

MARK S. KIPNES, MD PUBLICATIONS

ABSTRACTS/POSTER PRESENTATIONS

Virtual Endocrinologist: Hospital Diabetes Management Via Telemedicine. Mark S. Kipnes, 1 Steve Haffner, 2 Teri Lightner, 3 Rajesh Garg, 4 Firas Akhrass, 5 Vijayveer S. Pamar, 6 Amna a. Salhin, 7 Jacob Vadakekalam, 8 Javier Pena, 9 Syndy Kirkland, 10 Merri Pendergrass, 11. 1 DGD Clinic, San Antonio, TX; 2 San Antonio, TX; 3 See My Doc, Harlington, TX; 4 Harvard Medical School, Boston, MA; 5 DGD Clinic, San Antonio, TX; 6 DGD Clinic, San Antonio, TX; 7 DGD Clinic, San Antonio, TX, 8 DGD Clinic, San Antonio, TX,; 9 VENP, Harlingen, TX; 10 VENP, Harlingen, TX; 11 University of Arizona, Tucson, AZ. Abstract presented at the ADA 76th Scientific Sessions New Orleans, LA June 10-14, 2016.

Metabolic Effects and Safety of Single Rising-dose Sitagliptin in Adolescents with Type 2 Diabetes. Larry A. Fox,¹ Iain Fraser,² Naomi Neufeld,³ Mark S. Kipnes,⁴ Tracie L. Miller,⁵ Phillip S. Zeitler,⁶ Henry Rodriguez,^{7*} Jocelyn Gilmartin,² Susan J. Lee,² Jaclyn K. Patterson,² Xiujiang Li,² Lata Maganti,² Wen-Lin Luo,^{2**} Daniel Tatosian,² Edward A. O'Neill,² and S. Aubrey Stoch². © Merck, Sharp & Dohme Corp. 2013. Presented at the American Diabetes Association 73rd Scientific Sessions, June 21-25, 2013, Chicago, IL. 1 Nemours Children's Clinic, Jacksonville, FL; 2 Merck, Whitehouse Station, NJ; 3 Neufeld Medical Group, West Hollywood, CA; 4 DGD Clinic, San Antonio, TX; 5 University of Miami, Miami, FL; 6 Children's Hospital Colorado, Aurora, CO; 7 James Whitcomb Riley Hospital for Children, Indianapolis, IN; *Present affiliation: University of South Florida, Tampa, FL; **Present affiliation: Bristol-Myers Squibb, Princeton, NJ

Safety, Pharmacokinetics, and Pharmacodynamics of a Single Subcutaneous Dose of VRS-859 in Patients with Type 2 Diabetes. JEFFREY L. CLELAND, RONNIE ARONSON, Eric HUMPHRISS, CAMILLE SHORE, RONG ZHOU, Mark S. KIPNES. Redwood City, CA; Toronto, Canada; Cincinnati, OH; San Antonio, TX. Presented at the American Diabetes Association 72nd Scientific Sessions, Philadelphia, PA., June 8-12, 2012.

Safety, Tolerability and Efficacy of Azilsartan Medoxomil With or Without Chlorthalidone During and After 8 Months of Treatment for Hypertension. Mark S. Kipnes, MD. Published online in *The Journal of Clinical Hypertension* – JCH12474, January 24, 2015.

A Long-Acting Human Growth Hormone with Delayed Clearance (VRS-317): Results of a Double-Blind, Placebo-Controlled, Single Ascending Dose Study in Growth-Hormone-Deficient Adults. Kevin C. J. Yuen, Gerald S. Conway, Vera Popovic, George R. Merriam, Timothy Bailey, Amir H. Hamrahian, Beverly M. K. Biller, Mark Kipnes, Jerome A. Moore, Eric Humphriss, George M. Bright, and Jeffrey L. Cleland. Original Article Endocrine Research. Copyright © 2013 by The Endocrine Society Published Online April 12, 2013. *The Journal of Clinical Endocrinology & Metabolism*. June 2013, Volume 98. Number 06.

Macimorelin (AEZS-130)-Stimulated Growth Hormone (GH) Test: Validation of a Novel Oral Stimulation Test for the Diagnosis of Adult GH Deficiency. J.M. Garcia, R. Swerdloff, C. Want, M. Kyle, M. Kipnes, B.M. K. Biller, D. Cook, K.C. J. Yuen, V. Bonert, A. Dobs, M.E. Molitch, and G.R. Merriam. Original Article Endocrine Care. Copyright © 2013 by The Endocrine Society Published Online April 4, 2013. *The Journal of Clinical Endocrinology & Metabolism*. June 2013, Volume 98. Number 06.

Efficacy and Safety of the Farnesoid X Receptor Agonist Obeticholic Acid in Patients with Type 2 Diabetes and Nonalcoholic Fatty Liver Disease. A one-year Study to Assess the Safety and Efficacy of the CB1R inverse agonist taranabant in Overweight and Obese Patients with Type 2 Diabetes. M. S.; Hollander, P.; Fujioka, K.; Gantz, I.; Seck, T. Read by Scientific & Academic Publishing, May 2, 2012.

Randomized Control Trial of Topical Clonidine for Treatment of Painful Diabetic Neuropathy. Claudia M. Campbell^a, Mark S. Kipnes^b, Bruce C. Stouch^c, Kerrie L. Brady^d, Margaret Kelly^d, William K. Schmidt^d, Karin L. Petersen^{e,f}, Michael C. Rowbotham^{e,f}, James N. Campbell^d. *PAIN* (2012), <http://dx.doi.org/10.1016/j.pain.2012.04.014>

A 16-Week Open-Label, Multicenter, Pilot Study Assessing Insulin Pump Therapy in Patient with Type 2 Diabetes Suboptimally Controlled with Multiple Daily Injections. Juan P. Frias, MD¹, Bruce W. Bode, MD², Timothy S. Bailey, MD³, Mark S. Kipnes, MD⁴, Rocco Brunelle, MS⁵, Steven V. Edelman, MD¹. Article – July 2011 – Journal of Diabetes Science and Technology.

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A Novel Human Growth Hormone XTEN Construct (VRS-317) for Once-a-Month Subcutaneous Administration in a Phase 1a Study of Growth Hormone-Deficient Adults. Jeffrey L. Cleland¹, Nathan Geethring², Benjamin Spink², Soha Mottlagh², Yi Yao², Joshua Silverman², and Mark S. Kipnes³. Article – June 2011

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Topical Clonidine for Treatment of Painful Diabetic Neuropathy: a Randomized Double Blind Phase IIb Clinical trial. James N. Campbell, Prof., MD, jcampbell@arciontherapeutics.com, Arcion Therapeutics, Baltimore, MD, United States. Mark S. Kipnes, Dr., MD, mkipnes@dgdclinic.com, Cetero Research/Diabetes and Glandular Disease Clinic, San Antonio, TX, United States. Michael C. Rowbotham, Prof., MD, RowbotM@cpmcrl.org, California Pacific Medical Center Research Institute, Scientific Director, San Francisco, CA, United States. Karin L. Petersen, Prof., MD, Karin.petersen@ucsf.edu, University of California, Neurology, San Francisco, CA, United States. Bruce C. Stouch, Dr. PhD, bstouch@arciontherapeutics.com, Arcion Therapeutics, Baltimore, MA, United States. Margaret Kelly, Ms., MS, mkelly@arciontherapeutics.com, Arcion Therapeutics, Baltimore, MD, United States. Claudia M. Campbell, Dr., PhD, ccampb41@jhml.edu, Johns Hopkins University School of Medicine, Psychiatry, Baltimore, MD, United States. Kerrie Brady, Ms., MS, MBA, kbrady@arciontherapeutics.com, Arcion Therapeutics, Baltimore, MD, United States. William K. Schmidt, Dr., PhD,

wschmidt@arciontherapeutics.com, Arcion Therapeutics, Baltimore, MD, United States. *Presented at the ADA 71st Scientific Sessions, San Diego, CA, June 24-28, 2011*

