

CAROLYN BELL

Birmingham Research Group

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EDUCATION

1990 B.A Degree-Major: French; Minors: Business, Sociology
Auburn University, Auburn, Alabama

PROFESSIONAL EXPERIENCE

12-05 – Present	Clinical Research Coordinator	Birmingham Research Group, Birmingham, Alabama
6/99 – 11/05	Clinical Research Coordinator	Radiant Research, Birmingham, Alabama
2/99 – 3/00	Regulatory Specialist	Radiant Research, Birmingham, Alabama
11/97 – 1/99	Account Manager	Buffalo Rock, Inc., Hoover, Alabama
11/96 – 9/97	Office Manager	Walton Brown Realtors, Birmingham, Alabama
9/95 – 11/96	General Manager	Deborah Stone Day Spa, Birmingham, Alabama
10/93 – 8/95	Food and Beverage Manager	The Mountain Brook Inn, Birmingham, Alabama

RESEARCH EXPERIENCE

1. A Multicenter, Double-Blind Study to Evaluate XXX Nail Gel 8% and Vehicle in the Treatment of Mild to Moderate Distal Subungual Onychomycosis of the Toenail
2. A Multicenter, Double-Blind, Placebo-Controlled Evaluation of XXX for the Prevention/Blockage of the Progression of Cold Sore Lesion Development
3. A Phase III Double-Blind Efficacy and Safety Study of XXX in Addition to XXX Compared to Placebo in Subjects with Primary Hypercholesterolemia
4. A Randomized, Placebo-Controlled, Multiple-Dose, Double-Blind Study of the Efficacy of XXX Cream, 1% for the Prophylactic Treatment of Tinea Pedis
5. A Randomized, Double-Blind, Active Controlled Evaluation of the Antihypertensive Response to XXX in Subjects Uncontrolled on Calcium-Channel Blocker Monotherapy

6. A Randomized, Double-Blind, Active-Controlled Evaluation of the Antihypertensive Response to XXX in Subjects Uncontrolled on ACE Inhibitor Monotherapy
7. A Long Term Safety and Efficacy Study of XXX, 0.3% in Subjects with Acne Vulgaris
8. A Phase III, 12-Month, Double Blind, Randomized, Parallel Group, Placebo Controlled, Efficacy and Safety of XXX® in Overweight and Obese Subjects With a 12-Month Open-Label Extension Phase
9. A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Fixed-Dose, Multicenter Study of Weight-Reducing and Prevention of Weight Regain Effects and Safety of XXX in Obese Patients with or without Comorbidities
10. A Multicenter, Double-Blind, Randomized, Placebo- and XXX-Controlled Study to Assess Safety and Efficacy of XXX in the Prevention of Postmenopausal Osteoporosis
11. A Multicenter, Randomized, Double-Blind, Placebo Controlled Study to Assess the Safety and Efficacy of Different Doses and Regimens of XXX in Patients with Moderate to Severe and Active Rheumatoid Arthritis
12. A Phase III, Double-Blind, Randomized, Parallel Study Evaluating the Safety and Efficacy of XXX sublingual (2 and 3 mg) in the Treatment of Male Erectile Dysfunction
13. A Phase III, Twelve-Month, Open-Label, Flexible Dose, Safety Extension Study of XXX (2 and 3 mg) in the Treatment of Male Erectile Dysfunction
14. A Phase II, Dose-Response, Safety and Efficacy Study of Oral XXX in Subjects with Gout
15. A Phase II, Open-Label Study to Assess the Long-Term Safety of Oral XXX in Subjects with Gout
16. A 12-Week, Randomized, Double-Blind Multicenter Study Comparing the Clinical Efficacy and Safety of XXX 15% Gel with its Vehicle in Patients with Moderate, Papulopustular Facial Rosacea
17. A Vehicle-Controlled, Randomized, Double-Blind, Multicenter Study of the Efficacy and Safety of XXX Shampoo in the Treatment of Seborrheic Dermatitis of the Scalp
18. A Randomized, Double-Blind, Double-Dummy, Placebo-Controlled, Multicenter Study Assessing the Effects of XXX Acetate and XXX in the Improvement of Moderate to Severe Age-Related Skin Changes in Postmenopausal Women
19. A Phase III, Multinational, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled Study to Evaluate the Efficacy and Safety of XXX (300mcg/day) for 24 Weeks and Safety for a Further 28-Week Open-Label Period in Women with Hypoactive Sexual Desire Disorder on Concurrent Estrogen Replacement Therapy Who Have Undergone Hysterectomy and Bilateral Oophorectomy
20. A Phase III, Multinational, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled Study to Evaluate the Efficacy and Safety of XXX (300mcg/day) for 24 Weeks and Safety for a Further 28 Weeks in Naturally Menopausal Women with Hypoactive Sexual Desire Disorder on Concurrent Oral Hormone Replacement Therapy
21. A Multicenter, Double-Blind, Placebo-Controlled, Parallel Group, Randomized Study to Examine the Clinical Benefit of (0.45mg XXX Tablets) Administered Orally, qd, to Postmenopausal Women

