

## 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 North Belcher Road Clearwater, FL 33765  
Office Phone: 727-447-3000  
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[faverill@stfrancismed.com](mailto:faverill@stfrancismed.com)

### **RESEARCH OFFICE**

St Francis Medical Institute  
802 & 804 North Belcher Road  
Clearwater, FL 33765  
Phone: 727-210-4606  
Fax: 727-210-4609

### **EDUCATION:**

Medical:  
Graduated 1985

Doctorate in Medicine, M.D.  
New York Medical College  
Valhalla, NY

Medical:  
1981 - 1983

St. Georges University School of Medicine  
Grenada, West Indies

Undergraduate:

Bachelor of Science, B.S., Biology & Chemistry, Summa Cum Laude  
University of Richmond  
Richmond, VA

Business:  
Completed 1999

Executive Certificate in Business Management  
Business of Medicine Program  
School of Continuing Education  
John Hopkins University  
Baltimore, MD

Legal:  
Graduated 2008  
Member of Florida Bar 2009

Juris Doctor, (J.D.) Cum Laude  
Stetson University School of Law  
St. Petersburg, FL

Theology:  
Graduated 2021

Masters in Theology, M.A.  
St. Leo University  
St. Leo, FL  
(Ordained Deacon for the Diocese of St. Petersburg, FL 2021)

### **TRAINING:**

Fellowship:  
July 1990-October 1991

Johns Hopkins University  
Baltimore, MD  
Allergy & Immunology

Fellowship:  
July 1988-October 1991

Johns Hopkins University  
Baltimore, MD  
Pulmonary and Critical Care Medicine/Sleep Medicine

Internship/Residency:  
July 1985 – July 1988

Cleveland Clinic Foundation  
Cleveland, OH  
Internal Medicine

**BOARD CERTIFICATION:**

2003 – Permanently boarded  
1991 – Recertification, 2011  
1990 – Recertification, 2011, 2021  
1989 – Permanently boarded

American Board of Sleep Medicine  
ABIM, Subspecialty in Critical Care  
ABIM, Subspecialty in Pulmonary Medicine  
American Board of Internal Medicine

**LICENSURE:**

Florida: ME 0060749  
Florida Bar: 73738  
NPI #: 1629005020

**POSITIONS:**

2020 - Present Chairman, Safety Review Committee, Orinove  
2014 - Present Family Practice Professor for Nova SE University  
2014 - Present Clinical Instructor for University of South Florida  
2014 - 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  
2007-2010 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:**

2023 St. Joseph Moscati Physician Award  
2023 “Top 50 Doctors in America”, American Doctor Society  
2018, 2021 “Top Doctor” by Tampa Bay Magazine  
2016, 2017 “Top Doctors”, Castle Connolly  
2016 “Top Doctor”, Patient Reviews Certified  
2011-2009, 2015 “America’s Top Physicians”, Consumer’s Research Council  
2015 Lifetime Award for Distinguished Individuals  
2005, 2007 Distinguished Physician, Florida Medical Association

2003 "Best Physicians in the United States"  
 Stetson Scholarship Award, Dean's 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

1985 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 Medical Institute  
 Medical Director and Principal Investigator  
 Clearwater. FL

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:**

Advisory Board for InsMed  
 Advisory Board for United Therapeutics  
 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  
 American Bar Association Florida Bar

## PUBLICATIONS:

- 2022 Bushra Mina, Francis Averill, Asif Shaikh, Valentina Bayer, Florian Voss, Kristin Drda, Russell Gongwer, Bernet Kato, Vincent Willey. Exacerbation Risk in COPD Patients based on Eosinophil Count – Post hoc Analysis of the Randomized Pragmatic Trial, AIRWISE, Comparing Tiotropium/Olodaterol with Triple Therapy
- 2020 James D. Chalmers, MB, ChB, PhD, Charles S. Haworth, MB, ChB, MD, Mark L. Metersky, MD, Michael R. Loebinger, BM, BCh, PhD, Francesco Blasi, MD, PhD, Oriol Sibila, MD, PhD, Anne E. O’Donnell, MD, Eugene J. Sullivan, MD, Kevin C. Mange, MD, MSCE, Carlos Fernandex, MD, MPH, Jun Zou, PhD, Charles L., Daley, MD, on behalf of the WILLOW Investigators (Francis J. Averill, MD). A Phase 2 Study of the DPP1 Inhibitor Brensocatib in Bronchiectasis, 2020
- 2018 F Averill, J Smith, B Hester, E Davis, K Covington, D Higinbotham, E Conneeley, B Oudshoff, K Huffman, A Gove. Amikacin LOiposome Inhalation Suspension for Treatment-Refractory Lung Disease Caused by Mycobacterium avium Complex (CONVERT): A Prospective, Open-Label, Randomized Study, 2018
- 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 Naciero. 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 Naciero. 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 58<sup>th</sup> 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:

