60 mg QD and 90 mg QD) and an active comparator, lansoprazole (30 mg QD) on healing of erosive esophagitis. TAP Pharmaceuticals. T-EE04-085. 2005.

98. A phase 3 study to evaluate the efficacy and safety of TAK-390MR (60 mg QD and 90 mg QD) compared to placebo in maintenance of healing in subjects with healed erosive esophagitis. TAP Pharmaceuticals. T-EE04-087. 2005.

99. A phase 3, open-label study to assess the long-term safety of TAK-390MR (60 mg QD and 90 mg QD). TAP Pharmaceuticals. T-GI04-088. 2005.

100. A multi-center, randomized, double-blind, placebo-controlled, parallel group, phae 2 trial to evaluate the safety and efficacy of BMS-512148 as monotherapy in subjects with type 2 diabetes mellitus who are treatment naïve and have inadequate glycemic control on diet and exercise. Bristol-Myers-Squib. MB102008. 2006.

101. A randomized, double-blind, double-dummy, placebo-controlled, 3x4 factorial design trial to evaluate telmisartan 20 and 80 mg tablets in combination with ramipril 1.25, 10, and 20 mg capsules after eight weeks of treatment in patients with Stage I or II hypertension, with an ABPM sub-study. Phase 3. Boehringer Ingelheim. 2006.

102. A phase 3 prospective, multi-center, open-label, randomized, controlled clinical trial comparing the efficacy and safety in subjects with type 2 diabetes receiving subcutaneous basal insulin and prandial inhalation of Technosphere®/Insulin versus subcutaneous premixed insulin therapy over a 52-week treatment period and a 24-week follow-up. MannKind Corporation. MKC-TI-102. 2006.

103. A phase 2 study to investigate the safety and efficacy of dexloxiglumide for the relief of symptoms of functional dyspepsia. Forest Research Institute. DEX-MD-20. 2006.

104. A randomized, open-label, comparative, multi-center trial to evaluate contraceptive efficacy, cycle, control, safety and acceptability of monophasic combined oral contraceptive (COC) containing 2.5 mg nomegestrol acetate (NOMAC) and 1.5 mg estradiol (E2), compared to a monophasic COC containing 3 mg drospirenine (DRSP) and 30 mcg ethinyl estradiol (EE). Organon. 292992. 2006.

105. A randomized, double-blind, multicenter, placebo-controlled, parallel study evaluating the safety of PT-141 in subjects with controlled essential hypertension (stage 1 or 2). Palatin Technologies. PT-141-2006-32. 2006.

106. A phase 3, open-label long-term safety study of tramadol hydrochloride extended release and meloxicam QD combination in the treatment of moderate to

moderately severe pain associated with osteoarthritis. Biovail Laboratories International SRL. TMX-301. 2006.

107. The effect of dose titration and dose tapering on the tolerability of DVS SR in women with vasomotor symptoms associated with menopause: the PRIMMUS (PRIstiq for Managing Menopause and Understanding Symptoms) Study. Wyeth. 3151A2-405-NA. 2006.

108. A phase 3 study to evaluate the safety and efficacy of TAK-390MR (30 mg QD and 60 mg QD) compared to placebo in maintenance of healing in subjects with healed erosive esophagitis. TAP Pharmaceuticals. T-EE05-135. 2006.

109. A phase 3 study to evaluate the safety and efficacy of TAK-390MR (30 mg QD and 60 mg QD) compared to placebo on symptom relief in subjects with symptomatic non-erosive gastroesophageal reflux disease (GERD). TAP Pharmaceuticals. T-GD05-137. 2006.

110. A 12-week, randomized, double-blind, dose-ranging, placebo-controlled study of asimadoline in subjects with irritable bowel syndrome. Phase 2. Tioga Pharmaceuticals. ASMP2003. 2006..

111. A 36 week randomized, double-blind, parallel group, multi-center, active-controlled, optional titration study comparing an aliskiren-based regimen to a ramipril-based regimen in patients at least 65 years old with systolic essential hypertension. Phase 3b. Novartis. CSPP100A2344. 2006.

