

CURRICULUM VITAE
FRANCIS J. AVERILL, M.D., J.D.
Pulmonary, Critical Care, Sleep Disorders, Allergy & Immunology

**PRIMARY OFFICE
ADDRESS:**

St. Francis Sleep Allergy & Lung Institute
802 N. Belcher Road
Clearwater, FL 33765
Office Phone: 727-447-3000
Main Fax: 727-210-4600
faverill@stfrancismed.com

EDUCATION:

Medical: New York Medical College
Graduated 1985 Valhalla, NY
Medical Doctor (M.D.)

Medical: St. Georges University
1981 - 1983 Grenada, West Indies

Undergraduate: B.S., Biology & Chemistry, Summa Cum Laude
Graduated 1980 University of Richmond
Richmond, VA

Business: John Hopkins University
January 1998-August 1999 School of Continuing Education
Baltimore, MD
Business of Medicine Program
Executive Certificate in Business Management

Legal: Stetson University School of Law :
Graduated 2008 St. Petersburg, FL

Member of Florida Bar 2009 Juris Doctor (J.D.) Cum Laude

Theology: St. Leo University
September 2017-Present Th.M.- Class of 2021

TRAINING:

Fellowship: Johns Hopkins University
July 1990-October 1991 Baltimore, MD
Allergy & Immunology

Fellowship: Johns Hopkins University
July 1988-October 1991 Baltimore, MD
Pulmonary and Critical Care Medicine/Sleep Medicine

Internship/Residency: Cleveland Clinic Foundation
July 1985-July 1988 Cleveland, OH
Internal Medicine

BOARD CERTIFICATION:

2003 – Permanently boarded American Board of Sleep Medicine
1991 – Recertification, 2011 ABIM, Subspecialty in Critical Care
1990 – Recertification, 2011 ABIM, Subspecialty in Pulmonary Medicine
1989 – Permanently boarded American Board of Internal Medicine

LICENSURE:

Florida: ME 0060749
Florida Bar: 73738

POSITIONS:

Present Family Practice Professor for Nova SE University
Present Clinical Instructor for University of South Florida
Present Clinical Professor of Pulmonary Critical Care for Nova SE University
2007-Present President, St. Francis Sleep, Allergy & Lung Institute
2007-Present President, St. Francis Sleep Center
2007-Present President, St. Francis Wellness & Weight Loss Clinic
2008-2009 Vice Chief of Staff, Largo Medical Center
2007-2008 Physician Advisor, Nurse on Call HHC
2006-2007 Director of Bay Area Sleep Lab
2003-2006 Director of Sleep Management Services
2002-2005 Director of Professional Sleep Diagnostics
2001-2002 Director of American Sleep Diagnostics
2000-2007 Board of Directors, Diagnostic Clinic
1998-2007 Chairman of Research Committee, Diagnostic Clinic
1997-2001 Member, Medical Executive Committee, Largo Medical Center
1997-2000 Physician Advisor of Largo Medical Center
1997-1999 Director of Sabal Palms Pulmonary Services
1996-1999 Director, Arbors of St Petersburg Pulmonary Services/Respiratory Care
1995-2001 Founder/Director of Sleep Disorder Center, Largo Medical Center
1992-2002 Director of Largo Medical Center Critical Care
1991-2007 Physician, Diagnostic Clinic

AWARDS & HONORS:

2018 “Top Doctor” by Tampa Bay Magazine
2017, 2016 “Top Doctors”, Castle Connolly
2016 “Top Doctor”, Patient Reviews Certified
2015, 2011 - 2009 “America’s Top Physicians”, Consumer’s Research Council
2015 Life Time Award for Distinguished Individuals
2007, 2005 Distinguished Physician, Florida Medical Association
2003 “Best Physicians in the United States”
Stetson Scholarship Award, Deans List (Stetson),
Honors Roll (Stetson), Honors Program (Stetson)
2001 “Best Physicians in Tampa Bay”, Allergy-Tampa Bay Magazine
2001 “Best Physicians in Tampa Bay”, Pulmonary Medicine-Tampa Bay Magazine