1. (2024-Current) – Regeneron Study: R668-AS-2373: Aim4: Next Step – Asthma Uncontrolled With Ics In Medium Dose (Gina 4): Next Step; Efficacy Of Dupilumab Added To Medium Dose Ics/Laba In Comparison To Ics Dose Escalation To High Dose Ics/Laba In Patients With Uncontrolled Asthma.
2. (2024-Current) – Mannkind Study: MKC-CI-002: ICoN-1: A Randomized, Double-Blind, Placebo-Controlled Phase 3 Study of the Efficacy and Safety of Treatment With MNKD-101 (Clofazimine Inhalation Suspension) When Added to Guideline-Based Therapy in Participants with Pulmonary Nontuberculous Mycobacterial Infection (Part A) Followed by an Open-Label Extension (Part B).
3. (2024-Current) – GlaxoSmithKline PERFORM Study: 219912: A Phase 4, 52-week (primary analysis at 24-weeks), randomized, stratified, open-label, active-controlled, parallel-group, effectiveness study, comparing FF/UMEC/VI with non-ellipta usual care (ICS/LABA) in adult participants with uncontrolled asthma.
4. (2024-Current) – Amgen Trial: 20220093: A Phase 2, Randomized, Double-blind, Placebo-controlled, Dose Ranging Study to Assess the Efficacy and Safety of Rocatinlimab in Adult Subjects With Moderate-to-severe Asthma.
5. (2024-Current) – Apnimed OLE Trial: APC-APN-306: A Phase 3 Open Label Continuation Protocol of a Fixed Dose Combination of Aroxybutynin and Atomoxetine (AD109) in Obstructive Sleep Apnea.
6. (2024-Current) - Bristol Myers Squibb Trial: IM027068: A Multicenter, Randomized, Double-blind, Placebo-controlled, Phase 3 Study to Evaluate the Efficacy, Safety, and Tolerability of BMS-986278 in Participants with Idiopathic Pulmonary Fibrosis.
7. (2024-Current) - Bristol Myers Squibb Trial: IM0271015: A Multicenter, Randomized, Double-blind, Placebo-controlled, Phase 3 Study to Evaluate the Efficacy, Safety, and Tolerability of BMS-986278 in Participants with Progressive Pulmonary Fibrosis.
8. (2024-Current) - Boehringer Ingelheim FIBRONEER Trial: 1305-0031-IPF-OLE: An open-label extension trial of the long-term safety and efficacy of BI 1015550 taken orally in patients with idiopathic pulmonary fibrosis (IPF) and progressive pulmonary fibrosis (PPF) (FIBRONEER™).
1. (2023-Current) – Apnimed Trial: APC-APN-304: Phase 3 Randomized Double-Blind Placebo-Controlled 1 year Parallel-Arm Study to Compare a Fixed Dose Combination of Aroxybutynin/Atomoxetine (AD109) to Placebo in Obstructive Sleep Apnea (LunAIRO Study)
2. (2023-Current) – Genentech OLE Study: GB43374: A Phase Iii Open-Label Extension Study To Evaluate The Long-Term Safety Of Astegolimab In Patients With Chronic Obstructive Pulmonary Disease.
3. (2023-Current) – Tvardi Therapeutics Trial: TVD-101-003P: A Phase 2Multicenter, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Efficacy of TTI-101 in Participants with Idiopathic Pulmonary Fibrosis.
4. (2023-Current) – Kempharm Trial: KP1077.D01: A Phase 2, Placebo-Controlled, Double-Blind, Randomized Withdrawal Study to Determine the Safety and Efficacy of Oral SDX in Patients with Idiopathic Hypersomnia.