112. Worldwide, Multicenter, double-blind, parallel study to evaluate the tolerability of MK-0524A versus niacin extended-release. Phase 3. Merck. 054-00. 2006.

113. A Multi-Center, Randomized, Double-Blind, Placebo-Controlled Efficacy and Safety Study of Testosterone Gel 1.62% for the Treatment of Hypogonadal Men. Solvay. S176.3.104. 2007.

114. A Phase 3, Randomized, Multicenter, Double-Blind, Allopurinol-controlled Study Assessing the Efficacy and Safety of Oral Febuxostat in Subjects with Gout. F-GT06-153, 2007.

115. A 2-Month Safety Follow-up Trial of Subjects from Mannkind Protocols MKC-TI-009, MKC-TI-102, MKC-TI-103, and MKC-TI-030. MKC-TI-126, 2007.

116. A double-blind, randomized, placebo-controlled study of 100, 200 and 300 mg BID R-tofisopam in women with Irritable Bowel Syndrome. VPI-Tofp-203, 2007.

117. A two-week, double-blind, placebo-controlled, randomized, parallel group, efficacy and safety, out-patient trial with ORG 50081 in patients with primary chronic insomnia. 176001, 2007

118. A fifty two week, open label extension trial to evaluate safety and efficacy of ORG 50081 in outpatients with primary chronic insomnia who completed Clinical Trial Protocol 176001 or 176002. 176004, 2007.

119. A Long-Term Safety and Efficacy Study of Eszopiclone in Elderly Subjects With Primary Chronic Insomnia. 190-904, 2007.

120. A parallel-group, double-blind, randomized, placebo-controlled, active comparator, multicenter study to evaluate the efficacy, safety, tolerability and pharmacokinetics of two doses of GSK232802 administered orally as monotherapy for 12 weeks in healthy postmenopausal women with moderate to extremely severe vasomotor symptoms SRM105106, 2007.

121. A multicenter, Multiple dose, Double-Blind, Randomized, Placebo-Controlled, Parallel Group Study of the Safety and Efficacy of AGN 203818 in Female Patients with Fibromyalgia Syndrome. 203818, 2007.

122. A Multicenter, randomized, double-blind, 'crossover" Design Study to evaluate the lipid altering efficacy and safety of Mk-0524B combination tablet compared to MK524A + Simvastatin Coadministration in patients with primary dyslipidemia. 063-MK0524, 2007.

123. A randomized, double-blind, placebo-controlled, multi-center to evaluate the efficacy of CRX-102 in subjects with symptomatic knee osteoarthritis. CRX-102-006, 2007.

124. A phase 2, randomized, double-blind, placebo-controlled, parallel group study to evaluate the efficacy and safety of 12-week administration of PF-00734200 to subjects with type 2 diabetes mellitus and insufficient glycemic control on metformin treatment. Pfizer. A7941006. 2008.

125. Pulmonary Outcomes within a 2-year Period in Subjects with Diabetes Mellitus Treated with Technosphere®/Insulin or Usual Antidiabetic Treatment and in Subjects without Abnormalities in Glucose Control. Evaluation of the Effect of Symptomatic Upper Respiratory Infections on Pharmacological Characteristics of Technosphere®/Insulin in Subjects with Diabetes Mellitus after a Meal Challenge. MKC-TI-030

126. NN1998-1683: Inhaled Mealtime Insulin with the AERx® iDMS plus Pioglitazone versus Pioglitazone alone in Type 2 Diabetes: A 26-Week, Open-Label, Multicentre, Randomised, Parallel Trial to Investigate Efficacy and Safety IND # 56,993

127. A Phase 2 Double-Blind Study to Evaluate the Safety and Efficacy of laprazole (5 mg QD, 20 mg OD and 40 mg QD) and an Active Comparator, Lansoprazole (30 mg QD) on Healing of Erosive Esophagitis. Study Z-EE05-123

128. Validation of Patient Reported Outcome Measures for Influenza disease for use in Phase II POC/Phase III Flu Peptide Vaccine Program (V512) V-512-003. Completed 2007.