2000 "How to Find the Best Physicians in Florida"
Who's Who Among American Physicians
Who's Who Among College Students
Scholar-Athlete Award, President's Citation,
Cornell National Scholar, Phi Beta Kappa Scholarship Award,

RESEARCH EMPLOYMENT:

2010-current St. Francis Sleep Allergy & Lung Institute
DBA: St Francis Medical Institute
Medical Director and Principal Investigator

2000-2009 Innovative Research of West Florida Inc
Contracted Principal Investigator

1991-2007 Diagnostic Clinic
Director of Clinical Research

1980-1981 Rockefeller Institute; New York, New York
Department of Mass Spectrometry, Research Assistant

1981-1983 Mobil Oil Corporation; Princeton, New Jersey
Department of Toxicology
Research Assistant

GRANTS:

1991 Schering Travel Grand Award
American Academy of Allergy & Immunology

1990-1992 National Institutes of Health/National Research
Service Award

PROFESSIONAL ASSOCIATIONS:

American Bar Association
Florida Bar Association
Advisory Board for AstraZeneca
American Academy of Sleep Medicine, Fellow
American College of Chest Physicians, Fellow
American Thoracic Society
Florida Thoracic Society
American Lung Association of Gulf Coast Florida
Society of Critical Care Medicine
Phi Beta Kappa Society

PUBLICATIONS:

2017 F Averill, TE Albertson, DM Baratz, S Chaudhary, S Mobin, T
O'Brien, MB Scholand, TPM Whelan, m Poyurovsky, O Schueller, J
Ryan, KF Gibson. A Phase 2 Trial of KD025 to Assess Efficacy,
Safety and Tolerability in Patients with Idiopathic Pulmonary Fibrosis.

- 1995 FH Chilton, FJ Averill, WC Hubbard, AN Fonteh, M Triggiani and MC Liu. Antigen Induced Generation of Lysopholipids in Human Airways. *J. Clin Investigation*, 1995.
- 1994 MO Shin, FJ Averill, WC Hubbard, FJ Chilton, FM Barody, MC Liu and RM Nacierio. Nasal Allergen Challenge Generates 1-0-Hexadecyl-2-Lyso-SN-Glycero-3-Phosphocholine. *Am J Resp Crit Care Med*, Vol 149, pp 660-66, 1994.
- 1993 FJ Averill and G. Adkins. Use of Bilevel Positive Airway Pressure (BIPAP) in Patients with Acute Respiratory Failure. *Chest* 1993 104(2):1435.
- 1992 MD Shin, F Averill, WC Hubbard, FJ Chilton, MC Liu and RM Nacierio. Detection of Platelet Activating Factor (PAF) and It's 2-Lyso-Metabolite in Allergic Rhinitis Following Antigen Challenge. Submitted, *J. Allergy and Clin Immuno*. 1992.
- 1992 FJ Averill, HC Campbell, DS Morgenthaler and GD Leidel. Idiopathic Hetrotopic Pulmonary Ossification. ACCP 58th Annual Scientific Assembly 1992.
- 1992 F Averill, WC Hubbard, D Proud, GJ Gleich and MC Liu. Platelet Activation in the Lung Following Antigen Challenge in a Human Model of Allergic Asthma. *Am Rev Resp Dis* 1992 145:571-576.
- 1991 WC Hubbard, FJ Averill, FC Chilton, LM Lichtenstein and MC Liu. Simultaneous GC-MS Quantitation of Platelet Activating Factor and 1-0-Hexadecyl-2-Lysi-SN-Glycero-3-Phospholipids in Bronchoalveolar Lavage Fluid from Human Subjects. *American Society of Mass Spectrometry*. 1991.
- 1991 F Averill, WC Hubbard and MC Liu. Detection of Platelet Activating Factor and Lyso-PAF in Bronchoalveolar Lavage Fluids from Allergic Subjects Following Antigen Challenge. *Am Rev Resp Dis* 1991 83:A811.
- 1991 F Averill, MH Shin, WC Hubbard, F Chilton, R Nacierio and MC Liu. Metabolism of Platelet Activating Factor in Biological Fluids. *J. Allergy and Clin Immuno* 1991 87:247
- 1990 F Averill, WC Hubbard, D Proud and MC Liu. Evidence for Platelet Activation in the Lung Following Antigen Challenge in Allergic Asthmatics. *Am Rev Resp Dis* 1990 4:A876.
- 1985 F Averill, H Eisenberg and M Bergman. Ventilatory Response in Patients with Pulmonary Sarcoidosis during Exercise Testing. *J. Clin. Invest* 1985 33(3):768A