Continuous Subcutaneous Insulin Infusion (CSII) in Type 2 Diabetes: Reductions in A1c, Mean Glucose, and Variability. Author Block: H. Anhalt¹, D. Rodbard², T. Bailey³, B. Bode⁴, R. Brunelle⁵, S. Edelman⁶, J.P. Frias¹, M.S. Kipnes⁷; Animas Corporation, West Chester PA, USA, ³AMCR Institute Inc., Escondido CA, USA. ⁴Atlanta Diabetes Associates, Atlanta GA, USA. ⁵B2S Consulting, Carmel, IN, USA. UCSD/VA TCOYD, San Diego, CA, USA. ⁷Cetero Research/Diabetes and Glandular Disease Clinic, San Antonio, TX, USA. *Presented at the ADA 71st Scientific Sessions, San Diego, CA, June 24-28, 2011*

A Placebo Controlled Single Ascending Dose Phase 1 for Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics After Subcutaneous Administration of VRS-859 in Patients with Type 2 Diabetes Mellitus. Jeffrey L. Cleland¹, Camille R. Shore², and Mark S. Kipnes³ Diartis Pharmaceuticals, Inc, Mountain View, CA Versartis, Inc, Mountain View, CA . Cetero Research/DGD Clinic, San Antonio, TX *Presented at the ADA 71st Scientific Sessions, San Diego, CA, June 24-28, 2011*

A Study to Assess the Metabolic Effects of Ranolazine When Added to Ongoing Non-Insulin Medical Therapy in Subjects with Type 2 Diabetes Mellitus (T2DM). 1. Mark S. Kipnes, MD, mkipnes@dgdclinic.com, 2106148612, Cetero Research, San Antonio, TX, United States 2. Harold E. Bays, MD, HBaysMD@aol.com, 5025155672, Louisville Metabolic and Atherosclerosis Research Center, Louisville, KY, United States 3. Peter Staehr, MD, Peter.Staehr@gilead.com, 6505243883, Gilead Sciences, Clinical Pharmacology, Foster City, CA, United States 4. Rajneesh Nath, MD, PhD, jneesh.Nath@gilead.com, 6505243877, Gilead Sciences, Clinical Pharmacology, Foster City, CA, United States 5. David S. Kwon, MD, PhD, David.Kwon@gilead.com, 6505221571, Gilead Sciences, Clinical Pharmacology, Foster City, CA, United States 6. Millie D. Gottwald, Pharm D., Millie.Gottwald@gilead.com, 6505225903, Gilead Sciences, Clinical Pharmacology, Foster City, CA, United States 7. Luiz Belardinelli, MD, Luiz.Belardinelli@gilead.com, 6505243889, Gilead Sciences, Cardiovascular Therapeutic Area, Foster City, CA, United States. *Presented at the ADA 71st Scientific Sessions, San Diego, CA, June 24-28, 2011.*

Year Two Assessment of Fenofibric Acid and Moderate-Dose Statin Combination: A Phase 3, Open-Label, Extension Study. Kipnes MS, Roth EM, Rhyne JM, Setze CM, Lele A, Kelly MT, Sleep DJ, Stolzenbach JC. *Clinical Drug Investigation*; January 1, 2010; Volume 30 (Issue 1) pp: 51-61. *Source: DGD Research – a Cetero Research Company, San Antonio, Texas, USA*

A 16-Week Open-Label, Multicenter, Pilot Study Assessing Insulin Pump Therapy in Patient with Type 2 Diabetes Suboptimally Controlled with Multiple Daily Injections. Juan P. Frias, MD¹, Bruce W. Bode, MD², Timothy S. Bailey, MD³, Mark S. Kipnes, MD⁴, Rocco Brunelle, MS⁵, Steven V. Edelman, MD¹. *Presented at the European Association for the Study of Diabetes (Stockholm, Sweden, September 2010.*

“Macimorelin, an Oral Ghrelin-Incretin mimetic GH Secretagogue, as a Potential Diagnostic Test for Adult GH Deficiency” has been accepted for poster presentation at the *5th International Congress of the GRS-IGF Society at the Sheraton New York towers in New York, NY USA, October 3-7, 2010.*

Assessment of Continuous Glucose Monitoring Data in Insulin Pump-Treated Patients with Type 2 Diabetes. Steven V. Edelman, Bruce W. Bode, Timothy S. Bailey, Mark S. Kipnes, Rocco L. Brunelle, Xiaojing Chen, Juan P. Frias. *Presented at the American Diabetes Association 70th Scientific Sessions in Orlando, FL June 25th through 29th, 2010.*

Comparison of insulin lispro protamine suspension and insulin detemir in basal-bolus therapy in patients with Type 1 diabetes. Chacra AR¹, Kipnes M, Ilag LL, Sarwat S, Giaconia J, Chan J; COMPLETE T1D investigators. Abstract Diabetes Med May 2010

Insulin Pump Therapy in Patients with Type 2 Diabetes Safely Improve Glycemic Control Using a Simple Insulin Dosing Regimen. Steven V. Edelman MD¹, Bruce W. Bode, MD², Timothy S. Bailey, MD,³ Mark S. Kipnes, MD⁴, Rocco Brunette, M.S.⁵, Xiaojing Chen, M.S.⁶, and Juan P. Frias, MD⁶. *Diabetes Technology & Therapeutics, Volume 12, Number 8, 2010. © Mary Ann Liebert, Inc. DOI: 10.1089/dia.2010.0034.*

Single-Dose Pharmacokinetics and Pharmacodynamics of Sergliflozin Etabonate, a Novel Inhibitor of Glucose Reabsorption, in Healthy Volunteers and Subjects with Type 2 Diabetes Mellitus. Hussey EK¹, Clark RV, Amin DM, Kipnes MS, O'Connor-Semmes RL, O'Driscoll EC, Leong J, Murray SC, Dobbins RL, Layko D, Nunez DJ. *Abstract – PubMed Epub Jan 7, 2010*

Clinical Performance of the TRUE2go Blood Glucose System – A Novel Integrated System for Meter and Strips. Mark S. Kipnes, MD¹, Hal Joseph, RPA-C, CDE², Harry Morris, DO, MPH³, Jason Manko, BLOOD SUGAR⁴ and Douglas E. Bell, PHD⁴. Original Article published in DIABETES TECHNOLOGY & THERAPEUTICS. Volume 11, Number 10, 2009. © Mary Ann Liebert, Inc. DOI: 10.1089/dia.2009.0020

A One-Year Study to Assess the Efficacy, Safety and Tolerability of Taranabant, a Highly Selective CB1R Inverse Agonist, in Overweight and Obese Patients with Type 2 Diabetes: 36-Week Results. Troels Wolthers¹, Mark Kipnes², Priscilla Hollander³, Ira Gantz⁴, Thomas Seck⁴, Ngozi Erondu⁴, Yue Shentu⁴, Kaifeng Lu⁴, Shailaja Suryawanshi⁴, Margaret Chou⁴, Michael J. Davies⁴, Steve Heymsfield⁴, Keith D. Kaufman⁴, John M. Amatruda⁴. ¹Merck Sharp & Dohme, New South Wales, Australia. ²Diabetes and Glandular Disease Research Associates, San Antonio, Texas, USA, ³Endocrinology Center, Baylor University Medical Center, Dallas, TX, USA, ⁴Merck Research Laboratories, Rahway, NJ USA. 5th AOCO Presentation 2009, Mumbai, India

The efficacy and safety of 12-week treatment with fenofibric acid co-administered with low- or moderate-dose statin in patients 65 years or older with mixed dyslipidemia. Peter H. Jones¹, Mark S. Kipnes², Maria L. Rios³, Carolyn M. Setze⁴, Maureen T. Kelly⁴, Darryl J. Sleep⁴. ¹Baylor College of Medicine, Houston, TX. ²DGD Research Associates, San Antonio, TX. ³, ⁴Abbott, Abbott, Park, IL. Published in *J Clin Lipidol*, 2009.