5. (2022-Current) - Harmony BioSciences Trial: HBS-101-CL-011: An Open-Label Study to Evaluate the Long-Term Safety and Effectiveness of Pitolisant in Adult Patients with Idiopathic Hypersomnia who Completed Study HBS-101-CL-010
6. (2022-Current) - Boehringer Ingelheim FIBRONEER Trial: 1305-0014-IPF: A double blind, randomized, placebo-controlled trial evaluating the efficacy and safety of BI 1015550 over at least 52 weeks in patients with Idiopathic Pulmonary Fibrosis (IPF)
7. (2022-Current) - Boehringer Ingelheim FIBRONEER Trial: 1305-0023-PF-ILD: A double blind, randomized, placebo-controlled trial evaluating the efficacy and safety of BI 1015550 over at least 52 weeks in patients with Progressive Fibrosing Interstitial Lung Diseases (PF-ILDs)
8. (2022-Current) - Harmony BioSciences Trial: HBS-101-CL-010: A Double-Blind, Placebo-Controlled, Randomized Withdrawal Study to Evaluate the Safety and Efficacy of Pitolisant in Adult Patients with Idiopathic Hypersomnia
9. (2022-Current) – Bridge Biotherapeutics, Inc. Trial: BBT877-IPF-004: A Phase 2, Randomized, Double-blind, Placebo-controlled, 24-Week Study to Evaluate the Efficacy, Safety, and Tolerability of BBT-877, as mono- or add-on therapy, in Patients with Idiopathic Pulmonary Fibrosis (IPF)
10. (2022-Current) – Fibrogen Trial: FGCL-3019-095: Zephyrus II: A Phase 3, Randomized, Double-Blind, Placebo-Controlled Efficacy and Safety Study of Pamrevlumab in Subjects with Idiopathic Pulmonary Fibrosis (IPF).
11. (2022-Current) – NLS Pharma Trial: NLS-1021: A Four-week, Double-Blind, Placebo-controlled, Randomized, Multicenter, Parallel-group Study Of the Safety and Efficacy of NLS-2 (Mazindol extended release) In Adults for the treatment of Narcolepsy.
12. (2022-Current) – Genentech Study: GB43311: A Phase IIb, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study To Evaluate The Efficacy And Safety Of Astegolimab In Patients With Chronic Obstructive Pulmonary Disease.
13. (2022-Current) – Theravance Trial: 0180 (PIFR-2): A Phase 4, Randomized, Double-Blind, Double-Dummy, Parallel-Group Study Comparing Improvements in Lung Function in Adults With Severe to Very Severe Chronic Obstructive Pulmonary Disease and Suboptimal Inspiratory Flow Rate Following Once-Daily Treatment Over 12 Weeks With Either Revefenacin Inhalation Solution Delivered via Standard Jet Nebulizer or Tiotropium Delivered via a Dry Powder Inhaler (Spiriva® HandiHaler®).
14. (2021-Current) – Axsome Therapeutics Study: AXS-12-301: A Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study to Assess the Efficacy and Safety of AXS-12 in the Treatment of Cataplexy and Excessive Daytime Sleepiness in Subjects with Narcolepsy.
15. (2021-Current) – Axsome Therapeutics Study: AXS-12-302: An Open-Label Study to Assess the Long-term Safety and Efficacy of AXS-12 in the Treatment of Cataplexy and Excessive Daytime Sleepiness in Subjects with Narcolepsy.
16. (2021-Current) – United Therapeutics TETON Trial: RIN-PF-301: A Randomized, Double-blind, Placebo-controlled, Phase 3 Study of the Efficacy and Safety of Inhaled Treprostinil in Subjects with Idiopathic Pulmonary Fibrosis.

