



# CURRICULUM VITAE

**NAME**

Isaac Reuven Melamed, MD

**POSITION**

Principal Investigator / Sub-Investigator

**ADDRESS (ES)**

IMMUNOe Research Centers  
6801 South Yosemite Street  
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IMMUNOe Research Centers  
3260 East 104th Avenue  
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IMMUNOe Research Centers  
18620 Green Valley Ranch Blvd, Suite 101  
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1551 Professional Lane, Unit 280  
Longmont, CO 80501

**EDUCATION**

1969–1975: Hebrew University—Hadassah School of Medicine; Jerusalem

1965–1969: “Ahad Ha’am” High School; Petah Tikva

**TRAINING**

1992–1995: Post-doctoral fellow, Department of Pediatrics, Division of Basic Sciences, National Jewish Center for Immunology and Respiratory Medicine; Denver, Colorado

1992: Fellow of the American Academy of Allergy and Immunology

1989–1992: Post-doctoral fellow in the Dept. of Pediatrics, Division of Immunology/ Allergy, Hospital for Sick Children; Toronto, Canada

1986–1989: Senior Staff Physician—Danna Children Hospital; Tel Aviv



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- 1981–1986: Residency in Pediatrics, Rokach (Hadassah) Hospital, Tel Aviv Medical Center; Tel Aviv
- 1977–1981: I.D.F. and Heller Institute—Military Medicine, Sheba Medical Center; Tel-Hashomer
- 1975–1976: Internship—Hebrew University; Jerusalem Title of Doctoral Dissertation: *“Evaluation of a New Pneumatic Method as Treatment of Post-Mastectomy Lymphedema”*; Supervisor: Dr. A. Zelikovski

## EXPERIENCE

2002–Present: Private practice, IMMUNOe Research Centers, IMMUNOe International Research Center, 1st Allergy & Clinical Research Centers, and 1st International Clinical Research Centers, Centennial (CO), Green Valley Ranch (CO), Longmont (CO) and Thornton (CO).

1995–Present: Private practice, IMMUNOe Health Centers, Centennial, CO and Thornton, CO

## LICENSURE

1992– active: Colorado license to practice medicine (License #32130)

1986: Israel Board Certified Specialist in Pediatrics

## PROFESSIONAL AND ACADEMIC APPOINTMENTS

### INSTITUTIONAL AFFILIATIONS

2011 - Present: Assistant Clinical Professor of Medicine, Department of Pediatrics, School of Medicine, University of Colorado Anschutz Medical Campus

1995 – Present: Assistant Professor at Children’s Hospital and National Jewish Hospital, Denver, Colorado. Active in Pediatric Grand Rounds at National Jewish

2002-2011: Associate Clinical Professor, Department of Pediatrics, School of Medicine, University of Colorado Anschutz Medical Campus

1995 - 1998: Assistant Professor, Department of Pediatrics, University of Colorado, Health Sciences Medical Center

1992–1995: Post-doctoral fellow, Department of Pediatrics, Division of Basic Sciences, National Jewish Center for Immunology and Respiratory Medicine; Denver, Colorado.

1989–1992: Post-doctoral fellow in the Department of Pediatrics. Division of Immunology/Allergy, Hospital for Sick Children; Toronto, Canada

1988-1998 Associate Professor—Tel Aviv University, Sackler Medical School of Medicine, Tel Aviv, Israel

1986-1988 Lecturer, Tel Aviv University Sackler School of Medicine, Tel Aviv, Israel

## **AWARDS AND PRIZES**

2002: Award of Clinical Immunology Society

1993: Research Award of the American Academy of Allergy and Immunology

1991: Honorable certificate, The Third Canadian Annual Pediatric Fellows Research Symposium, Univ. of Manitoba

1990: Tisdale award for excellence in research, Dept. of Pediatrics, University of Toronto, Hospital for Sick Children

1978: Faculty prize for doctoral dissertation, Hebrew University— Hadassah Medical School; Jerusalem