129. Evaluation of the Effect of Symptomatic Upper Respiratory Infections on Pharmacological Characteristics of Technosphere®/Insulin in Subjects with Diabetes Mellitus after a Meal Challenge MKC-TI-112.

130. Comparison of the change in HbA1c and the safety of Bedford Laboratories 70/30 (Biphasic) 100 IU/mL rh-Insulin and Novo Nordisk Novolin® 70/30 rh-Insulin in subjects with type 1 and type 2 diabetes. Bedford Laborities. INSU-170/30-PVCL-1.

131. A Phase 3, Multi-center, Open-label, Randomized, Clinical Trial to Evaluate the Safety of Technosphere® Insulin Inhalation Powder in Subjects with Type 1 or Type 2 Diabetes and Mild Obstructive Pulmonary Disease over a 12-Month Treatment Period with a 3-Month Follow-up. Mannkind Corporation. MKC-TI-134.

132. A phase 3, randomized, double-blind, placebo-controlled multicenter study of the analgesic efficacy & safety of tanezumab in patients with osteoarthritis of the knee or hip. Pfizer. A4091011 (OA knee) & A4091014 (OA hip). 2008.

133. An adaptive dose-ranging, multi-center, single-blind, double-dummy, active-controlled trial to determine the target does of canakinumab (ACZ885) in the treatment of acute flares in gout patients who are refractory or contraindicated to NSAIDs and/or colchicine. Novartis. CACZ885H2255. 2008.

134. An 8 week randomized, double-blind, parallel group, multi-center, active controlled study to evaluate the efficacy and safety of valsartan administered in combination with aliskiren (160/150 mg, 320/300 mg) versus valsartan alone (160 mg, 320 mg) in patients with stage 2 hypertension. Novartis. CSPV100AUS01. 2009.

135. A phase 3b multicenter, single-blind trial to evaluate the efficacy of dexlansoprazole MR 30 mg in maintaining control of gastroesophageal reflux disease in subjects on prior twice daily proton ump inhibitor therapy. Takeda. T-GD08-178. 2009.

136. A phase 3, double-blind, randomized, factorial, efficacy and safety study of TAK-491 plus chlorthalidone fixed-dose combination vs. Benicar HCT (olmesartan medoxomil-hydrocholorthiazide) in subjects with moderate to severe hypertension. Takeda. TAK-491CLD_301. 2009.

137. A phase 3, double-blind, randomized, factorial, efficacy and safety study of TAK-491 plus chlorthalidone fixed-dose combination in subjects with moderate to severe hypertension. Takeda. TAK-491CLD_302. 2009.

138. A 24-Week, Dose-Ranging, Multi-Center, Double-Blind, Double-Dummy, Active-Controlled Study To Evaluate Canakinumab (ACZ885) For Prophylaxis Of Signs And Symptoms Of Acute Flares In Chronic Gout Patients Initiating Allopurinol Therapy. Novartis. Protocol No. CACZ885H2251. 2009.

139. A Phase III Randomized, Double Blind, Placebo Control, Multicenter Study To Investigate The Efficacy And Safety Of SER120 Nasal Spray Formulation In Patients With Nocturia. Protocol Number: Serneniyt Pharmceuticals. SPC-SER120-DB1-200901. 2009.

140. A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Trial Of Linaclotide Administered Orally For 12 Weeks Followed By A 4-Week Randomized Withdrawal Period In Patients With Irritable Bowel Syndrome With Constipation. Forrest Research Institute. LIN-MD-31. 2009.

141. A Phase 3 Randomized, Double Blind Placebo And Naproxen Controlled Multicenter Study Of The Analgesic Efficacy And Safety Of Tanezumab In Patients With Osteoarthritis Of The Knee. Pfizer. Protocol A4091015

142. A Randomized, Double-Blind, Placebo- And Active-Controlled, Parallel-Group, Multicenter Study To Determine The Efficacy And Safety Of Albiglutide When Used In Combination With Metformin Compared With Metformin Plus Sitagliptin, Metformin Plus Glimepiride, And Metformin Plus Placebo In Subjects With Type 2 Diabetes Mellitus GSK. GLP 112753. 2009.