CLINICAL RESEARCH**Principal Investigator:**

2018- Current	PERFECT COPD Study: A Phase 3, Randomized, Placebo-controlled, Double-blind, Adaptive Study to Evaluate the Safety and Efficacy of Inhaled Treprostinil in Patients with Pulmonary Hypertension due to Chronic Obstructive Pulmonary Disease (PH-COPD).
2018- Current	SOURCE OCS Asthma Study: A Phase 3 Study to Evaluate the Efficacy and Safety of Tezepelumab in Reducing Oral Corticosteroid Use in Adults with Oral Corticosteroid in Reducing Oral Corticosteroid Use in Adults with Oral Corticosteroid Dependent Asthma.
2017- Current	WILLOW Bronchiectasis Study: A Multi-Center Study to Assess the Efficacy, Safety and Tolerability, and Pharmacokinetics of INS1007 Administered Once Daily for 24 Weeks in Subjects with Non-Cystic Fibrosis Bronchiectasis, the Willow Study.
2017- Current	JNJ-42847922 Insomnia Study: A Placebo Controlled Polysomnography Study to Evaluate the Efficacy, Safety, and Tolerability of JNJ-42847922 in Subjects with Insomnia Disorder.
2017- Current	ANDHI Asthma Study: A Phase 3b Study to Evaluate the Safety and Efficacy of Benralizumab 30 mg sc in Patients with Severe Asthma Uncontrolled on Standard of Uncontrolled on Care Treatment.
2017- Current	BEAM Asthma Study: A dose ranging study to evaluate the efficacy and safety of doses of CHF 718 pMDI (beclomethasone dipropionate) in asthmatic subjects.
2017- Current	GLIMMER COPD Study: A dose ranging study to evaluate the efficacy and safety of 4 doses of CHF 5259 pMDI (glycopyrronium bromide) in subjects with Chronic Obstructive Pulmonary Disease (COPD).
2017- Current	Novo Nordisk NN1250-4252 A trial comparing the efficacy and safety of insulin degludec and insulin glargine 3000 units/mL in subjects with type 2 diabetes mellitus inadequately treated with basal insulin and oral anti diabetic drugs
2017- Current	United Therapeutics TDE-PH-401 A Patient Registry of the Real-world Use of Orenitram..
2017- Current	Capstone-1 1602T0831 A Study of a Single Dose of S-033188 Compared with Placebo or Oseltamivir 75 mg Twice Daily for 5 Days in Otherwise Healthy Patients with influenza.
2017- Current	Capstone-2 1602T0832 A Study of a Single Dose of S-033188 Compared with Placebo or Oseltamivir 75 mg Twice Daily for 5 Days in Patients with Influenza at High Risk of Influenza Complications.
2017- Current	Symbicort Generic CSP-07-000034 A Study Comparing the Therapeutic Equivalence of a 3M Inhaler and a Symbicort® Reference Inhaler Each Delivering Budesonide/Formoterol Fumarate (80 µg/4.5 µg) in Adult Subjects with Asthma.
2017-	INS-312 A Study of Liposomal Amikacin for Inhalation (LAI) in Adult Patients with