## **PROFESSIONAL ORGANIZATIONS**

2003: European Society of Neuroimmunology

1999: European Pediatric Immunodeficiency Society

1998: European Society of Allergy and Immunology

1997: The Asthma Committee by Prudential

1997: The Autistic Society—research/clinical advisory committee

1998: Aetna/Prudential Provider Advisory Committee

- 1994: Colorado Medical Society
- 1993: Colorado Allergy and Asthma Society
- 1993: American Society of Research
- 1992: Canadian Society for Allergy and Immunology
- 1991: American College of Allergy and Immunology
- 1991: American Association of Immunologists
- 1990: Clinical Immunology Society
- 1990: American Academy of Allergy and Immunology
- 1986: Committee of Pediatric training—Sackler Medical School
- 1981 Israel Society for Clinical Pediatrics

## PRESENTATIONS

1995–Present Lecturer in the training programs of:

- Immuno-clinical correlated-topics - National Jewish Health, Denver, CO
- Early B-cell signaling Cell Biology Section - University of Colorado Health Sciences Center, Denver, CO
- The Role of Signaling in Immunodeficiency - University of Colorado Health Sciences Center, Denver, CO, Immune Deficiency Clinic
- Signaling defects in immune deficiency patients (currently on Wiskot Aldrich) - University of Colorado Health Sciences Center, Denver, CO, Immune Deficiency Clinic

1. I. Melamed, V. Zakuth, E. Tzechoval and Z. Spirer: Suppressor T-cell activity in splenectomized subjects. Israel Pediatric Association Meeting, Herzelia, 1981.
2. I. Melamed, Y. Romem, G. Keren and E. Dolev: Acute exertional rhabdomyolysis in recruits. 12th World Congress of Israel Medical Association, Jerusalem, 1982.
3. I. Melamed, D. Chitayat, V. Zakuth and Z. Spirer: Transient immune deficiency in children. Israel Pediatrics Association, Herzelia, 1982.

4. I. Melamed, S. Shemer, V. Zakuth, M. Pras and Z. Spierer: The immune system in familial Mediterranean fever. Israel Pediatric Association, Tel Aviv, 1983.
5. Y. Bujanover, I. Melamed, Y. Siegman-Igra, V. Zakuth and Z. Spierer: Campylobacter enteritis in normal and immunodeficient children. European Society of Pediatric Gastroenterology, Graz, Austria, 1983.
6. I. Melamed, et al: Campylobacter enteritis in immune deficient children. 2nd International Workshop of Campylobacter Infection, Brussels, Belgium, 1983.
7. I. Melamed, V. Zakuth, Y. Burenstein and Z. Spierer: Blastogenic response to V-Z antigen in normal and immune suppressed children. Israeli Pediatrics Association, Tel Aviv, 1984.
8. I. Melamed: The immune response to campylobacter infection. 3rd International Workshop on Campylobacter Infection, Ottawa, Canada, 1985.
9. I. Melamed, J.D. Kark and Z. Spierer: Serum IgA levels in different ethnic groups. Israel Pediatrics Association, Tel Aviv, 1985.
10. I. Melamed: The association of NEC to campylobacter infection. IVth International Workshop on Campylobacter Infection, Goeteborg, Sweden, 1987.
11. D. Schwartz and I. Melamed: Enzyme-linked immunosorbent assay in diagnosis of campylobacter jejuni infection in Israel children. Israel Microbiology Association, Rehovot, 1987. Abstract: Israel Journal of Med Sci 23:855-856, 1987.
12. I. Melamed, J. Kark and Z. Spierer: Coffee and the immune system. European Immunology Congress, Zagreb, 1987.
13. I. Melamed, S. Kabili and Z. Spierer: Familial Mediterranean fever and the immune system. European Immunology Congress, Zagreb, 1987.
14. I. Melamed, V. Zakuth and Z. Spierer: Decreased IL-1 and IL-2 production post splenectomy. Israel Society of Immunology, Beer Sheva, 1988.
15. I. Melamed, D. Schwartz and Y. Goldharer: Campylobacter and necrotizing enterocolitis. 5th International Workshop on Campylobacter Infections. Mexico, 1988.