22. A 6-Week, Double-Blind, Placebo Controlled, Randomized, Parallel Group, Multicenter, Multidose Study of the Efficacy and Safety of XXX in Patients with Overactive Bladder Symptoms of Increased Urinary Frequency, Urgency and Urge Incontinence
23. A Multicenter, Double-Blind, Randomized, Parallel Study Comparing the Efficacy and Safety of XXX 120 mg BID, XXX 240 mg QD and Placebo in Subjects with Perennial Allergic Rhinitis
24. A Phase III, Randomized, Multicenter Study Comparing the Safety and Efficacy of Oral XXX Versus XXX in Subjects with Gout
25. A Phase II, 3 Month, Randomized, Double-Blind Study to Evaluate the Efficacy and Safety of Three Doses of XXX 0.5, 1.5 and 5 mg QD, Versus Placebo in Subjects with Endometriosis
26. A Multi-Center Study to Determine the Exposure of Adult U.S. Smokers to Cigarette Smoke
27. A Multi-Center, Randomized, Investigator-Blinded, Parallel Group Study Designed to Evaluate the Safety and Clinical Equivalence of XXX in the Treatment of Vulvovaginal Candidiasis (Moniliasis) Caused by Candida Species
28. A Multicenter, Double-Blind, Double-Dummy, Placebo-Controlled, Parallel-Group Study to Compare the Efficacy, Safety and Tolerability of New XXX in Patients with Onychomycosis of the Toenails
29. Multicenter, Randomized, Active-Controlled Comparison Study of the Incidence of Gastroduodenal Ulcers Associated with XXX + Low Dose XXX Versus XXX + Low Dose XXX in Healthy Subjects 50-75 Years of Age
30. A Four-Arm Study Comparing the Analgesic Efficacy and Safety of XXX Once a Day, 100, 200, and 300 mg Versus Placebo for the Treatment of Pain Due to Osteoarthritis of the Knee
31. A 12-Week, Multicenter,, Double-Blind, Randomized, Parallel-Design Study of 5% XXX Topical Gel and Vehicle Control in Patients with Acne Vulgaris
32. A Multicenter, Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Safety and Efficacy of XXX for the Treatment of Moderate Acne Vulgaris in Women with or Without Hirsutism
33. A Multicenter, Randomized, Double Blind, Active- and Vehicle-Controlled Study of XXX Gel for the Treatment of Acne Vulgaris
34. A Phase II, Randomized, Vehicle-Controlled, Double-Blind, Multi-Center Study to Evaluate the Safety and Efficacy of XXX Applied Topically for 12 Weeks to Subjects with Acne Vulgaris
35. A Randomized, Double-Blind, Placebo Controlled, Parallel Group Study to Assess the Safety and Efficacy of XXX in the Treatment of Chronic Plaque Psoriasis
36. A Phase III, Multicenter, Randomized, Double-Blind, Double-Dummy, Vehicle-Controlled Study of the Safety and Efficacy of XXX Versus XXX for the Treatment of Acne Vulgaris
37. Evaluation of the Efficacy and Safety of XXX in Patients with Moderate to Severe Facial Atopic Dermatitis: A Phase II Clinical Trial
38. A Multicenter, Randomized, Double-Blind, Parallel-Group, Placebo Control, Clinical Evaluation of XXX in Combination with XXX Compared to XXX Plus Placebo for 24 Weeks in Subjects with Type 2 Diabetes Who are Inadequately Controlled on XXX