Current	Nontuberculous Mycobacterial (NTM) Lung Infections Caused by Mycobacterium avium complex (MAC) That are Refractory to Treatment.
2017- Current	Novelty D2287R00103 A NOVEL observational longitudinal study on patients with a diagnosis or suspected diagnosis of asthma and/or COPD to describe patient characteristics, treatment patterns and the burden of illness over time and to identify phenotypes and endotypes associated with differential outcomes that may support future development of personalized treatment strategies.
2017- Current	Lupin COPD TB-DPI-301 A Study to Assess the Efficacy and Safety of Once Daily Administration of Lupin Tiotropium Bromide Inhalation Powder Compared to SPIRIVA® HANDIHALER® and Placebo in Patients with COPD including a 12-Week Open-Label Extension to Assess Inhaler Robustness
2017- Current	A Comparative Study of FV-100 vs. Valacyclovir for the Prevention of Post-Herpetic Neuralgia and Treatment of Acute Herpes Zoster-Associated Pain.
2016- Current	CIRT An event-driven trial of weekly low-dose methotrexate (LDM) in the prevention of cardiovascular events among stable coronary artery disease patients with type 2 diabetes or metabolic syndrome.
2016- Current	Kadmon IPF A Study to Evaluate the Safety, Tolerability, and Activity of KD025 in Subjects with Idiopathic Pulmonary Fibrosis (IPF)
2016- Current	PAH 201 A trial to Evaluate the Safety and Efficacy of Inhaled Treprostinil in Subjects with Pulmonary Hypertension due to Parenchymal Lung Disease.
2016- Current	Evidera Insomnia Patient Interview Study to Assess Content Validity of the Numeric Rating Scale. (NRS) for Use in the Insomnia Daytime Symptoms and Impacts Questionnaire (IDSIQ)
2016- Current	A 12-week, double blind, randomized, placebo controlled, parallel group trial followed by a single active arm phase of 40 weeks evaluating the effect of oral nintedanib 150mg twice daily on changes in biomarkers of extracellular matrix (ECM) turnover in patients with idiopathic pulmonary fibrosis (IPF) and limited forced vital capacity (FVC) impairment
2016 Current	A multicenter, open-label, safety extension study with Benralizumab for asthmatic adults on inhaled corticosteroid plus long-acting β_2 agonist.
2016- Current	Multi-center, double-blind, randomized, placebo-controlled, active reference, parallel-group, polysomnography dose response study to assess the efficacy and safety of ACT-541468 in adult subjects with insomnia disorder.
2016- Current	INS-212A Study of Liposomal Amikacin for inhalation (LAI) in Adult Patients with Nontuberculous Mycobacterial (NTM) Lung Infections Caused by Mycobacterium avium complex (MAC) That are Refractory to Treatment
2016-2016	Utility of PharmacoGenomics for Reducing Adverse Drug Effects. (Upgrade Registry)
2015- Current	Efficacy, Immunogenicity, and Safety Study of Clostridium Difficile Toxoid Vaccine in Subjects at risk For C. Difficile Infection (C-DIFFense)