143. A Randomized, Open-Label, Parallel-Group, Multicenter Study To Determine The Efficacy And Long Term Safety Of Albiglutide Compared With Insulin In Subjects With Type 2 Diabetes Mellitus. GSK. GLP 112754.

144. A Randomized, Double-Blind, Placebo- And Active-Controlled, Parallel-Group, Multicenter Study To Determine The Efficacy And Safety Of Albiglutide Administered In Combination With Metformin And Glimepiride Compared With Metformin Plus Glimepiride And Placebo And With Metformin Plus Glimepiride And Pioglitazone In Subjects With Type 2 Diabetes Mellitus. GSK. GLP 112757.

145. A Multi-Center, Randomized, Double-Blind, Active-Controlled Study Of The Safety And Efficacy Of Rilonacept Administered Subcutaneously For The Treatment Of An Acute Gout Flare. Regeneron. Protocol Number IL1T-GA-0814.

146. A Phase 3, Double-Blind, Randomized, Factorial, Efficacy And Safety Study Of TAK-491 Plus Chlorthalidone Fixed-Dose Combination In Subjects With Moderate To Severe Hypertension. Takada. TAK-491CLD_302.

147. A phase 3 randomized, double-blind, placebo-controlled, multicenter study to investigate the efficacy and safety of Ser120 nasal spray formulation in patients with nocturia. Serenity Pharmaceuticals Corp. SPC-SER120-200901.

148. A multi-center, randomized, double-blind, placebo controlled trial of the safety of rilonacept for the prophylaxis of gout flares in patients on urate lowering therapy. Regeneron. IL1T-GA-0815.

149. A phase 3b, double-blind, randomized, 12-week efficacy and safety study comparing the TAK-491 plus chlorthalidone fixed-dose combination vs olmesartan medoxomil-hydrochlorthiazide in subjects with moderate to severe hypertension. Takeda. TAK-491CLD_303. 2010.

150. A one-year, randomized, open-label, parallel-group, multiple-dose long-term safety study with controlled adjustment of dose of tapentadol extended-release (ER) and oxycodone controlled-release (CR) in subjects with chronic, painful diabetic peripheral neuropathy (DNP). Johnson & Johnson. R331333PAI3028 (DM DPN). 2010.

151. A randomized, double-blind, placebo-controlled, parallel-group, 26-week, multicenter study with a 78-week extension, to evaluate the efficacy, safety, and tolerability of JNJ-28431754 (canagliflozin) compared with placebo, in the treatment of subjects with type 2 diabetes mellitus inadequately controlled on glucose lowering therapy. Johnson & Johnson. 2010.

152. A randomized, active-controlled, double-blind, double-dummy, parallel group design, multi-center trial to compare the efficacy and safety of 2.5 microgram and 5 microgram tiotropium inhalation solution delivered by the Respimat® inhaler with tiotropium inhalation capsules 18 microgram delivered by the HandiHaler®. Boehringer Ingelheim. 2010.

153. A randomized, double-blind, multi-center, placebo-controlled, combination study to evaluate the urate-lowering activity, safety and potential PK interaction of oral BCX4208 and allopurinol administration in subjects with gout. BioCryst BCX4208 202. 2010.

154. The effect of LY2189265 on blood pressure and heart rate as assessed by ambulatory blood pressure monitoring in patients with type 2 diabetes mellitus. Eli Lilly H9X-MC-GBDN. 2010.

155. Phase II, multicenter, randomized, double-blind, placebo-controlled, dose-ranging study to evaluate the efficacy, safety, and tolerability of JNJ-42160443 (fulranumab) in subjects with neuropathic pain, followed by a double-blind safety extension and an open-label extension. Johnson & Johnson. Clinical protocol 42160443-NPP-2001. 2010.

156. A phase II, multicenter, randomized, double-blind, parallel-group, placebo-controlled study of S-707106 in subjects with type 2 diabetes mellitus and inadequate glycemic control with metformin therapy. Shionogi USA, Inc. Protocol 1010N0921. 2010.