“Continuous Subcutaneous Insulin Infusion in Patients with Type 2 Diabetes Safely Improved Glycemia Control Using a Simple Insulin Dosing Regimen.” Selected for Poster Presentation at the 45th EASD Annual Meeting, Vienna, September 29 – October 2, 2009.

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Performance of the TRUE2go (TM) Blood Glucose System: A Novel Integrated System for Meter and Strips; Douglas E. Bell, Ph.D; Hal Joseph, RPA-C, CDE; Mark S. Kipnes, MD; Jason Manko, BS; Harry Morris, DO, MPH, Home Diagnostics, Inc., Fort Lauderdale, Florida, USA 2009

Evaluation of Various Doses of Recombinant Human Thyrotropin in Patients with Multinodular Goiters. Braverman L; Kloos RT; Law B Jr.; Kipnes M; Dionne M; Magner, J. Abstract – Endocr Pract Oct 2008

Sitagliptin, A Selective DPP-4 Inhibitor, Improves Glycemic Control when Added to a Sulfonylurea or to a Sulfonylurea and Metformin in Patients with Type 2 Diabetes. Kjeld Hermansen, Mark Kipnes, Edmund Luo, Fanurik Hootan Khatami, Peter P. Stein, Aarhus, Denmark, San Antonio, TX, Rahway, NJ. Presented at the 67th A.D.A. Meeting & Scientific Sessions, June 22 through 26, 2007, Chicago, IL.

Safety and Pharmacodynamics of CJC-1134-PC, a Novel GLP-1 Receptor Agonist, in Patients with Type 2 Diabetes Mellitus: A Randomized Placebo-Controlled, Double-Blind, Dose-Escalation Study. MAGGIE WANG, MARK KIPNES, STEPHANIE MATHESON, STELLA WEN, BETTY LAWRENCE, KAREN THIBAUDEAU, JEAN-PAUL CASTAIGEN, THOMAS ULRICH, Montreal, PQ, Canada, San Antonio, Texas. Presented at the 67th A.D.A. Meeting & Scientific Sessions, June 22 through 26, 2007, Chicago, IL.

Efficacy and Safety of the Dipeptidyl Peptidase-4 Inhibitor, Sitagliptin, in Patients with Type 2 Diabetes Mellitus Inadequately controlled on Glimepiride Alone or on Glimepiride and Metformin. Kjeld Hermansen, MD¹, Mark Kipnes, MD², Edmund Lui, Ph.D. ³, Debra Fanurik, Ph.D., Hootan Khatami, MD³, Peter Stein, MD³, for the Sitagliptin Study 035 Group.* Aarhus University Hospital, Aarhus, Denmark; ²Diabetes and Glandular Disease Clinic, San Antonio, Texas, USA; ³Merck Research Laboratories, Rahway, NJ, USA; *See online appendix for list of Sitagliptin Study 035 investigators. *Diabetes, Obesity and Metabolism. June 2007.*

Sitagliptin Monotherapy Improved Glycemic Control in the Fasting and Postprandial States and Beta-Cell Function after 24 Weeks in Patients with Type 2 Diabetes (T2DM). PABLO ASCHNER, MARK KIPNES, JARED LUNCEFORD, CAROLYN MICKEL, MICHAEL

DAVIES, DEBORA WILLIAMS-HERMAN. *Bogota, Columbia, San Antonio, TX, Rahway, NJ. Late Breaking Abstract at the 66th Scientific Sessions, A.D.A. Meeting June 9-13, 2006, Washington D.C.*

Single Treatment, Phase 1b Trial of a Zinc Finger DNA-Binding Protein (ZFP) Activator (SB-509) of Vascular Endothelial Growth Factor (VEGF) in Subjects with Diabetic Neuropathy (DN) Shows Clinical Tolerability and Improvements in Pain and Neurologic Effects. MARK S. KIPNES, DALE G. ANDO. San Antonio, Texas; Richmond California. *Late Breaking Abstract at the 66th Scientific Sessions, A.D.A. Meeting June 9-13, 2006, Washington D.C.*

"Denosumab in Postmenopausal Women with Low Bone Mineral Density." Michael R. McClung, M.D., E. Michael Lewiecki, M.D., Stanley B. Cohen, M.D., Michael A. Bolognese, M.D., Grattan C. Woodson, M.D., Alfred H. Moffett, M.D., Munro Peacock, M.D., Paul D. Miller, M.D., Samuel N. Lederman, M.D., Charles H. Chestnut, M.D., Douglas Lain, M.D., Alan J. Kivitz, M.D., Donna L. Holloway, Ph.D., Charlie Zhang, Ph.D., Mark C. Peterson, Ph.D., and Pirow J. Bekker, M.D., Ph.D., for the AMG 162 Bone Loss Study Group.* Abstract published in *The NEW ENGLAND JOURNAL of MEDICINE* 354:8, February 23, 2006.

"Co-Administrator of MK-0431 and Metformin in Patients with Type 2 Diabetes Does Not Alter the Pharmacokinetics of MK-0431 or Metformin." GARY HERMAN, ARTHUR BERGMAN, BINGMING YI, CATHY STEVENS, ALAN XIAO, LI CHEN, AMY WANG, WEI ZENG, MICHAEL DAVIES, MARK KIPNES, JOHN WAGNER. *Rahway, NJ; West Point, PA; San Antonio, TX. Presented at the 65th Scientific Sessions. Friday June 10 – Tuesday June 14, 2005. The San Diego Convention Center, San Diego, California*

"Efficacy of Tadalafil for the Treatment of Erectile Dysfunction in Men with Diabetes; Results from MOMENTUS (Multiple Observations in Men with ED in National Tadalafil Study in the US). SAM ENGEL, LEONARD MARKS, MARK S. KIPNES, MICHAEL A. MARX, FANNI NATANEGARA, David G. WONG, SANJEEV AHUJA. *Norwalk, CT; Culver City, CA; San Antonio, TX; Indianapolis, IN. Presented at the 65th Scientific Sessions. Friday June 10 – Tuesday June 14, 2005. The San Diego Convention Center, San Diego, California*

Effects of DAC-GLP: (CJC-1131) on Glycemic Control and Weight Over 12 Weeks in Metformin-Treated Patients with Type 2 diabetes. Robert E. Ratner; PH Guivarch; Jean-Francois Dreyfus; [...] Mark Kipnes. Conference Paper at the 65th Annual Meeting of The American Diabetes Association. Jan 2005.