2015- Current	A Phase 3, 52-Week, Study to Evaluate the Safety and Tolerability of Nebulized TD-4208 in Subjects with Chronic Obstructive Pulmonary Disease.
2015-2017	A 52 Week, Phase 3 Study to Evaluate the Efficacy and Safety of Tralokinumab in Adults and Adolescents with Asthma Inadequately Controlled on Inhaled Corticosteroid Plus Long Acting B2-Agonist (STRATOS 1)
2015- Current	A Phase 3 Study to Evaluate the Efficacy and Safety of Tralokinumab in Reducing Oral Corticosteroid Use in Adults and Adolescents with Oral Corticosteroid Dependent Asthma (TROPOS) 2015-current
2015- Current	A Parallel Group Study to Evaluate the Efficacy and Safety of Dupilumab in Patients with Persistent Asthma. (EFC13579)
2015- Current	A Safety Extension Study to Evaluate the Safety and Tolerability of Benralizumab (MEDI-563) in Asthmatic Adults and Adolescents on Inhaled Corticosteroid Plus Long-acting B2 Agonist (BORA)
2014- Current	A 56-week Study to Evaluate the Efficacy and Safety of 3 Doses of Benralizumab (MEDI-563) in Patients with Moderate to Very Severe Chronic Obstructive Pulmonary Disease (COPD) with a History of COPD Exacerbations (TERRANOVA)
2014-2016	A Phase 3 Efficacy and Safety Study of Benralizumab (MEDI-563) Added to High-dose Inhaled Corticosteroid Plus Long-acting B2 Agonist in Patients with Uncontrolled Asthma (SIROCCO)
2014-2015	A 12 Week, Double-Blind, Placebo-Controlled, Efficacy and Safety of Fluticasone Propionate Multidose Dry Powder Inhaler Compared with Fluticasone/Salmeterol Multidose Dry Powder Inhaler in Adolescent and Adult Patients with Persistent Asthma Symptomatic Despite Low-dose Inhaled Corticosteroid Therapy (FSS-AS-301)
2014-2015	A Randomized, Double-Blind, Double-Dummy, Placebo-Controlled, Parallel-Group, 12-Week Clinical Study to Assess the Efficacy and Safety of Beclomethasone Dipropionate Delivered via Breath-Actuated Inhaler (BAI) or Metered-Dose Inhaler (MDI) in Adolescent and Adult Patients 12 Years of Age and Older with Persistent Asthma (BDB-AS-301)
2014- Current	A Phase III, Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of Lebrikizumab in Patients with Uncontrolled Asthma Who are on Inhaled Corticosteroids and a Second Controller Medication
2014-2015	A 28-Week, Multi-Center, Randomized, Double-Blind, Parallel-Group, Active-Controlled Safety Extension Study to Evaluate the Safety and Efficacy of PT003, PT001, and PT005 in Subjects with Moderate to Very Severe COPD, with Spiriva Handihaler as an Active Control
2014-2016	A Prospective Observational Study to Evaluate Predictors of Clinical Effectiveness in Response to Omalizumab.
2014-2014	A Randomized, Open-label Study to Characterize the Pharmacokinetics, Pharmacodynamics, and Safety of Single and Multiple Doses of Armodafinil in Children and Adolescents with Excessive Sleepiness Associated with Narcolepsy.

- 2013-2015 A Randomized, Double-Blind, Chronic Dosing (24 weeks), Placebo-Controlled, Parallel Group, Multi- Center Study to Assess the Efficacy and Safety of PT003, PT005, and PT001 in Subjects with Moderate to Very Severe COPD Compared with Placebo
- 2013-2014 A 12-week Dose-ranging Study to Evaluate the Efficacy and Safety of Fp Spiromax Administered Twice Daily compared with Placebo in Adolescent and Adult Subjects with Severe Persistent Asthma Uncontrolled on High Dose Inhaled Corticosteroid Therapy.
- 2013-2014 A 12-week Dose-ranging Study to Evaluate the Efficacy and Safety of Fp Spiromax Administered Twice Daily compared with Placebo in Adolescent and Adult Subjects with Persistent Asthma Uncontrolled on Non-Steroidal Therapy
- 2013-2014 A Clinical Outcomes Study to compare the effect of Fluticasone Furoate/Vilanterol Inhalation Powder with Placebo on survival in Subjects with Moderate Chronic Obstructive Pulmonary Disease (COPD) and a history of or at risk for Cardiovascular Disease
- 2013-2014 A Randomized, Double-Blind, Parallel-Group Study to Assess the Efficacy and Safety of 12 Weeks of Once Daily, Co-Administration of Olodaterol (delivered by the Respimat Inhaler) and Tiotropium (delivered by the HandiHaler) in patients with Chronic Obstructive Pulmonary Disease (COPD).
- 2012-2014 Long-Term natural History of Patients with Severe or Difficult-to-Treat Asthma from the TENOR Observational Study
- 2012-2014 A Phase III, Long-Term, Randomized, Double-Blind, Extension Study of the Efficacy, Safety and Tolerability of Two Fixed Dose Combinations of Aclidinium Bromide/Formoterol Fumarate, Aclidinium Bromide, Formoterol Fumarate and Placebo for 28-Weeks Treatment in Patients with Moderate to Severe, Stable Chronic Obstructive Pulmonary Disease (COPD)
- 2012-2014 A Randomized, Placebo-Controlled, Double-Blind, Parallel-Group, Multi-Center Study to Assess the Safety and Efficacy of Tiotropium Bromide delivered via the HandiHaler in Chronic Obstructive Pulmonary Disease (COPD) Subjects recovering from Hospitalization for an Acute Exacerbation
- 2012-2014 An Open-Label Extension Study to Evaluate the Long-Term Safety and Efficacy of Reslizumab As Treatment for Patients with Eosinophilic Asthma Who Completed a Prior Study in Eosinophilic Asthma.
- 2012-2014 A 12 Month, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of Reslizumab in the Reduction of Clinical Asthma Exacerbations in Patients (12-75 Years of Age) with Eosinophilic Asthma.
- 2012-2014 A 26 Week, Randomized, Double-Blind, Parallel-Group, Active Controlled, Multicenter, Multinational Safety Study Evaluating the Risk of Serious Asthma-Related Events during Treatment with Symbicort, a fixed combination of Inhaled Corticosteroid (ICS) and a Long -Acting Agonist (LABA) as compared to Treatment with ICS alone in Adult and Adolescent (12 years of age or greater) Patients with Asthma.
- 2011-2013 A Phase IV, Multi-Center, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Persistency of Response with or without Xolair after Long Term Therapy.