17. (2021-Current) – Horizon Trial: HZN-825-303: A Phase 2b/3 Randomized, Double-blind, Placebo-controlled, Repeat-dose, Multicenter Trial to Evaluate the Efficacy, Safety and Tolerability of HZN-825 in Subjects with Idiopathic Pulmonary Fibrosis.
18. (2021-Current) – Lung Biotechnology OLE PERFECTO Study: RIN-PH-305: An Open-Label Extension Study of Inhaled Treprostinil in Patients with Pulmonary Hypertension due to Chronic Obstructive Pulmonary Disease (PH-COPD).
19. (2021-Current) Paratek Study: PTK0796-NTM-20203: A Phase 2, Double-Blind, Randomized, Parallel-Group, Placebo-Controlled, Multi-Center Study to Evaluate the Efficacy, Safety, and Tolerability of Oral Omadacycline in Adult Subjects with Nontuberculous Mycobacterial (NTM) Pulmonary Disease Caused by Mycobacterium abscessus Complex (MABc).
20. (2021-Current) – Teva Pharmaceuticals Trial: TV45779-IMB-30086: A Multinational, Multicenter, Randomized, Double-Blind Study to Evaluate the Efficacy, Pharmacokinetics, Pharmacodynamics, Safety, Tolerability, and Immunogenicity of TEV-45779 Compared to Omalizumab (XOLAIR®) in Patients With Chronic Idiopathic Urticaria/Chronic Spontaneous Urticaria who Remain Symptomatic Despite Antihistamine (H1) Treatment.
21. (2021-Current) – Chiesi Study: CLI-06001AA1-05: A 52-week, randomized, double-blind, double-dummy, placebo- and active- controlled (Roflumilast, Daliresp® 500µg), parallel group, study to evaluate the efficacy and safety of two doses of CHF6001 DPI add-on to maintenance triple therapy in subjects with Chronic Obstructive Pulmonary Disease (COPD) and chronic bronchitis.
22. (2021-Current) – Astrazeneca LOGOS Study: D5982C00008: A Randomized, Double-Blind, Double Dummy, Parallel Group, Multicenter 24 to 52 Week Variable Length Study to Assess the Efficacy and Safety of Budesonide, Glycopyrronium, and Formoterol Fumarate Metered Dose Inhaler (MDI) Relative to Budesonide and Formoterol Fumarate MDI and Symbicort® Pressurized MDI in Adult and Adolescent Participants with Inadequately Controlled Asthma.
23. (2021-Current) – GlaxoSmithKline NIMBLE Study: 206785: A 52-week, randomised, double-blind, double-dummy, parallel group, multi-centre, non-inferiority study assessing exacerbation rate, additional measures of asthma control and safety in adult and adolescent severe asthmatic participants with an eosinophilic phenotype treated with GSK3511294 compared with mepolizumab or benralizumab.
24. (2021-Current) – United Therapeutics Tyvaso Trial: RIN-PF-301: A Randomized, Double-blind, Placebo-controlled, Phase 3 Study of the Efficacy and Safety of Inhaled Treprostinil in Subjects with Idiopathic Pulmonary Fibrosis.
25. (2021-Current) – Takeda Trial: TAK-994-1504: Dose-Blind Extension Study With Double-blind, Placebo-Controlled, Randomized Withdrawal Period to Evaluate the Safety and Explore the Pharmacokinetics and Pharmacodynamics of TAK-994 in Adults With Narcolepsy With Cataplexy.
26. (2021-Current) – Orinove Trial: ORIN1001-002-IPF - Phase 1b Double-Blind, Placebo-Controlled, Ascending Dose Trial: ORIN1001 in Subjects with Idiopathic Pulmonary Fibrosis.