Striant™SR: A Novel, Effective and Convenient Testosterone Therapy for Male Hypogonadism. Marta Korbonits¹, Mark Kipnes², Ashley B. Grossman¹. *International Journal of Clinical Practice. Volume 58 Issue 11, Page 1073 - November 2004. doi:10.1111/j.1368-5031.2004.00383.x*

Modulation of the Immune Response in Type 1 Diabetics by NBI-6024, an Altered Peptide Ligand of an Immunodominant Epitope of Insulin. David Alleva, Richard Maki, Amy Putnam, Mark Kipnes, Paresch Dandona, Jennifer Marks, Debra Simmons, Roland Jimenez, Donna Deboer, Henry Pan, Paul Conlon, Peter Gottlieb. *Presented at A.D.A. 64th Scientific Sessions, June 4-8, 2004. #45-LB*

Safety of Mitemincal Fumarate (GM-611) in Patients with Symptomatic Gastroparesis. Mark S. Kipnes¹, Colleen M. Schmitt², John K. DiBaise³, John C. Fant⁴, Irene Sarosiek⁵. San Antonio, TX, Chattanooga, TN, Omaha NE, Salt Lake City, UT, Kansas City, KS. *Presented at A.D.A. 64th Scientific Sessions 2004, June 5, 2004. Chugai Pharma.*

"Effect of Mitemincal Fumarate (GM-611) on Gastric Emptying, Safety and Tolerability with Diabetic or Idiopathic Gastroparesis." *Endo 2004 Meeting for poster presentation. Friday, June 18, 2004, 11:00 to 12:00 & 2:30 p.m. to 3:30 p.m., Exhibit Hall, Poster Board # P3-577. Chugai Pharma.*

Effect of Mitemincal Fumarate (GM-611) on Gastric Emptying in Patients with Idiopathic or Diabetic Gastroparesis": Digestive Disease Week (DDW) 2004 meeting for a AGA Poster Session in May. Tuesday, May 18, 2004, Abstract ID#: 103158, Poster Session ID#: 1817, Session Type: Gastric Motility and Sensation. 12:00 to 2:00 p.m.

"Comparing the Efficacy and Tolerability of Metformin XT QD to Immediate-Release Metformin BIDD In Patients with Type 2 Diabetes": AACE 2004 as a poster presentation. Mark S. Kipnes, MD¹, Prachi K. Dandekar, Pharm.D.². Friday, April 30, 2004 from 9:45 to 10:30 a.m. *Andrx Labs, Inc., 411 Hackensack Ave., Hackensack, New Jersey 07601, U.S.A.*

"Comparison of Extended-Release Metformin with the Evening Meal to Immediate-Release Metformin bid in Type 2 Diabetes. Mark S. Kipnes, MD¹, Prachi K. Dandekar, Pharm.D.². Friday, April 30, 2004 from 9:45 to 10:30 a.m. *Andrx Labs., Inc.*, 411 Hackensack Ave., Hackensack, New Jersey 07601, U.S.A.

Clamp Study to Evaluate Steady State Relationship Between ISF And Blood Glucose. Philip J. Stout¹ and Mark S. Kipnes². ¹Integ, Inc., St. Paul, MN 55113, ²Diabetes & Glandular Disease Research Associates, P.A., San Antonio, Texas 78229. *Presented at the Third Annual Diabetes Technology Meeting, San Francisco Airport Hyatt Regency Hotel, November 6-8, 2003.*

Plasma Glucose and Insulin Response to Isocaloric Amounts of Enteral Formulas in Persons with Type 2 Diabetes Mellitus. S.L. Schwartz, M.D.; J. Fischer, M.D.; M. Kipnes, M.D. and L. Kelly, R.N. Diabetes and Glandular Disease Research Center, San Antonio, TX. *Currently used by Novartis Nutritional, in their brochures and on their Website. January, 2003.*

"Efficacy and Safety of Treatment with Simvastatin in Thiazolidinedione-Treated Type 2 Diabetic Patients." M. S. Kipnes¹, A. J. Lewin², L. F. Meneghini³, I. Perevovskaya⁴, S. Shah⁴, D. Plotkin, J. Tobert⁴; ¹Diabetes & Glandular Disease Research Associates, P.A., San Antonio, TX, ²National Research Institute, Los Angeles, CA, ³University of Miami School of Medicine Diabetes Research Institute, Miami, FL, ⁴Merck Research Laboratories, Rahway, NJ. *European Association for the Study of Diabetes (EASD₂₀₀₂). March 29, 2002.*

"Durability of Glycemic Control with Pioglitazone in Long-Term Combination and Monotherapy". DANIEL EINHORN, MARK KIPNES, N. BRADLEY GLAZER, WILLIAM WISHNER, PIOGLITAZONE STUDY GROUP. San Diego CA; San Antonio, TX; Lincolnshire, IL. *Diabetes, A Journal of The American Diabetes Association, Abstract Book, 61st Scientific Sessions, Monday, June 25, 2001. Volume 50, Supplement 2.*

"Twelve-Month Effectiveness of Insulin Glargine Use in Diabetic Patients from an Endocrinology Specialty Practice". JEROME S. FISCHER, CRAIG S. ROBERTS, TRENT MCLAUGHLIN, LITZA LOZA, REBECCA BEAUCHAMP, LAURA ANTELL, SHERWYN SCHWARTZ, MARK KIPNES. San Antonio, TX; Yardley, PA; Bridgewater NJ. Scientific Sessions – A.D.A. Annual Meeting – American Diabetes Association.

"COMMUNITY SCREENING FOR DIABETES: SHOULD DEMOGRAPHICS BE A FACTOR"? Mark S. Kipnes, Sherwyn L. Schwartz, Jerome S. Fischer, William F. Trigos, Amna A. Salhin, Jacob Vadakekalam, Daina Dreimane, William D. Linn. American Association of Clinical Endocrinologists 10th Annual Meeting & Clinical Congress. May 2-6, 2001. San Antonio, Texas.

"Pioglitazone Hydrochloride in Combination with Metformin in the Treatment of Type 2 Diabetes Mellitus: A Randomized, Placebo-Controlled Study. Daniel Einhorn MD¹, Marc Rendell, MD², James Rosenzweig, MD³, John W. Egan,⁴ Annette L. Mathisen, PhD⁴ and Roberta L. Schneider, MD⁴, for the Pioglitazone 027 Study Group* ¹Diabetes and Endocrine Associates and Sharp HealthCare, San Diego, California, ²Creighton Diabetes Center, Omaha, Nebraska, and the Rose Salter Medical Research Foundation, Baltimore, Maryland, ³Joslin Diabetes Center, Boston, Massachusetts, and

⁴Takeda America Research and Development Center, Inc, Princeton, New Jersey. *Clinical Therapeutics.2000;22:1395-1409.* Parts of this work were presented at the 59th Annual Meeting and Scientific Sessions of the American Diabetes Association, June 19-20, 1999, San Diego, California, and published as an abstract in *Diabetes*, Supplement 1, May 1999. *Members of the Pioglitazone 027 Study Group are listed in the Acknowledgements. *Mark S. Kipnes: Part of 027 the Study Group.

"A Comparison of the Pharmacodynamic Effects of Inhaled Insulin versus Subcutaneous Insulin in Type 1 Diabetic Patients". MARK KIPNES, BABATUNDE OTULANA, PER CLAUSON, JEROME FISCHER, STEPHEN J. FARR, VIBEKE HATORP, SHERWYN SCHWARTZ, HAYWARD, CA. *Diabetes, A Journal of the American Diabetes Association, Abstract Book, 59th Scientific Sessions, May 1999, Volume 48, Supplement I, pp. A95.*

"Glycemic Response to An Induced -Viscosity Complex Incorporated Into A Glucose Beverage In Healthy Adult Subjects". B.W. Wolf, C.-S. Lai, M. S. Kipnes, K. B. Wheeler and K. A. Garleb, MDs. *The FASEB Journal, March 1998, Abstracts Part I, Volume 12, Number 4*

DOES GASTRIC EMPTYING STATUS IN PATIENTS WITH DIABETES INFLUENCE THE EFFECTIVENESS OF DOMPERIDONE? D. Patterson, Seattle, WA; D. Silvers, Metairie, LA; M. Kipnes, San Antonio, TX; V. Broadstone, Louisville, KY; EMM. Quigley, Omaha, NE; R.

McCallum, Kansas City, KA; A. Joslyn, Titusville, NJ. Annual Meetings of: American Gastroenterological Association and American Association for the Study of Liver Diseases. May 11-14, 1997.