39. A Phase IIIa, Multicenter, Randomized, Double-Blind, Parallel-Group, Placebo Controlled Study on the Efficacy and Safety of XXX in Chronic Idiopathic Urticaria
40. A Randomized, Multiple-Dose, Double-Blind, Placebo-Controlled Comparative Study of XXX and Open-Label XXX in Patients with Type 2 Diabetes
41. The Efficacy and Safety of XXX for the Treatment of Type 2 Diabetes
42. A Multi-Center, Double-Blind, Randomized, Vehicle Controlled, Parallel Group Study Comparing XXX to XXX and Both Active Treatments to a Vehicle Control in the Treatment of Tinea Pedis (Athlete's Foot)
43. A Randomized, Double-Blind, Placebo Controlled, Parallel Design, Multiple-Site Study to Evaluate the Clinical Equivalence of Two XXX Shampoos in Patients with Tinea (Pityriasis) Versicolor
44. A Randomized, Double-Blind, Placebo-Controlled, Phase III Study of an XXX for the Treatment of the Inflammatory Lesions of Acne Vulgaris.
45. A Randomized, Double-Blind, Placebo-Controlled Study Evaluating XXX in the Treatment of Osteoarthritis of the Hip or Knee.
46. Comparative Efficacy and Safety of XXX and Placebo for the Treatment of Pain due to Osteoarthritis of the Knee.
47. A Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study of the Safety and Efficacy of Two Concentrations of XXX Applied Twice Daily in Adults with Mild to Moderate Atopic Dermatitis.
48. A Multi-Center, Randomized, Double-Blind, Parallel Group, Placebo-Control, Clinical Evaluation of XXX for 24 Weeks in Subjects with Type 2 Diabetes who are Inadequately Controlled on XXX.
49. A Market Research Study Among Women who Completed or Participated for at Least 8 Weeks in the Blinded, Efficacy and Safety Portion of XXX Clinical Study Numbers XXX or XXX.
50. A Phase III Randomized, Multi-Center, Allopurinol and Placebo-Controlled Study Assessing the Safety and Efficacy of XXX in Subjects with Gout.
51. A Phase III Open-Label Study to Assess the Long-Term Safety of XXX in Subjects with Gout.
52. A 52-Week Open-Label Extension to the Randomized, Double-Blind, Multi-Center, Multi-Factorial, Placebo-Controlled, Parallel Group Study to Evaluate the Efficacy and Safety of XXX Combined and Alone in Hypertensive Patients.
53. (Avoiding Cardiovascular Events Through Combination Therapy in Patients Living with Systolic Hypertension), Multi-National, Multi-Center, Double-Blind, Randomized, Active-Controlled Trial to Compare the Effects of XXX Combined on the reduction of Cardiovascular Morbidity and Mortality in Patients with High Risk Hypertension.
54. A Phase III Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Factorial Study of XXX and Their Combination in Patients with Essential Hypertension.
55. A Randomized, Double-Blind, Multi-Center, Multi-Functional, Placebo-Controlled, Parallel Group Study to Evaluate the Safety and Efficacy of XXX and XXX Alone and in Combination in Hypertensive Patients.