- 2011-2014 A Postmarketing Observational Study to Assess Respiratory Tract Adverse Events in Pulmonary Arterial Hypertension Patients Treated with Tyvaso Inhalation Solution.
- 2011-2013 A Phase III, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy, Safety and Tolerability of two Fixed Dose Combinations of Aclidinium Bromide/Formoterol Fumarate Compared with Aclidinium Bromide, Formoterol Fumarate and Placebo for 24 Weeks Treatment in Patients with Moderate to Severe, Stable Chronic Obstructive Pulmonary Disease (COPD).
- 2011-2013 Rapid Evaluation of Acute Kidney Injury with NGAL.
- 2011-2013 A Randomized, Double-Blind, Parallel-Group Study to assess the Efficacy and Safety of 52 weeks of Once Daily Treatment of Orally Inhaled Tiotropium Plus Olodaterol Fixed Dose Combination Delivered by the Respimat Compared with the Individual Components delivered by Respimat in patients with Chronic Obstructive Pulmonary Disease (COPD).
- 2011-2013 A 52 week, double-Blind, Randomized, Placebo-Controlled, Parallel-Group Study to Evaluate the Effect Of Roflumilast 500 mq 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)
- 2011-2013 A 12 Month Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of Reslizumab in the Reduction of Clinical Asthma Exacerbations in Patients (12-75 years of age) with Eosinophilic Asthma.
- 2011-2012 A Safety and Efficacy Trial Evaluating the use of Apixaban for the Extended Treatment of Deep Vein Thrombosis and Pulmonary Embolism.

CLINICAL RESEARCH STUDIES CONDUCTED BETWEEN 2001 through 2011

1. A Randomized, Double-Blind, Placebo-Controlled, Forced-Titration, Phase IV study comparing XXXXX Verses XXXXXX taken orally for 8 weeks in patients with Stage 1 or Stage 2 Hypertension.
2. A Pivotal Long-Term, Open-Label, Parallel Study of the Efficacy and Safety of Human Insulin Inhalation Powder in Patients with Type I Diabetes.
3. A Pivotal, Open-label, Parallel Study to Evaluate the Safety and Efficacy of Human Insulin Inhalation Powder Compared to Injectable insulin in Patients with Diabetes and COPD or Asthma.
4. A Double-Blind, Randomized, Placebo-Controlled Study of the Efficacy, Safety and Tolerability of an 8-week Treatment of Rozerem 8 mg in Sleep Disturbed, Community Dwelling, Mild to Moderately Severe Alzheimer's Disease.
5. A Randomized Double-Blind, Double-Dummy, Placebo-Controlled, Parallel-Group, Multi-Center, Dose Ranging Study to Evaluate the Efficacy and Safety of GW685698X Inhalation Powder Once Daily and Fluticasone Propionate Inhalation Powder 100 mcg Twice Daily compared with Placebo for 8 weeks In Adolescent and Adult Subjects with Persistent Asthma Symptoms on Non-Steroidal Asthma Therapy.