* M.S. Kipnes – member of study group

Metabolic Effects and Safety of Single Rising-Dose Sitagliptin in Adolescents with Type 2 Diabetes. Larry A. Fox, Iain P. Fraser, Naomi Neufield, Mark S. Kipnes, Tracie L. Miller, Phillip S. Zeitler, Henry Rodriguez, Jocelyn Gilmartin, Susi Lee, Jacklyn K. Patterson, Xiujiang Li, Lata Maganti, Wen-Lin Lui, Daniel Tatosian, Edward A. O'Neill, S. Aubrey Stoch, Jacksonville, FL, Whitehouse Station, NJ, West Hollywood, CA, San Antonio, TX, Miami, FL, Aurora, CO, Indianapolis, IN. Presented at the American Diabetes Association 73rd Scientific Sessions, June 21-25, 2013, Chicago, IL.

Pharmacokinetics and Pharmacodynamics of Sitagliptin in Adolescents with Type 2 Diabetes. Iain P. Frasier, Naomi Neufield Larry A. Fox, Mark S. Kipnes, Tracie L. Miller, Phillip S. Zeitler, Henry Rodriguez, Jocelyn Gilmartin, SUZI Lee, Jacklyn K. Patterson, Xiujiang Li, Lata Maganti, Wen-Lin Luo, Daniel Tatosian, Edward A. O'Neill, S. Aubrey Stoch, Whitehouse Station, NJ, West Hollywood, CA, San Antonio, TX, Miami, FL, Aurora, CO, Indianapolis, IN. Presented at the American Diabetes Association 73rd Scientific Sessions, June 21-25, 2013, Chicago, IL.

Safety, Pharmacokinetics, and Pharmacodynamics of a Single Subcutaneous Dose of VRS-859 in Patients with Type 2 Diabetes. Jeffrey L. Cleland, Ronnie Aronson, Eric Humphriss, Camille R. Shore, Rong Zhou and Mark S. Kipnes. Presented at the 48th Annual Meeting of the European Association for the Study of Diabetes in Berlin, Germany, from October 1-5, 2012. (LMC | Diabetes & Endocrinology)

A Multiple-Ascending-Dose Study to Evaluate Safety, Pharmacokinetics, and Pharmacodynamics of a novel GPR40 agonist, TAK-875, in subjects with Type 2 diabetes. July 2012. Leifke E¹, Naik H. Wu J, Viswanathan P, Demanno D, Kipnes, M, Vakilynejad M.

Efficacy and Safety of Taspoglutide Monotherapy in Drug-Naive Type 2 Diabetic Patients After 24 Weeks of Treatment
Itamar Raz; Vivian Fonseca; Mark S. Kipnes; Raffaella Balena – Diabetes Care, March 2012

Response to Topical Capsaicin Correlates With The Efficacy of Topical Clonidine As a Treatment For Painful Diabetic Neuropathy (PDN)
J. N. Campbell; Mark Kipnes; Michael C. Rowbotham; W. K. Schmidt– September 2011 Conference Paper Meeting of Peripheral Nerve Society.

A Placebo Controlled Single Ascending Dose Phase 1 for Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics After Subcutaneous Administration of VRS-589 in Patients with Type 2 Diabetes Mellitus. Jeffrey L. Cleland¹, Camille R. Shore², and Mark S. Kipnes³. Presented at the American Diabetes Association Annual Meeting 2011 Poster Presentation 1016-P 01-D Clinical Therapeutics/New Technology June 25, 2011; 11:30-1:30 am

Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of TAK-875, a Novel GPR40 Agonist, Following Once-Daily Oral Administration for 2 Weeks in Type 2 Diabetic Subjects. Eckhard Leifke, Jingtao Wu, Prabhakar Viswanathan, Mark S. Kipnes, Majid Vakilynejad, Takeda Global Research & Development Center, Inc., Deerfield, IL, DGD Research, San Antonio, TX. Presented at the American Diabetes Association Annual Meeting 2011 Poster Presentation 1016-P 01-D Clinical Therapeutics/New Technology June 25, 2011; 11:30-1:30 am

Topical Clonidine for Treatment of Painful Diabetic Neuropathy: A Randomized Double Blind Phase IIb Clinical Trial. AUTHORS: 1. James N. Campbell, Prof., MD, jcampbell@arciontherapeutics.com, 410-522-8701, Arcion Therapeutics, Baltimore, MD, United States. 2. Mark S. Kipnes, Dr., MD, mkipnes@dgdclinic.com, 210-614-8612, Cetero Research / Diabetes and Glandular Disease Center, San Antonio, TX, United States. 3. Michael C. Rowbotham, Prof., MD, RowbotM@cpmcri.org, 415-600-1600, California Pacific Medical Center Research Institute, Scientific Director, San Francisco, CA, United States. 4. Karin L. Petersen, Prof., MD, karin.petersen@ucsf.edu, 415-885-7814, University of California, Neurology, San Francisco, CA, United States. 5. Bruce C. Stouch, Dr., PhD, bstouch@arciontherapeutics.com, 610-356-8658, Arcion Therapeutics, Baltimore, MD, United States. 6. Margaret Kelly, Ms., MS, mkelly@arciontherapeutics.com, 540-525-7335, Arcion Therapeutics, Baltimore, MD, United States. 7. Claudia M. Campbell, Dr., PhD,

ccampb41@jhmi.edu, 410-550-7989, Johns Hopkins University School of Medicine, Psychiatry, Baltimore, MD, United States. 8. Kerrie Brady, Ms., MS, MBA, kbrady@arciontherapeutics.com, 410-522-8701, Arcion Therapeutics, Baltimore, MD, United States. 9. William K. Schmidt, Dr., PhD, schmidt@arciontherapeutics.com, 650-438-3018, Arcion Therapeutics, Baltimore MD, United States Presented at the American Diabetes Association 71st Scientific sessions – June 24-28, 2011 San Diego

Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of TAK-875, a Novel GPR40 Agonist, Following Once- Daily Administration for 2 Weeks in Type 2 Diabetic Subjects. Authors: Eckhard Leifke^{1*}, Jingtao Wu¹, Prabhakar Viswanathan¹, Mark Kipnes², Majid Vakilynejad¹Takeda Global Research & Development Center, Inc., Deerfield, IL; ²dgd Research, San Antonio, TX Presented at the ADA 71st Scientific Sessions, San Diego, CA, June 24-28, 2011

A Novel Human Growth Hormone XTEN Construct (VRS-317) for Once-a-Month Subcutaneous Administration in a Phase 1a Study of Growth Hormone-Deficient Adults. Jeffrey L. Cleland¹, Nathan Geethring², Benjamin Spink², Soha Motlagh², Yi Yao², Joshua Silverman², and Mark S. Kipnes³. Presented at the Endocrine Society's 93rd Annual Meeting & Expo, June 4-7, 2011 – Boston

AEZS-130, An Oral Ghrelin-Mimetic GH Secretagogue, As a Potential Diagnostic Test for Adult Growth Hormone Deficiency." Biller, Beverly M.K., M.D., K.C.J. Yuen, V. Bonert, M. Chen, A. Dobs, J.M. Garcia, M. Kipnes, M. Molitch, R. Swerdloff, C. Wang, D. Cook, I.R. Altomose, G.R. Merriam Presented at The 5th International Congress of the GRS/IgF Society meeting. October 3-7, 2010 in New York City, New York.

Taspoglutide, a Once-Weekly Human GLP-1 Analog, as Monotherapy Significantly Lowered A1c and Body Weight in Patients with Type 2 Diabetes (T2D): Results from the T-Emerge 1 Phase 3 Trial. Itamar Raz, Vivian Fonseca, Mark Kipnes, Laurence Durrwell, John Hoekstra, Mark Boldrin, Raffaella Balena. Presented at the American Diabetes Association 70th Scientific Sessions in Orlando, FL June 25th through 29th, 2010.