27. (2021-Current) – Eisai Trial: E2006-A001-113: A Multicenter, Randomized, Double-Blind, Placebo-Controlled, 2-Period, Crossover Study to Evaluate the Respiratory Safety of Lemborexant in Adult and Elderly Subjects With Moderate to Severe Obstructive Sleep Apnea and Adult and Elderly Subjects With Moderate to Severe Chronic Obstructive Pulmonary Disease
28. (2021-Current) – Bellus Trial: BUS-P2-02: A Randomized, Adaptive, Double-Blind, Placebo-Controlled, Parallel-Arm, Phase 2b Study to Evaluate the Efficacy and Safety of Multiple Doses of BLU-5937 in Adult Participants With Refractory Chronic Cough.
29. (2021-Current) – RedHill Biopharma Study: RHB-204-01: Study of RHB-204 for the Treatment of Pulmonary Mycobacterium avium Complex (MAC) Disease in Adults with Nodular Bronchiectasis.
30. (2020-Current) – Insmed 301 Study: INS1007-301: A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, MultiCenter Study to Assess the Efficacy, Safety, and Tolerability of INS1007 Administered Once Daily for 52 Weeks in Subjects with Non-Cystic Fibrosis Bronchiectasis.
31. (2020-Current) – Verona Pharma Study: RPL554-Co-301: A Phase III Randomized, Double-Blind, Placebo-Controlled Study To Evaluate The Efficacy And Safety Of Ensifentrine Over 24 Weeks (With A 48-Week Safety Subset) In Subjects With Moderate To Severe COPD.
32. (2020-Current) – Dermira Long Term Study: DRM06-AD07/KGAA: A Long-Term Study To Assess The Safety And Efficacy Of Lebrikizumab In Patients With Moderate-To-Severe Atopic Dermatitis.
33. (2020-Current) – Bellerophon Study: PULSE-PHPF-001: A Randomized, Double-Blind, Placebo-Controlled Dose Escalation And Verification Clinical Study To Assess The Safety And Efficacy Of Pulsed, Inhaled Nitric Oxide (iNO) In Subjects At Risk Of Pulmonary Hypertension Associated With Pulmonary Fibrosis On Long Term Oxygen Therapy (Part 1 And Part 2).
34. (2020-Current) – Spero Therapeutics Study: SPR720-201: A Randomized, Partially Blinded, Placebo-and Comparator-Controlled, Multicenter, Phase 2a, Dose-Ranging, Proof-of-Concept Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Efficacy of SPR720 as Compared with Placebo or Standard of Care for the Treatment of Patients with Mycobacterium avium Complex (MAC) Pulmonary Disease.
35. (2020-Current) – Insmed ARISE Study: INS-415: Randomized, Double-Blind, Placebo-Controlled, Active Comparator, Multicenter Study to Validate Patient-Reported Outcome Instruments in Adult Subjects with Newly Diagnosed Nontuberculous Mycobacterial (NTM) Lung Infection Caused by Mycobacterium avium Complex (MAC).
36. (2020-Current) – Insmed ENCORE Study: INS-416: A Randomized, Double-Blind, Placebo-Controlled, Active Comparator, Multicenter Study to Evaluate the Efficacy and Safety of an Amikacin Liposome Inhalation Suspension (ALIS)-Based Regimen in Adult Subjects with Newly Diagnosed Nontuberculous Mycobacterial (NTM) Lung Infection Caused by Mycobacterium avium Complex (MAC).
37. (2020-Current) – Sanofi-Aventis Study: DRI15103: A randomized, double-blind, placebo-controlled dose-ranging study to evaluate the efficacy, safety, and tolerability of SAR440340 (anti-IL-33 mAb) in patients with moderate-to-severe asthma.