56. A Phase III Study to Evaluate the Long-Term Effects of XXX on Endocrine Function in Adult Subjects with Chronic Insomnia.
57. An Open-Label, Parallel Design, Long-Term Phase III Trial of the Safety and Efficacy of XXX Male Patients with Erectile Dysfunction.
58. A Multi-Center, Investigator-Blind, Vehicle-Controlled, Non-Inferiority Study of the Safety of XXX Compared to XXX and a Superiority Study of XXX Compared to XXX in the Treatment of Seborrheic Dermatitis of the Scalp for 4 Weeks.
59. A Multi-Center, Double-Blind, Randomized, Vehicle-Controlled, Parallel Group Study Comparing XXX and Both Active Treatments to a Vehicle Control in the Treatment of Tinea Pedis.
60. The Efficacy and Safety of XXX for the Treatment of Type 2 Diabetes
61. A Multi-Center, Double-Blind, Randomized, Vehicle Controlled, Parallel Group Study Comparing XXX to XXX and Both Active Treatments to a Vehicle Control in the Treatment of Tinea Pedis (Athlete's Foot)
62. A Double Blind, randomized, 6- Month Evaluation of the Safety and Efficacy of Topical XXX in Hysterectomized Women with Female Sexual Arousal Disorder (FSAD)
63. A Multicenter, Placebo Controlled, Randomized, Double Blind, Subject Initiated Study of the Safety and Efficacy of a Single Topical Iontophoretic Application of XXX cream with an Open Label Conventional Therapy Treatment Arm, and a Blinded Evaluator, for the Episodic Treatment of Recurrent Herpes Labialis
64. A double-blind, randomized, parallel group study to evaluate the safety, tolerability and efficacy of XXX alone or co-administered with XXX in subjects with primary dyslipidemia
65. A double-blind, randomized, parallel-group, multicenter clinical study to compare the efficacy and tolerability of XXX and co-administration of XXX with XXX in subjects with COPD
66. A Randomized, Double-Blind, Placebo-controlled, Parallel-group Multicenter 52 week study to Evaluate the Efficacy and Safety of Transdermal Patches Delivering XXX in Menopausal Women with Low Libido Not Receiving Systemic Estrogen or Estrogen Progestin Therapy
67. A multi-site open clinical study to collect biological specimens and phenotypic data from a large cohort of subjects for inclusion in a Repository and use in Genomic (from DNA and RNA), Serologic and Metabolic (from Serum) and Proteomic (from Protein) Research Studies
68. A Collection of Blood, Urine, Throat Swab, Nose Swab, Skin Swab and Synovial Fluid Specimens with matching Demographic, Clinical and Medical History of Psoriasis
69. A Double-Blind, Multicenter, Randomized, Placebo-Controlled Study to Evaluate the Safety and Efficacy of XXX in the Acute Treatment of Migraine Headaches
70. An Open Label, Repeat dose Study of the Safety of XXX in the Treatment of Multiple Episodes of Acute Migraine over 12 Months
71. Clinical Utility of XXX in Simultaneously Achieving Blood Pressure and Lipid Endpoints in a Specific Patient Population
72. A 10-12 week multicenter, randomized, double blind, parallel group study to evaluate the efficacy and safety of the combination of XXX and XXX compared to XXX and XXX monotherapies in essential hypertension and hypercholesterolemia

73. An 8-week double-blind, multicenter, randomized, multifactorial, placebo-controlled, parallel-group study to evaluate the efficacy and safety of XXX administered alone and in combination with XXX in patients with essential hypertension
74. A randomized, investigator blinded, active-controlled, parallel-group study to compare the efficacy and safety of 6-week treatment with XXX versus 6-week treatment with XXX in children with Tinea capitis
75. A prospective, multinational, multicenter, double-blind, randomized, active-controlled trial to compare the effect of XXX to XXX and XXX combined on the reduction of cardiovascular morbidity and mortality in patients with high risk hypertension
76. A 6-week, randomized double-blind, placebo-controlled, multicenter study, to assess the efficacy and safety of XXX and XXX in female patients with dyspepsia
77. A one year, open-label, multi-center, extension to XXX to assess the long term safety of XXX in female patients with symptoms of dyspepsia
78. A double-blind, randomized, placebo- and active-controlled forced titration study evaluating the effects of XXX on blood pressure and heart rate in African American patients with hypertension
79. A Randomized, Comparative, Evaluator-Blinded Study for the Safety and Efficacy of XXX and XXX in Patients with Fitzpatrick Skin Types 4, 5, or 6
80. A Prospective, randomized, Comparative, Multi-Center Study of Sensitization to XXX and XXX and including an Acute Safety Profile Assessment
81. A Pediatric Safety Study of XXX in the Treatment of Tinea Corporis and/or Tinea Pedis
82. The Safety and Efficacy of a Combination of XXX and XXX in Patients with Dyslipidemia: A Dose-Ranging Study
83. A double-blind, randomized, controlled study to evaluate the immunogenicity and safety of XXX in healthy HSV seronegative and seropositive female subjects aged 10 – 17.
84. Study of XXX in Women of Different Demographic Characteristics and Co-morbidities with Stress Urinary Incontinence: Evaluation of Efficacy and Safety
85. A Double-Blind, Randomized, Parallel-Group, Placebo-Controlled, Multi-Center Study to Compare the Clinical Equivalence of XXX and XXX in Subjects with Moderate to Severe Acne Rosacea
86. An Open-label, Single Site Study, Comparing the Tolerability of XXX Alone to XXX and XXX in the Treatment of Mild to Moderate Acne Vulgaris
87. A Multicenter, Randomized, Double-Blind, Vehicle Controlled Study of the Safety and Efficacy of XXXX in the Treatment of Mild to Severe Atopic Dermatitis
88. A 6-month, Double-Blind, Double-Dummy, Randomized, Parallel group, Multi-center Efficacy and Safety Study of XXX compared to XXX and XXX in COPD Patients.
89. A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Clinical Trial to Determine the Effects of XXX versus XXX for the Treatment of Rosacea
90. A Multicenter, Double-Blind, randomized, Vehicle-Controlled, Parallel-Group Study Comparing XXX to XXX and Both Active Treatments to XXX in the Treatment of Tinea Pedis