A New Therapy for Nonalcoholic Fatty Liver Disease and Diabetes? INT-747-The First FXR Hepatic Therapeutic Study. Arun J. Sanyal; Sunder Mudaliar; Robert R. Henry; Hanns-Ulrich Marschall; Linda Morrow; Cathi I. Sciacca; Paul Dillon; Paul Clopton; Mark S. Kipnes; David Alexander Shapiro. Conference Paper. Presented at The Liver Meeting 2009: American Association for the Study of Liver Disease, Boston – Hepatology 2009; 50 (S4): A183. Intercept Pharmaceuticals.

Farnesoid-X Receptor Agonists: A New Therapeutic Class for Diabetes and Fatty Liver Disease? The First FXR Therapeutic Study in Diabetes. Robert R. Henry, Sunder Mudaliar, Linda Morrow, Marcus Hompesch, Mark Kipnes, Arun Sanyal, Paul Clopton, Olaf Bohm, Cathi Sciacca, Annie Mavian, Mark Pruzanski, David Shapiro. San Diego, CA, Chula Vista, CA, San Antonio, TX, Richmond, VA, Munich, Germany. Conference Paper Presented at the A.D.A. 69th Scientific Sessions, New Orleans, LA, June 5-9, 2009.

Continuous Subcutaneous Insulin Infusion in Patients with Type 2 Diabetes Safely Improved Glycemic Control Using a Simple Insulin Dosing Regimen. Steve V. Edelman, Bruce W. Bode, Timothy S. Bailey, Mark S. Kipnes, Juan P. Frias. San Diego, CA, Atlanta, GA, Escondido, CA, San Antonio, TX, West Chester, PA. Presented at the A.D.A. 69th Scientific Sessions, New Orleans, LA, June 5-9, 2009.

Alogliptin Added to Sulfonylurea Therapy in Patients with Type 2 Diabetes Reduces HbA_{1c} without Increasing Hypoglycemia. Richard Platley, Mark Kipnes, Penny Fleck, Craig Wilson, Qais Mekki, Burlington, VT, San Antonio, TX, Deerfield, IL. Selected for Poster Presentation at the American Diabetes Association 68th Scientific Sessions, June 6-10, 2008 in San Francisco, CA. Also, printed in the Scientific Sessions Abstract Book, the June 2008 supplement to the journal, Diabetes.

Safety and Functionality Results of a Clinical Feasibility Study with the TANTALUS®: An Investigational Device – Intended to Improve Glycemic Control in Overweight Subjects with Type 2 Diabetes. Mark Kipnes, Philip Barnett, Edy Soffer, Scott Cunneen, Jeffrey Conklin, John Pilcher, Edward Harvey Phillips, San Antonio, TX, Los Angeles, CA. Selected for Poster Presentation at the American Diabetes Association 68th Scientific Sessions, June 6-10, 2008 in San Francisco, CA. Also, printed in the Scientific Sessions Abstract Book, the June 2008 supplement to the journal, Diabetes.

A Phase II, Multi-center, Multi-dose Study of an Extended-release, Crystalline Formulation of Recombinant Human Growth Hormone (ALTU-238) in Growth Hormone Deficient Adults. Randall J. Urban¹, Mark Kipnes², Susie Estes¹, Stephen J. Winters³, Sujit K. Basu⁴, Ken Loveday⁴, Lisa A. Herman⁴, Frederick T. Murray⁴ and Alan Kimura⁴. 1. University of Texas Medical Branch, Galveston TX, United States;

2. Diabetes & Glandular Disease Clinic, San Antonio, TX, United States; 3. University of Louisville, Louisville KY, United States; 4. Altus Pharmaceuticals, Inc., Cambridge, MA, United States. Presented at The Endocrine Society's 89th Annual Meeting – ENDO 07, June 2-5, 2007. Toronto, Canada.

Safety and Pharmacodynamics of CJC-1134-PC, a Novel GLP-1 Receptor Agonist, in Patients with Type 2 Diabetes Mellitus: A Randomized Placebo-Controlled, Double-Blind, Dose-Escalation Study. Maggie Wang, Mark Kipnes, Stephanie Matheson, Stella Wen, Betty Lawrence, Karen Thibaudeau, Jean-Paul Castaigen, Thomas Ulrich, Montreal, PQ, Canada, San Antonio, Texas. *Poster Presentation at the 67th A.D.A. Meeting & Scientific Sessions, June 22 through 26, 2007, Chicago, IL.*

Effects of Renal Impairment on The Pharmacokinetics of Sorafenib And Its Metabolites. Smith V¹, Marbury T¹, Kipnes M³, Cihon F⁴, Lettieri J⁴, Mazzu A⁴. ¹Orleans Center for Clinical Research, Knoxville Affiliate, Knoxville, TN; ²Orlando Clinical Research Center, Orlando, FL; ³Diabetes and Glandular Disease Clinic, PA, San Antonio, TX; ⁴Bayer Pharmaceuticals Corporation, West Haven, CT, USA. Poster for Sorafenib Renal Study, 11804, to be presented at the AACR Meeting, April 2007.

Time Course of Body Composition Changes Following Pioglitazone in Patients with Type 2 Diabetes: Increase in Body Fluid is Detected Earlier (at 24-Weeks) Than Fat Mass (at 4-8 Weeks). NAOTO UEMURA, SMITA ABBI, ANDREW E. DENKER, HAMISH WRIGHT, GOUTAM MISTRY, ALLISON MOREAU, CHARLES BOWDEN, MARK S. KIPNES, ANDREW AHMANN, NORMAN n. LUNDE, GARY MEININGER, CHAU THACH, KIMBERLY BRODOVICZ, KEITH GOTTESDIENER, JOHN WAGNER. *Rahway, NJ; San Diego, CA; San Antonio, TX; Portland OR; St. Paul, MN.* Late Breaking Abstract at the 66th Scientific Sessions, A.D.A. Meeting June 9-13, 2006, Washington D.C.

"A Phase 1 Clinical Trial of a Zinc Finger DNA-Binding Protein (ZFP) Activator (STABLE-509) of Vascular Endothelial Growth Factor (VEGF) in Subjects with Diabetic Neuropathy (DN)." Poster presentation number PO5.101. Selected for presentation at the 58th American Academy of Neurology Annual Meeting, April 1-8, 2006, at the San Diego Convention Center in San Diego, California.

Pharmacokinetics and Pharmacodynamics of a Novel Long-acting Crystalline Growth Hormone Formulation (ALTU-238) in Normal Healthy Men and Women. F.T. Murray, S. K. Basu, M.S. Kipnes², S. Limauro, G. J. Wright and A. L. Margoin (Sponsored by E. Rilter). Altus Pharmaceuticals Inc., Cambridge, MA, Diabetes & Glandular Disease Clinic, San Antonio, TX, University of Cincinnati, Cincinnati, OH, Baystate Children's Hospital, Springfield, MA. (Altus Poster September 13, 2005)

Treatment of Combined Hyperlipidemia with Simvastatin plus Fenofibrate. S.M. Grundy, MD¹, G.L. Vega, PhD¹, Z. Yuan, MD, PhD², J. Palmisano, MD² for the SAFARI Study Group.* Poster presented at the A.D.A. meeting, June, 2004.

Effect on LDL Pattern Distribution of Treatment with Simvastatin plus Fenofibrate in Patients with Combined Hyperlipidemia. S.M. Grundy, MD¹, G.L. Vega, PhD¹, Z. Yuan, MD, Ph.D.², W. Battisti, PhD², J. Palmisano, MD² for the SAFARI Study Group.* Poster presented at the Endocrine Society Meeting, June 2004.