38. (2020-Current) – BIPI Study: 1305-0013: A randomised, double-blind, placebo-controlled parallel group study in IPF patients over 12 weeks evaluating efficacy, safety, and tolerability of BI 1015550 18mg taken orally b.i.d.
39. (2020-Current) – Takeda Idiopathic Hypersomnia Study: TAK-925-2002: A Phase 1b Randomized, Double-Blind, Placebo-Controlled, Crossover Study of a Single Intravenous Infusion Dose of TAK-925 in Patients With Idiopathic Hypersomnia.
40. (2020-Current) – Takeda DREEM Study: TAK-994-0001: A Study to Assess the Frequency and Characteristics of Wake and Sleep State Transitions Over Multiple Nights in Subjects With Narcolepsy Type 1 Compared With Healthy Subjects Using a Portable Electroencephalogram Device.
41. (2020-Current) – Sanofi-Aventis Study: NOTUS: EFC15805: A Randomized, Double-blind, Placebo-controlled, Parallel-group, 52-week Pivotal Study to Assess the Efficacy, Safety, and Tolerability of Dupilumab in Patients with Moderate-to-severe Chronic Obstructive Pulmonary Disease (COPD) with Type 2 inflammation.
42. (2020-Current) – Takeda Idiopathic Hypesomnia Study: TAK-925-2002: A Phase 1b Randomized, Double-Blind, Placebo-Controlled, Crossover Study of a Single Intravenous Infusion Dose of TAK-925 in Patients With Idiopathic Hypersomnia.
43. (2020-Current) – TARGET PharmaSolutions, Inc. Study: TARGET-RWE: A Longitudinal Observational Study of Patients with Chronic Disease.
44. (2020-Current) – Takeda SPARKLE Study: TAK-994-1501: A Randomized, Double-Blind, Placebo-Controlled, Multiple Rising Oral Dose Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of TAK-994 in Patients with Type 1.
45. (2020-Current) – Dermira Study: DRM06-AD06: A Randomized, Double-Blind, Placebo-Controlled Trial To Evaluate The Efficacy And Safety Of Lebrikizumab When Used In Combination With Topical Corticosteroid Treatment In Patients With Moderate-To-Severe Atopic Dermatitis.
46. (2019-Current) – InsMed Observational NTM PRO Study: 19145: A Randomized, Parallel-Group, Placebo-Controlled, Clinical Endpoint Bioequivalence Study of Generic Fluticasone Propionate 100 µg and Salmeterol Xinafoate 50 µg Inhalation Powder Compared with Advair Diskus® 100/50 in Subjects with Asthma.
47. (2019-Current) – Dermira Study: DRM06-AD04: A Randomized, Double-Blind, Placebo-Controlled Trial To Evaluate The Efficacy And Safety Of Lebrikizumab In Patients With Moderate-To-Severe Atopic Dermatitis.
48. (2019-Current) – Avillion DENALI Study: AV004: A 12-week, Randomized, Double-blind, Placebo-controlled, Multicenter, Parallel Group, Phase III Study Evaluating the Efficacy and Safety of PT027 Compared to PT008 and PT007 Administered QID in Adults and Children 4 Years of Age or Older with Asthma.

49. (2019-Current) – Astrazeneca RESOLUTE Study: D3251C00014: A Multicenter, Randomized, Double-blind, Chronic-dosing, Parallel-group, Placebo-controlled Phase 3 Study To Evaluate The Efficacy And Safety Of Benralizumab 100 Mg In Patients With Moderate To Very Severe Chronic Obstructive Pulmonary Disease (COPD) With A History Of Frequent COPD Exacerbations And Elevated Peripheral Blood Eosinophils.
50. (2019-Current) – Fibrogen Study: FGCL-3019-091: A Phase 3, Randomized, Double-Blind, Placebo-Controlled Efficacy and Safety Study of Pamrevlumab in Subjects with Idiopathic Pulmonary Fibrosis
51. (2019-Current) – Paratek Study: PTK0796-CABPPO-19109: A Phase 1 Multi-Center Study to Measure the Pharmacokinetics of Oral Omadacycline in Adult Subjects with Community-Acquired Bacterial Pneumonia (CABP).
52. (2019-Current) – Suven Life Sciences Study: CTP2S13031H3: A Phase 2, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Efficacy of 2 mg and 4 mg SUVN G3031 Compared to Placebo in Patients with Narcolepsy with and without Cataplexy.
53. (2019-Current) – Imbrium Therapeutics Study: OAG2002: A Phase 2, Randomized, Double-Blind, Multi-Center, Placebo-Controlled, Parallel-Group Study to Evaluate the Safety, Tolerability, and Efficacy of V117957 in Subjects with an Alcohol Use Disorder who are Experiencing Insomnia Associated with Alcohol Cessation.
54. (2019-Current) – GSK Matinee Study: 208657: A multi-center, randomized, double-blind, parallel-group, placebo-controlled study of mepolizumab 100 mg SC as add-on treatment in participants with COPD experiencing frequent exacerbations and characterized by eosinophil levels.
55. (2019-Current) – TEVA Compleware Study: TPI-18-03: A Phase 2, Randomized, Placebo-controlled, Double-blind, Open-label Extension Multicenter Study to Evaluate the Efficacy and Safety of KD025 in Subjects with Diffuse Cutaneous Systemic Sclerosis.
56. (2019-Current) – Lung Biotechnology Study: RIN-PRN-201: An Observational Study to Assess Patient Global Impression Instruments for Activity-Induced Symptoms in Patients with Pulmonary Arterial Hypertension.
57. (2019-Current) – Avillion MANDALA Study: AV003: A Long-term, Randomized, Double-blind, Multicenter, Parallel-Group, Phase III Study Evaluating the Efficacy and Safety of PT027 Compared to PT007 Administered as Needed in Response to Symptoms in Symptomatic Adults and Children 4 Years of Age or Older with Asthma.
58. (2019-2020) – XHALE Study: AI-BDP-001: A Randomized, Blinded, Multiple-Dose, Placebo-Controlled, Multi-Center Study Comparing Beclomethasone Dipropionate HFA Inhalation Aerosol, 40 mcg to QVAR® 40 mcg (beclomethasone dipropionate HFA), Inhalation Aerosol in Treatment of Subjects with Asthma.
59. (2018-Current) – Idorsia Extension Study: ID-078A303: Multi-center, double-blind, parallel-group, randomized, placebo-controlled, three doses, 40-week extension to studies ID-078A301 and ID-078A302 to assess the long-term safety and tolerability of ACT-541468 in adult and elderly subjects with insomnia disorder.