91. A Randomized, Double-Blind, Placebo-Controlled Phase III study of an XXX for the treatment of the inflammatory lesions of Acne Vulgaris.
92. A Phase II, Multiple-Dose Study to Assess Safety and Efficacy of XXX, XXX, and XXX Concentrations of XXX Applied 1, 2, and 3 Times a Week for 4 Weeks in Subjects with Actinic Keratosis.
93. The Safety and Efficacy of a Combination of XXX and XXX in Patients with Dyslipidemia: A Dose-Ranging Study.
94. Compare the tolerability of using XXX and XXX with XXX for subjects with mild to moderate acne (This is a physician initiative study).
95. A Pediatric Safety Study of XXX in the Treatment of Tinea Corporis and/or Tinea Pedis.
96. A Double Blind, randomized, 6- Month Evaluation of the Safety and Efficacy of Topical XXX in Hysterectomized Women with Female Sexual Arousal Disorder (FSAD).
97. A Prospective, Multinational, Multicenter, Double-Blind, Randomized, Active-Controlled Trial to Compare the Effects of XXX to XXX Combined on the Reduction of Cardiovascular Morbidity and Mortality in Patients with High Risk Hypertension.
98. A Phase II, Open-Label Study, to assess the Long-Term Safety of XXX in Subjects with Gout Incorporating Amendment Nos. 1, 2, 3 and 4.
99. A Phase III, Open-Label, Randomized, XXX Study to Assess the Long-Term Safety of XXX in Subjects with Gout.
100. A Phase III, Vehicle-Controlled Study of XXX Applied Two Times per Week for Two Weeks for each Recurrence of Anogenital Herpes over 12 Months.
101. A Phase IV, Double-Blind, Multicenter, Randomized, Cross-Over Study to Further Evaluate the Risk of Hematological Adverse Events in G6PD-Deficient Subjects with Acne Vulgaris Treated with XXX.
102. A Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Multi-center Study Comparing XXX to XXX and Both Active Treatments to XXX in the Treatment of Tinea Versicolor.
103. A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multi-center Study of XXX for Cyclical Mastalgia in Otherwise Healthy Premenopausal Women Ages 18-50 with Regular Menstrual Cycles.
104. A Randomized, Double-Blind, Placebo-Controlled, Forced-Titration, Phase IV Study Comparing XXX Versus XXX Taken Orally for Eight Weeks in Patients with Stage 1 or Stage 2 Hypertension.
105. Observer-Blinded, Randomized, Phase III Study to Investigate the Non-Inferiority of XXX Versus XXX as Vaccines for Japanese Encephalitis in Healthy Subjects.

106. A Double-Blind, Randomized, Parallel-Group, Multi-Center Clinical Study to Compare the Efficacy and Tolerability of XXX Versus the Co-Administration of XXX with XXX in Subjects with COPD.