6. A Randomized Double-Blind, Double-Dummy, Placebo-Controlled, Parallel-Group, Multicenter Dose Ranging study to Evaluate the Efficacy and Safety of GW685698X Inhalation Powder Once Daily and Fluticasone Propionate Inhalation Powder 250 mcg Twice Daily compared with Placebo for 8 weeks in Adolescent and Adult Subjects with persistent Asthma Symptoms on Low-Dose ICS Therapy.
7. A Randomized, Double-blind, Double-Dummy, Placebo-Controlled, Parallel-Group, Multi-Center Dose Ranging Study to Evaluate the Efficacy and Safety of GW685698X Inhalation Powder Once Daily and Fluticasone Propionate Inhalation Powder 500 mcg Twice Daily compared with Placebo for 8 weeks in Adolescent and Adult Subjects with Persistent Asthma Symptoms on Moderate-Dose ICS Therapy.
8. An Open Label, single arm study to assess the safety and Immunogenicity of Omalizumab Liquid Administered subcutaneously in a pre-filled safety syringe (75mg or 150 mg) over a 6-month period to male and female adolescents and adults with moderate to severe persistent allergic asthma.
9. ND# 65,127 Protocol 205.372: A Randomized, Double-Blind, Placebo-Controlled, Parallel- Group Study to Assess Long Term (one year) Efficacy and Safety of Tiotropium Inhalation Solution Delivered by the Respimat Inhaler in Patients with Chronic Obstructive Pulmonary Disease (COPD).
10. Phase 2, Double-Blind, Placebo-Controlled, Multi-Center Proof-of-Concept Study to Evaluate the Safety and Efficacy of Rozerem 8 mg QD in combination with Gabapentin 800mg QD in treatment of patients with Chronic insomnia. (GEMINI).
11. A Phase III, Multi-Center, Randomized, Double-Blind, Active-Controlled, Parallel-Group Study of the Safety and Efficacy of the IV and po formulations of the Neurokinin-1 receptor Antagonist, Casopitant in combination with Ondansetron and Dexamethasone for the Prevention on nausea and vomiting induced by chemotherapy.
12. A Randomized Double-Blind, Placebo-Controlled, Parallel-Group Study to assess long Term efficacy and safety of Tiotropium delivered by Respimat in patients with COPD.
13. A 28 day, Polysomnographic and Subjective assessment of GW679769, for primary Insomnia.
14. A 12 month Double-blind, Double-dummy, randomized, parallel group, multicenter Efficacy and safety Study of Symbicort MDI and Placebo in patients with COPD.
15. Effect of Roflumilast on exacerbation rate in patients with COPD.
16. A randomized, double-blind, placebo-controlled, parallel group trial assessing the rate of decline of lung function with tiotropium 18mcg, inhalation capsule once daily in patients with chronic obstructive pulmonary disease (COPD) (UPLIFT).
17. Study of omalizumab (Xolair), anti-IgE antibody in the treatment of moderate to severe Asthma in allergic patients. (EXCELS).
18. A comparison of ipratropium bromide/salbutamol delivered by the Respimat®, COMBENT® Inhalation Aerosol and Placebo of each formulation in a 12-week, double-Blind, Safety and efficacy study in adults with chronic obstructive pulmonary disease.
19. A multicentre, randomised, double-blind, parallel group, placebo-controlled study to investigate the long-term effects of salmeterol/fluticasone propionate (Seretide™/Viani™/Advair™) 50/500 ug b.i.d.,

salmeterol 50 ug bd, all delivered via the Diskus™/Accuhaler™ inhaler, on the survival of subjects with chronic obstructive pulmonary disease (COPD) over 3 years of treatment. (TORCH).