Safety of Metemcinal Fumarate (GM-611) in Patients with Symptomatic Gastroparesis": Poster presented at the 2004 A.D.A. Meeting, Saturday June 5, 2004, 12:15 to 2:15 p.m. & 5:00 p.m. to 6:00 p.m.

Effect of Mitemcinal Fumarate (GM-61) on Gastric Emptying in Patients with Idiopathic or Diabetic Gastroparesis": Digestive Disease Week (DDW) 2004 meeting for a AGA Poster Session in May. Tuesday, May 18, 2004, Abstract ID#: 103158, Poster Session ID#: 1817, Session Type: Gastric Motility and Sensation. 12:00 to 2:00 p.m.

Impact of Achieved Systolic Blood Pressure on Renal Function in Type 2 Diabetic Nephropathy. Marc A. Pohl, MD¹; Samuel Blumenthal, MD²; Lawrence G. Hunsicker, MD³ and **The Collaborative Study Group**⁴. ¹Cleveland Clinic Fdn., Cleveland Ohio; ²Veterans Administration, Milwaukee, Wisconsin; ³University of Iowa Hospitals and Clinics, Iowa City, Iowa and ⁴Rush Medical College, Chicago, Illinois. Presented at the ASN Meeting, November 2002.

Impact of Angiotensin Receptor Blockade with Irbesartan On Renal Function at Different Systolic Blood Pressure (SBP) Levels in Type 2 Diabetic Nephropathy. Marc A. Pohl, MD¹; Daniel J. Cordonnier, MD²; Samuel Spitalowitz, MD³ and **The Collaborative Study Group**⁴.

¹Cleveland Clinic Foundation, Cleveland Ohio; ²University of Grenoble, Grenoble, France; ³Brooklyn Hospital Medical Center, Brooklyn, NY and ⁴Rush Medical College, Chicago, Illinois. Presented at the ASN Meeting, November 2002.

The Severity Of Orthostatic Hypotension Is A Risk Factor In The Progression Of Type 2 Diabetic Nephropathy. Matthew R. Weir, MD and Lawrence G. Hunsicker, MD, for **The Collaborative Study Group**, Chicago Illinois. Presented at the ASN Meeting, November 2002.

The Presence of Retinopathy Is Associated with Poor Renal and Cardiovascular Outcomes In Type 2 Diabetic Nephropathy. Roger Rodby, MD¹; Richard Gilbert, MD², for **The Collaborative Study Group**, ¹Chicago, Illinois USA. ²Victoria, Australia. Presented at the ASN Meeting, November 2002.

Predictors of The Progression of Renal Insufficiency in Patients with Type 2 Diabetes And Overt Diabetic Nephropathy. John P. Middleton, Julia Lewis, for **The Collaborative Study Group** University of Texas Southwestern, Dallas, Texas; Vanderbilt University, Nashville, Tennessee. Presented at the ASN Meeting, November 2002.

Cardiovascular Outcomes in The Irbesartan Diabetic Nephropathy Trial (IDNT) Of Patients with Type 2 Diabetes and Overt Nephropathy. Tomas Berl, MD¹ for **The Collaborative Study Group**². ¹Division of Renal Diseases and Hypertension, University of Colorado², Denver, Colorado Department of Medicine, Rush Medical Center, Chicago, Illinois. Presented at the ASN Meeting, November 2002.

"Albutropin™ In Subjects with Adult Growth Hormone Deficiency." Anne Klibanski, M.D.¹, Mark Kipnes, M.D.², David Kleinberg, M.D. ³, David Cook, M.D.⁴, Peter Snyder, M.D.⁵, Maria Walker⁶ and Daniel Odenheimer, PhD⁷. ¹Massachusetts General Hospital, Boston, MA, 02114; ²Diabetes and Glandular Disease Clinic, San Antonio, TX 78229; ³New York University School of Medicine, New York, NY, 11016; ⁴Oregon Health Sciences University, Portland, OR, 97201; ⁵University of Pennsylvania, Philadelphia PA, 19104; ⁶Human Genome Sciences, Rockville, MD, 20850; ⁷Human Genome Sciences, Rockville, MD, 20850. Presented at the First Joint Symposium GH-IGF-2002. October 8, 2002.

"Efficacy and Safety of Treatment With Simvastatin in Thiazolidinedione-Treated Type 2 Diabetic Patients." M. S. Kipnes¹, A. J. Lewin², L. F. Meneghini³, I. Perevozskaya⁴, S. Shah⁴, D. Plotkin, J. Tobert⁴; ¹Diabetes & Glandular Disease Research Associates, P.A., San Antonio, TX, ²National Research Institute, Los Angeles, CA, ³University of Miami School of Medicine Diabetes Research Institute, Miami, FL, ⁴Merck Research Laboratories, Rahway, NJ. Poster Number 1205. Presented at the 38th EASD Annual Meeting, Budapest, Hungary, September 1-5, 2002.

"Impact of Use of Insulin, Glargine, on Hgb A1c and BMI in a Specialty (Endocrine) Practice Population." Jerome S. Fischer, M.D. Riad G. Dirani, M.D., Sherwyn L. Schwartz, M.D., Mark S. Kipnes, M.D., Fernando W. Trigos, M.D., Amna A. Salhin, M.D., Jacob Vadakekalam, M.D., Daina Dreimane, M.D., Litza Loza, San Antonio, Texas. For presentation at the American Diabetes Association 62nd Scientific Sessions, June 14-18, 2002, San Francisco, California.

"Effects of Multiple Doses of Orally Administered Hexyl Insulin M2 (HIM2) on Postprandial Blood Glucose (PPG) Concentrations in Type 1 Diabetic (T1) Patients." Stephen Clement, M.D., Mark S. Kipnes, M.D., Helmut Steinberg, M.D., S. Edwin Fineberg, M.D., Louis Jovanovic, M.D., Nancy Rikalo, M.D., Jennifer Marks, M.D., Diana Gibson, M.D., J. Gordon Still, M.D., Gordana Kosutic, M.D. For presentation at the American Diabetes Association 62nd Scientific Sessions, June 14-18, 2002, San Francisco, California.

"Glycemia control and Lipid Profile in Type 2 Diabetes are Improved by Long-Term Pioglitazone/Sulfonylurea Combination Therapy." M. Menon-Raju, M. Kipnes, and NB Glazer. Takeda Pharmaceuticals North American, Inc., Lincolnshire, IL, USA; Diabetes & Glandular Disease Clinic, San Antonio, TX, USA. Presented at The Diabetes UK Annual Conference, March 13-15, 2002. Birmingham, UK.

"Glycemic Control in Type 2 Diabetes is Improved by Long-Term Pioglitazone/Sulfonylurea Combination Therapy." M. Kipnes¹ and A. Boss.² For presentation at the 37th Annual Meeting of the European Association for the Study of Diabetes. September 9 – 13, 2001. Glasgow, Scotland. Hosted by Diabetes UK. Dr. Michael Hall Chairman.

"The Effects of an Oral Modified Insulin on Postprandial Blood Glucose Levels in Patients with Type 2 Diabetes Mellitus". Mark S. Kipnes, Paresh Dandona, J. Gordon Still, Gordana Kosutic. Diabetes and Glandular Disease Clinic, San Antonio, TX; Diabetes-Endocrinology

Center of Western, Buffalo, NY; Nobex Corporation, Research Triangle, NC. For presentation at the President's Poster Session and Reception, American Diabetes Association 61st Scientific Sessions, Sunday, June 24, 2001, Philadelphia Pennsylvania.