157. A randomized, double-blind, dose response study of safety and efficacy of oral BCX4208 added to allopurinol in subjects with gout who have not adequately responded to allopurinol monotherapy. BioCryst. BCX4208-203. 2011.

158. A randomized, double-blind, placebo-controlled, 3-arm, parallel-group, 26-week, multicenter study with a 26-week extension, to evaluate the efficacy, safety and tolerability of canagliflozin in the treatment of subjects with type 2 diabetes mellitus who have moderate renal impairment. Johnson & Johnson. 28431754DIA3003. 2011.

159. Multicenter, randomized, ctive-0control, phase 3b study to evaluate the cardiovascular safety of febuxostat and allopurinol in subjects with gout and cardiovascular comorbidities. Takeda. TMX-67_301. 2011.

160. A phase 3, multi-center global, open-label 52 week treatment study to assess the long-term safety of NKTR-118 in opioid-induced constipation in patients with non-cancer related pain. AstraZeneca. D3820C00008. 2011.

161. A Multicenter, Randomized, Placebo-Controlled, Blinded Study fo the Efficacy and Safety of Colchicine (Colcrys®) for the Prevention of Gout Flares During the Initiation of Allopurinol. Regeneron Pharmaceuticals IL1T-GA-1103. 2011.

162. A 52-week, double-blind, randomized, placebo-controlled, parallel-group study to evaluate the effect of roflumilast 500 mcg on exacerbation rate in subjects with chronic obstructive pulmonary disease (COPD) treated with a fixed-dose combination of long-acting beta agonist and inhaled corticosteroid (LABA/ICS). Forest ROF-MD-07. 2011.

163. A phase 3, randomized, double-blind, placebo-controlled study evaluating the efficacy, safety, and tolerability of two fixed dose combinations of aclidinium bromide/formoterol fumarate and placebo for 24-weeks treatment in patients with moderate to severe, stable chronic obstructive pulmonary disease (COPD). Forest LAC-MD-31. 2011.

164. A phase 3A, double-blind, placebo-controlled, randomized clinical trial assessing safety and efficacy of MF101 for hot flushes and menopausal symptoms in postmenopausal women. BioNovo, Inc. MF101-004. 2011.

165. A phase 3, randomized, double-blind, multicenter, placebo-controlled, combination study to evaluate the efficacy and safety of lesinurad and allopurinol compared to

allopurinol alone in subjects with gout who have had an inadequate hypouricemic response to standard of care allopurinol. Ardea Biosciences, Inc. RDEA594-302. 2012.

166. A phase 3, randomized, double-blind, multicenter, placebo-controlled, study to assess the efficacy and safety of lesinurad monotherapy compared to placebo in subjects with gout and an intolerance or contraindication to a xanthine oxidase inhibitor. Ardea Biosciences, Inc. RDEA594-303. 2012. A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of NKTR-118 in Patients With Non-Cancer-Related Pain and Opioid-Induced Constipation (OIC). AstraZeneca. D3820C00005. 2012.

167. A 16-Week, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Reslizumab (3.0 mg/kg) Treatment in Patients With Moderate to Severe Asthma. Cephalon. C38072/3084. 2012.

168. TECOS: A Randomized, Placebo Controlled Clinical Trial to Evaluate Cardiovascular Outcomes After Treatment With Sitagliptin in Patients With Type 2 Diabetes Mellitus and Inadequate Glycemic Control. Merck. MK-0431-082. 2012.

169. A randomized, double-blind, placebo-controlled, phase 3 study to evaluate the efficacy, safety, and tolerability of JNJ-27018966 in the treatment of patients with diarrhea-predominant irritable bowel syndrome. Furiex Pharmaceuticals. 27018966IBS3001. 2012.

170. A randomized, double-blind, double-dummy, placebo-controlled, active controlled, parallel-group, multicenter trial of oxycodone/naloxone controlled-release tablets (OXN) to assess the analgesic efficacy (compared to placebo) and the management of opiod-induced constipation (compared to oxycodone controlled-release tablets (OXY) in opiod-experienced subjects with uncontrolled moderate to severe chronic low back pain and a history of opioid-induced constipation who require around-the-clock opioid therapy. Purdue Pharma. ONU3704. 2012.