60. (2018-Current) – Galapagos Trial: GLPG1690-CL-304: A Phase 3, randomized, double-blind, parallel-group, placebo-controlled multicenter study to evaluate the efficacy and safety of two doses of GLPG1690 in addition to local standard of care for minimum 52 weeks in subjects with idiopathic pulmonary fibrosis.
61. (2018-Current) – AIRWISE COPD Study: 1237-0064: Pragmatic Randomized Clinical Trial in a Community-Based Setting Comparing Tiotropium bromide + Olodaterol FDC (STIOLTO® RESPIMAT®) vs. ICS-LABA plus LAMA (Triple Therapy) in Patients with COPD.
62. (2018-Current) - DORA-2018 Insomnia Study: ID-078A301: Multi-center, double-blind, randomized, placebo-controlled, parallel-group, polysomnography study to assess the efficacy and safety of ACT-541468 in adult and elderly subjects with insomnia disorder.
63. (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).
64. (2018-Current) – Astrazeneca CHRONICLE Asthma Study: D3250R00023: A Longitudinal Prospective Observational Study of the Characteristics, Treatment Patterns and Health Outcomes of Individuals with Severe Asthma in the United States.
65. (2018-2019) - VOLCANO 2 Chronic Cough Study: A double-blind, randomized, placebo-controlled study of the Efficacy and safety of three doses of orvepitant in subjects with Chronic refractory cough.
66. (2018-2019) – Westward Study: FLSA-P100/50-PVCL-2: A Randomized, Parallel-Group, Placebo-Controlled, Clinical Endpoint Bioequivalence Study of Generic Fluticasone Propionate 100 µg and Salmeterol Xinafoate 50 µg Inhalation Powder Compared with Advair Diskus® 100/50 in Subjects with Asthma.
67. (2018-2019) - TRELEGY COPD Study: 207609: A Phase IV, 12-week study to compare single inhaler triple therapy, fluticasone furoate/umeclidinium/vilanterol (FF/UMEC/VI) with multiple inhaler therapy (budesonide/formoterol plus tiotropium) based on lung function and symptoms in participants with chronic obstructive pulmonary disease.
68. (2018-2019) – Astrazeneca SOURCE Asthma Study: D5180C00009: A Multicentre, Randomized, Double-Blind, Placebo Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of Tezepelumab in Reducing Oral Corticosteroid Use in Adults with Oral Corticosteroid Dependent Asthma.
69. (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.
70. (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 Care Treatment.
71. (2017-Current) – Astrazeneca NOVELTY Trial: 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.

72. (2017-2019) - JNJ-42847922 Insomnia Study: A Placebo Controlled Polysomnography Study to Evaluate the Efficacy, Safety, and Tolerability of JNJ-42847922 in Subjects with Insomnia Disorder.
73. (2017-2019) - BEAM Asthma Study: A dose ranging study to evaluate the efficacy and safety of 3 doses of CHF 718 pMDI (beclomethasone dipropionate) in asthmatic subjects.
74. (2017-2019) - INS-312: A 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.
75. (2017-2018) - Lupin COPD: 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.
76. (2017-2018) - 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).
77. (2017-2018) - CAPSTONE-2: 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.
78. (2017-2018) - Symbicort Generic: 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.
79. (2017) - Novo Nordisk Trial: 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.
80. (2017) - United Therapeutics TDE-PH-401: A Patient Registry of the Real-world Use of Orenitram.
81. (2017) - Capstone-1: 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.
82. (2017) - A Comparative Study of FV-100 vs. Valacyclovir for the Prevention of Post-Herpetic Neuralgia and Treatment of Acute Herpes Zoster-Associated Pain.
83. (2016-Current) - PAH 201 Study: RIN-PH-201: A Multicenter, Randomized, Double-Blinded, Placebo-Controlled Trial to Evaluate the Safety and Efficacy of Inhaled Treprostinil in Subjects with Pulmonary Hypertension due to Parenchymal Lung Disease.