20. A randomized, multicenter, open-label, parallel group study comparing the efficacy and safety of Foradil® MDT (Formoterol and Salmeterol) 50 ug *b.i.d.* in patients with COPD.
21. A Phase IV, Multicenter, prospective, open-label, observational study to evaluate clinical practice patterns of Innohep® (tinzaparin sodium injection) in the treatment of acute symptomatic deep venous thrombosis.
22. A randomized, 12-week, Double-blind, Placebo-controlled, Parallel-group Study to Evaluate the Safety and Tolerability of Ariflo 15 mg Twice Daily in Patients with Chronic Obstructive Pulmonary Disease (COPD).
23. A randomized, double-blind, placebo-controlled, parallel group trial assessing rate of Decline of lung function with tiotropium 18 mcg capsule one daily in patients with Chronic Obstructive Pulmonary Disease.
24. Double-Blind, randomized, multicenter, parallel-group study of Levalbuterol (xopenex) In the treatment of subjects with Chronic Obstructive Pulmonary Disease.
25. An observational study of the epidemiology and natural history of asthma: Outcomes and treatment requirements (Tenor Study).

CLINICAL RESEARCH STUDIES CONDUCTED PRIOR TO 2001

(2000) - A prospective, multicenter study of anemia of critical illness and transfusion in the critically ill patient.

(2000) - A multinational, randomized, double blind, active controlled study for evaluation of Efficacy and safety of oral HMR 3647 VS Ufuroxime treatment of acute maxillary sinusitis in adults.

(2000) - A double blind randomized, placebo, and active controlled multicenter, parallel group, dose ranging study of L-753099 in patients with COPD.

(1999) - A comparative study of the safety, efficacy and effectiveness of Clarithromycin extended release tablets and Augmentin® tablets for the treatment of subjects with acute exacerbation of chronic bronchitis.

(1999) - A study to compare the safety and efficacy of Lansoprazole 30 mg BID versus placebo in patients with asthma associated with symptomatic gastroesophageal reflux (GER).

(1999) - A double blind, stratified, randomized, placebo controlled surveillance study of asthma Event outcomes in subjects receiving either usual pharmacotherapy of asthma or usual pharmacotherapy plus Salmeterol 42mcg/(2puffs) twice daily (Smart Trial).

(1999) - Open-label, comparative, randomized, multicenter Phase III study of intravenous treatment Of Synercid plus Aztreonam versus standard therapy in the treatment of adult hospitalized Patients with nosocomial pneumonia.

(1999) - Prospective randomized, double blind, multicenter comparison of the safety and efficacy of sequential (IV to PO) BAY 12-8039 400/400 mg QD for 7-14 days versus sequential Trovan™ IV/

Trovan™ tablets 200/200 mg QD for 7 -14 days in the treatment of patients with community acquired pneumonia.

(1998) - A double blind, stratified, randomized, placebo controlled study of Ro 64-0796 (also Known as GS4104) in the treatment of influenza infection in chronically ill adults.

(1998) - OTC Pravachol trial in an observed naturalistic setting (OPTIONS). A multicenter, Pharmacy based, open label, actual use study with pravachol (pravastatin sodium) to assess consumer behavior, compliance and safety in a naturalistic setting.

(1998) - An open label, long term study of the tolerability of Seratrodast in patients with moderate to severe COPD.

(1998) - A Comparative Study of the Efficacy and safety of Clarithromycin extended release Tablets and Loracarbef Pulvules for the Treatment of Subjects with Secondary Bacterial Infections of Acute Bronchitis.

(1998) - Phase IV, Multicenter, Open-label, Randomized Study to compare the safety and Efficacy Of Levofloxacin v. Ceftriaxone Sodium and Erythromycin followed by Clarithromycin and Amoxicillin/Clavulanate in the Treatment of Serious Community-Acquired Pneumonia in Adults.

(1997) - Study of Tiotropium, an anticholinergic bronchodilator, in COPD.

(1997) - Study of Accolate, a leukotriene antagonist, in asthma (ACCEPT).

(1996) - Study of the combination of albuterol and ipratopium in COPD.

(1994) - Epidemiologic study of Prostep, a nicotine replacement patch, in smoking cessation.

Sub-Investigator:

(2016-2017) - A Comparative Study of FV-100 vs. Valacyclovir for the Prevention of Post-Herpetic Neuralgia and Treatment of Acute Herpes Zoster-Associated Pain.

(2016) - PHN TEVA Study to Evaluate the Safety and Efficacy of Topically Applied TV 45070 (4% and 8% w/w Ointment) in Patients with Postherpetic Neuralgia