171. A phase 3, long-term, randomized, double-blind, extension study of the efficacy, safety and tolerability of two fixed dose combinations of aclidinium bromide, formoterol fumarate and placebo for 28-weeks treatment in patients with moderate to severe, stable chronic obstructive pulmonary disease (COPD). Forest Research Institute, Inc. LAC-MD-36. 2012.

172. A randomized, double-blind, placebo-controlled, fixed-dose, parallel-group study jto compare the efficacy, tolerability, and safety of 3 doses of gabapentin enacarbil (GSK1838262) with placebo in the treatment of subjects with moderate-to-severe primary restless legs syndrome (RLS). GSK. 2011N117120_01. 2012.

173. A phase 2, randomized, double-blind, placebo-controlled, parallel-group, multicenter, worldwide, dose-ranging, clinical trial with a proof-of-concept lead

cohort to evaluate the safety, tolerability, and efficacy of MK-8457 + MTX in patients with active rheumatology despite methotrexate therapy. Merck. MK-8457-008. 2012.

174. 6-Month, Multicenter, Randomized, Open-label, Parallel-group Study Comparing the Efficacy and Safety of a New Formulation of Insulin Glargine and Lantus® Injected in the Morning or Evening in Patients with Type 1 Diabetes Mellitus with a 6-Month Safety Extension Period. Sanofi. EFC-12456. 2012.

175. 6-Month, Multicenter, Randomized, Open-label, Parallel-group Study Comparing the Efficacy and Safety of a New Formulation of Insulin Glargine and Lantus® in Insulin-Naïve Patients with Type 2 Diabetes Mellitus not Adequately Controlled with Non-Insulin Antihyperglycemic Drugs with a 6-Month Safety Extension Period. Sanofi. EFC-12347. 2012.

176. Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study to Evaluate Cardiovascular Outcomes of TAK-875, 50 mg in Addition to Standard of Care in Subjects with Type 2 Diabetes and with Cardiovascular Disease or Multiple Risk Factors for Cardiovascular Events. TAKEDA. TAK-875_306. 2012.

177. A long-term open-label extension study for subjects completing phase 3 efficacy and safety study of lesinurad monotherapy in subjects with gout. Ardeas Biosciences. ADEA594-305. 2013.

178. A phase 4 multicenter, international, randomized, parallel group, double-blind, placebo-controlled, cardiovascular safety and remal microvascular outcome sutyd with linagliptin, 5 mg once daily in patients with type 2 diabestes mellitus at high vascular risk (CARMELINA). Boehringer Ingelheim. No. 1218.22. 2013.

179. A randomized, double blind, placebo controlled, multicenter study to investigate the efficacy and safety of SER12 nasal spray formulation in patients with nocturia. Serenity Pharmaceuticals. SPC-SER120-DB4-201301. 2013.

180. A randomized, double-blind, placebo-controlled, parallel group, multicenter study to evaluate the blood pressure reduction with ambulatory blood pressure reduction with ambulatory blood pressure monitoring (ABPM), safety, and tolerability of canaglifozen in the treatment of subjects with hypertension and type 2 diabetes mellitus. Janssen Scientific Affairs. Johnson & Johnson. 28431754DIA4002. 2013.

181. A randomized, double-blind, parallel group, multicenter study to evaluate the efficacy and safety of ETC-1002, ezetimibe, and the combination in hypercholesterolemic patients with or without statin intolerance. Esperion. 2013.

182. A phase 3, multicenter, randomized, double-blind, active-comparator-controlled clinical trial to study the safety and efficacy of the addition of ertuglifozin (MK-8835/PF-04971729) compared with the addition of glimerpiride in subjects with

type 2 diabetes mellitus who have inadequate control on metformin. Merck MK-8835-002-00. 2014.

183. A phase 2, multicenter, randomized, double-blind (within dose), placebo-controlled, parallel-group, dose-range-finding study to evaluate the efficacy, safety, and pharmacokinetics of X0002 spray versusplacebo in subjects with mild to moderate osteoarthritis of the knee. Techfields-Covance TF-X0002-21. 2014.

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