PSYCHIATRIC RESEARCH EXPERIENCE

- 2005 A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study of Bifeprunox in the Treatment of Depression in Outpatients with Bipolar Disorder. Protocol 3168A2-304-US
Sponsor: Wyeth Pharmaceuticals
- 2005 An Extension Study to Evaluate the Long-Term Safety and Tolerability of Bifeprunox in the Treatment of Outpatients with Bipolar Disorder.
Protocol 3168A2-307 Sponsor: Wyeth Pharmaceuticals
- 2005 An Eight-Week, Double-Blind, Placebo-Controlled, Multicenter Study with Escitalopram (10 mg qd) as Positive Control, Evaluating the Efficacy, Safety, and Tolerability of a Fixed Dose of SR58611A (350 mg q12) in Outpatients with Major Depressive Disorder (MDD). Protocol EFC 5041
Sponsor: Sanofi-Aventis, Inc.
- 2006 A multicenter, randomized, 30- to 52-week, double-blind, placebo-controlled study to evaluate the efficacy, safety, and tolerability of saredutant 100 mg once daily in the prevention of relapse or recurrence of depressive symptoms in outpatients with major depressive disorder who maintained clinical stability after an initial response to open-label treatment with saredutant 100 mg once daily. Protocol EFC 5576
Sponsor: Sanofi-Aventis, Inc.
- 2006 A Multi-centre, Double-blind, Randomized-withdrawal, Parallel-group, Placebo-controlled Phase III Study of the Efficacy and Safety of Quetiapine Fumarate Sustained Release (SEROQUEL SR™) as Monotherapy in the Maintenance Treatment of Patients with Major Depressive Disorder Following an Open-label Stabilization Period.
Protocol D1448C00005 Sponsor: Astra Zeneca Pharmaceuticals
- 2006 A Phase 2, Double-Blind, Placebo-Controlled Trial to Investigate the Safety and Efficacy of AV608 in Subjects with Social Anxiety Disorder
Protocol AV608-105 Sponsor: Avera Pharmaceuticals
- 2006 A Phase III Multicenter, Randomized, Double-Blind, Placebo-Controlled Study of the Safety and Efficacy of Gabapentin Extended Release (G-ER) Tablets in the Treatment of Patients with Postherpetic Neuralgia
Protocol 81-0045 Sponsor: Depomed, Inc.
- 2007 A Multi-centre, Double-Blind, Randomized, Parallel-Group, Placebo-Controlled Phase III Study of the Efficacy and Safety of Quetiapine Fumarate Sustained Release (Seroquel SR™) as Mono-Therapy in the Treatment of Elderly Patients with Major Depressive Disorder (SAPPHIRE STUDY)
Protocol D1448C00014 Sponsor: Astra Zeneca

- 2007 A Multi-Centre, Double-Blind, Randomized, Parallel-Group, Placebo-Controlled Phase III Study of the Efficacy and Safety of Quetiapine Fumarate Sustained Release (Seroquel SR™) as Mono-therapy in the Treatment of Elderly Patients with Generalized Anxiety Disorder (CHROMIUM STUDY)
Protocol D1448C00015 Sponsor: Astra Zeneca
- 2007 A Randomized, Double-Blind, Two-Arm Study Comparing the Efficacy and Safety of Trazodone Contramid® OAD and Placebo in the Treatment of Unipolar Major Depressive Disorder
Protocol 04ACL3-001 Sponsor: Labopharm, Inc.
- 2007 An eight-week, double-blind, placebo-controlled study to evaluate the efficacy, safety and tolerability of saredutant 100 mg once daily in combination with escitalopram 10 mg once daily in patients with major depressive disorder
Protocol EFC 10290 Sponsor: Sanofi-Aventis
- 2007 A multi-center, double-blind, parallel group, fixed dose, 4-arm, placebo and paroxetine controlled 8-week efficacy study of 2 oral doses of SR58611A (175 mg or 350 mg, b.i.d.) in adult population with Major Depressive Disorder
Protocol C10953/2032/DP/US Sponsor: Cephalon, Inc.
- 2007 Efficacy and Safety of 2mg/day of MI00907 on Sleep Maintenance Insomnia with a sub-study of the effect of MI 00907 on stable Type II Diabetes Mellitus: a 12-week, multi-center, randomized, double-blind, placebo-controlled study.
Protocol LTE6672 Sponsor: Sanofi-Aventis