84. (2016-Current) – PAH-202-Study: RIN-PH-202: An Open-Label Extension Study of Inhaled Treprostinil in Subjects with Pulmonary Hypertension due to Parenchymal Lung Disease
85. (2016-Current) - Kadmon IPF: A Study to Evaluate the Safety, Tolerability, and Activity of KD025 in Subjects with Idiopathic Pulmonary Fibrosis (IPF).
86. (2016-2019) - 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.
87. (2016-2018) - INS-212: A 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.
88. (2016-2018) - 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. (BIPI 1199.227)
89. (2016-2017) - 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).
90. (2016-2017) - 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.
91. (2016) - Utility of PharmacoGenomics for Reducing Adverse Drug Effects. (Upgrade Registry).
92. (2015-2018) - Efficacy, Immunogenicity, and Safety Study of Clostridium difficile Toxoid Vaccine in Subjects at risk For C. difficile Infection (C-DIFFense).
93. (2015-2018) - A Parallel Group Study to Evaluate the Efficacy and Safety of Dupilumab in Patients with Persistent Asthma (EFC13579).
94. (2015-2017) - 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).
95. (2015-2017) - A Phase 3, 52-Week, Study to Evaluate the Safety and Tolerability of Nebulized TD-4208 in Subjects with Chronic Obstructive Pulmonary Disease.
96. (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).
97. (2015-2017) - 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).

98. (2014-2018) - 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).
99. (2014-2017) - 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. (LAVOLTA)(2014-2016) - A Prospective Observational Study to Evaluate Predictors of Clinical Effectiveness in Response to Omalizumab.
100. (2014-2015) - 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).
101. (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).
102. (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.
103. (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.
104. (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.
105. (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.
106. (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.
107. (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.
108. (2013-2014) - 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.

109. (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).
110. (2012-2014) - Long-Term Natural History of Patients with Severe or Difficult-to-Treat Asthma from the TENOR Observational Study.
111. (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).
112. (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.
113. (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.
114. (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.
115. (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.
116. (2011-2014) - A Postmarketing Observational Study to Assess Respiratory Tract Adverse Events in Pulmonary Arterial Hypertension Patients Treated with Tyvaso Inhalation Solution.
117. (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.
118. (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.
119. (2011-2013) - Rapid Evaluation of Acute Kidney Injury with NGAL.

120. (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).
121. (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).
122. (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.
123. (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 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 access long Term efficacy and safety of Tiotrpium 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®, COMBNENT® 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. (2001) - An observational study of the epidemiology and natural history of asthma: Outcomes and treatment requirements (Tenor Study).

#### **CLINICAL RESEARCH STUDIES CONDUCTED PRIOR TO 2001**

26. (2000) - A prospective, multicenter study of anemia of critical illness and transfusion in the Critically ill Patient.
27. (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.
28. (2000) - A double blind randomized, placebo, and active controlled multicenter, parallel group, dose ranging study of L-753099 in patients with COPD.
29. (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.
30. (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).
31. (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).
32. (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.
33. (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.
34. (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.
35. (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.
36. (1998) - An open label, long term study of the tolerability of Seratrodast in patients with moderate to severe COPD.
37. (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.
38. (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.

39. (1997) - Study of Tiotropium, an anticholinergic bronchodilator, in COPD.
40. (1997) - Study of Accolate, a leukotriene antagonist, in asthma (ACCEPT).
41. (1996) - Study of the combination of albuterol and ipratropium in COPD.
42. (1994) - Epidemiologic study of Prostep, a nicotine replacement patch, in smoking cessation.
43. (1994) - Epidemiologic study of Prostep, a nicotine replacement patch, in smoking cessation.

**Sub-Investigator:**

1. (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.
2. (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.