"Clinical Utility of rhTSH-stimulated Thyroglobulin Testing Without Scan in Management of Differentiated Thyroid Cancer". Leonard Wartofsky, M.D.; Washington Hospital Center Washington, D.C. For the rhTSH-Stimulated Thyroglobulin Investigators Group*, supported by a Research Grant from Genzyme Corp., Boston, Mass. Poster For presentation at the Endocrine Society Annual Meeting in Denver Thursday, June 21, 2001.

A Clinical Trial In Patients With Overt Type 2 Diabetic Nephropathy. EJ Lewis; LG Hunsicker; WC Clarke for **The Collaborative Study Group**, Chicago IL and Iowa City, Iowa. Presented at the ASN meeting November 2001.

"THE AVANDIA WORLDWIDE AWARENESS REGISTRY (AWARE®): AN INTERNET-BASED PROGRAM FOR EVALUATION OF CLINICAL, HUMANISTIC AND ECONOMIC OUTCOMES OF PATIENTS WITH TYPE 2 DIABETES." Bakst A.W., Meletiche D.M., Arnold R., Pettit K., Harjono H., Najib M., Cobitz A., Schwartz S., Kipnes M., Fischer J., GlaxoSmithKline, Collegeville PA, Pharmacon International, New York, N.Y. Poster presented at ISPOR meeting May, 2001.

"Pharmacokinetics and Pharmacodynamics of Pulmonary Insulin Delivered via the AERx® Insulin Diabetes Management System in Type 1 Diabetics". M. Kipnes, B. Otulana, S. Farr, J. Jendle, J. Thiphawong and S. Schwartz. For presentation at the 36th Annual Meeting of The European Association for the Study of Diabetes, held at the Jerusalem ICC - International Convention Center and the adjacent Crowne Plaza Hotel, September 18, 2000, Jerusalem, Israel.

"Effects of Troglitazone on HbA_{1c} and ALT Levels in Clinical Practice". Sherwyn L. Schwartz, M.D., Jerome S. Fischer, M.D., Mark S. Kipnes, M.D., San Antonio, TX. For presentation at the President's Poster Session and Reception, American Diabetes Association 59th Scientific Sessions, June 20, 1999, San Diego, CA.

*M.S. Kipnes – member of study group

ORAL PRESENTATIONS

CLINICAL – What's New in Diagnosis & Treatment of GH Dysfunction? Oral Sessions. AEZS-130 (Macimorelin)-Stimulated GH Test: Validation of a Novel Test For The Diagnosis of Adult Growth Hormone Deficiency (AGHD). Jose M. Garcia; Ronald S. Swerdloff; Christina Wang; Michael Kyle; Mark Kipnes; Beverly MK Biller; David Cook; Kevin CJ Yuen; Vivien Bonert; Adrian Dobs; Mark Molitch; George Merriam. *Medicine, Molecular and Cell Biology, MEDVAMC, Baylor College of Medicine, Houston, TX, Medicine, Harbor-UCLA Medical Center and Los Angeles Biomedical Research Institute, Torrance, CA; Radiant Research, Inc, Chicago, IL; DGD Clinic, San Antonio, TX; Medicine,*

Massachusetts General Hospital/Harvard Medical School, Boston, MA; Medicine, Oregon Health & Science University, Portland, OR; Medicine, Cedars-Sinai Medical Center, Los Angeles, CA; Medicine Johns Hopkins Medical Institutions, Baltimore, MD; Medicine, Northwestern University, Chicago, IL; Medicine, VA Puget Sound Health Care System/University of Washington, Seattle and Tacoma, WA. Presented at The Endocrine Society's 94th Annual Meeting & Expo – Houston, TX June 23-26, 2012.

CLINICAL – What's New in Diagnosis & Treatment of GH Dysfunction? Oral Sessions. A Phase 1 Trial of Safety, Pharmacokinetics (PK) and Pharmacodynamics (PD) of a Single Dose of a New Human Growth Hormone Analogue (VRS-317) for Monthly Subcutaneous Administration in Adults with Growth Hormone Deficiency. Timothy Bailey, BMK Biller; Gerard S. Conway; Mark Kipnes; Vera Popova-Brkic; Kevin CJ Yuen; Eric Humphriss; George M. Bright; Jeffrey L. Cleland. *Endocrinology, AMCR Institute, Escondido, CA; Neuroendocrine Unit, Massachusetts General Hospital, Boston, MA; Endocrinology, University College London Hospitals, London, UK; Endocrinology, DGD Clinic, San Antonio, TX; Endocrinology, University Clinic Center, Belgrade, Serbia; Endocrinology, Diabetes and Clinical Nutrition; Oregon Health Sciences University, Portland, OR; Clinical Operations, Versartis Inc., Redwood City, CA; Medical Affairs,*

Versartis, Inc., Redwood City, CA; Executive Versartis, Inc., Redwood City, CA. Presented at The Endocrine Society's 94th Annual Meeting & Expo – Houston, TX June 23-26, 2012.

Interim Results of a Phase I/II Clinical Trial of a DNA Plasmid Vaccine (BHT-3021) for Type 1 Diabetes. Peter Gottlieb, Peter G. Colman, Mark Kipnes, Robert Ratner, Vanita Aroda, Marc Rendell, Murray Gerstman, Leonard Zemel, Peter Dunn, Richard Hays, Vernon Heazlewood, John Baker, Russell Scott, Timothy Davis, Carla Greenbaum, Jeremy Krebb, Paul Norwood, Fernando Ovalle, Phillip Raskin, Jay S. Skyler, Joanne Quan, Nanette Solvason, Bart Roep, Leonard C. Harrison, George Eisenbarth, Lawrence Steinman, Hideki Garren. *Aurora, CO, San Mateo CA, San Antonio, TX, Parkville, Victoria, Australia, Seattle WA, Washington, DC, Miami, FL, Wellington, FL, Birmingham, AL, Fresno, CA, Omaha, NE, Dallas, TX, Ringwood East, Victoria, Australia, Fremantle, WA, Australia, Kippa-Ring, QLD, Australia, Auckland, New Zealand, Christchurch, New Zealand, Hamilton, New Zealand, Wellington, New Zealand, Leiden, Netherlands Antilles, Stanford, CA, Denver, CO.* Presented at the A.D.A. 69th Scientific Sessions, New Orleans, LA, June 5-9, 2009.

Evidence of Neuroregeneration using Vascular Endothelial Growth Factor Zinc Finger Protein Activator (SB-509) in Diabetic Neuropathy: A Chronic Degenerative Polyneuropathy. Mark Kipnes, Michael Merren, Warren Douglas, Scott Hamilton, Ya-Li Lee, S. Kaye Spratt, Ely Benaim, Dale Ando, *San Antonio, TX, Richmond, CA.* Selected for Oral Presentation at the American Diabetes Association 68th Scientific Sessions, June 6-10, 2008 in San Francisco, CA. Also, printed in the Scientific Sessions Abstract Book, the June 2008 supplement to the journal, *Diabetes*.

The DP-IV Inhibitor MK-0431 Enhances Active GLP-1 and Reduces Glucose Following an OGTTX in Type 2 Diabetics. Gary A. Herman, Peng-Liang Zhao, Bruno Dietrich, Georg Golor, Andreas Schrodter, Bart Keymeulen, Kenneth C. Lasseter, Mark S. Kipnes, Deborah Hilliard, Michael Tanen, Inge De Lepeleire, Caroline Cilissen, Cathy Stevens, Wesley Tanaka, Keith M. Gottesdiener, John A. Wagner, *Rahway NJ; Berlin, Germany; Neuss, Germany; Brussels, Belgium; Miami, FL, San Antonio, TX.* *Presented at A.D.A. 64th Scientific Sessions June 4-8, 2004*