16. D. Schwartz, I. Melamed, Z. Spire, D. Cohen, N. Konforty and J. Goldhar: ELISA for *Campylobacter jejuni* antibodies in Israeli children and soldiers. Proceeding of the 16th International Congress of Chemotherapy, Israel, June 1989.
17. I. Melamed, G. Downey and C.M. Roifman: Cytoskeletal changes associated with B cell activation, FASEB meeting, Washington DC, 1990.
18. I. Melamed, G. Downey and C.M. Roifman: Mitogen induced microfilament assembly. Clinical Immunology Society, Chicago, IL, 1990.
19. I. Melamed, G.P. Downey, A. Choen and C.M. Roifman: B cell activation is dependent on vimentin, Atlanta, FASEB Meeting, 1991.
20. I. Melamed and C.M. Roifman: Unrelated matched bone marrow transplantation for Ommen's Syndrome. American College of Allergy, Asthma & Immunology annual meeting (ACAAI), 1992.
21. I. Melamed, R.A. Franklin, C. Brodie, J. Lucas and E.W. Gelfand: Signaling of B lymphocytes by nerve growth factor: tyrosine phosphorylation of phospholipase C $\alpha$ 1, MAP2-Kinase and GP140trk. American Association of Immunology meeting, Denver, CO, 1993.
22. R.A. Franklin, C. Brodie, I. Melamed, N. Terada, J. Lucas, E.W. Gelfand: Nerve growth factor induced activation of MAP2-Kinase and P90rsk in B lymphocytes. American Association of Immunology meeting, Denver, CO, 1993.
23. I. Melamed, C.A. Kelleher, R.A. Franklin, C. Brodie, J.B. Hempstead, D. Kaplan and E.W. Gelfand: Signaling of B lymphocytes by nerve growth factor: gp140trk as a neuro-immune adaptor. Cell Biology Meeting, New Orleans, LA, 1993.
24. I. Melamed, C. Turner, E.W. Gelfand: 893 Nerve growth factor (NGF) triggers microfilament assembly and paxillin phosphorylation in B lymphocytes. American Academy of Allergy, Asthma and Immunology annual meeting (AAAAI), New Orleans, LA, 1996.
25. I. Melamed, E.W. Gelfand: Modulation of activated B and T cell tyrosine phosphorylation by intravenous immunoglobulin (IVIG), American Academy of Allergy, Asthma & Immunology annual meeting (AAAAI), New Orleans, LA, 1996.
26. I. Melamed, H. Patel, E.W. Gelfand: Trk tyrosine kinase dependent activation of Vav/Ras in human B cells by nerve growth factor, American Academy of Allergy, Asthma and Immunology annual meeting (AAAAI), San Francisco, CA, 1997.

27. I. Melamed, H. Patel, E.W. Gelfand: Activation of Vav and Ras through nerve growth factor. 5th IUBMB –The Biochemistry of Health and Diseases meeting, Jerusalem, 1998.
28. I. Melamed, E.W. Gelfand: Microfilament Assembly is Involved in Apoptosis, 5th IUBMB –The Biochemistry of Health and Diseases meeting, Jerusalem 1999.
29. I. Melamed, C.M. Roifman, E.W. Gelfand: 654 A New Autosomal Recessive Skeletal Dysplasia with Immune Deficiency and Abnormal Vitamin D Signaling, American Academy of Allergy, Asthma and Immunology meeting(AAAAI), 2000.
30. I. Melamed: The Role of Signaling in Immunodeficiency. International Allergy meeting, Israel, 2000.
31. I. Melamed, J. Levy, S. Shatzky, R. Parvari, E.W. Gelfand: A Novel Immunodeficiency Trk A-Mutation in patients with Congenital Insensitivity to Pain and Anhidrosis (CIPA). FOCIS, San Francisco, 2002.
32. I. Melamed: Immunotherapy - How early is early? American College Allergy, Asthma and Immunology annual meeting (ACAAI), New Orleans, 2003.
33. I. Melamed: Parvovirus B-19 infection as a cause of severe ataxia in immunodeficient patient and the benefit of high dose IVIG. American College of Allergy Asthma and Immunology annual meeting (ACAAI), New Orleans, 2003.
34. I. Melamed, B.G. Bender, M.Z. Wamboldt: The Benefit of Using Cetirizine (Zyrtec) With Stimulant in Children With Comorbid Allergy and ADHD. American Academy Allergy, Asthma and Immunology meeting (AAAAI), 2004.
35. I. Melamed, S.B. Beard: The benefit of high-dose IVIG treatment in an immunocompromised patient who presented with idiopathic tremors. American Academy Allergy, Asthma and Immunology meeting (AAAAI), 2004.
36. I. Melamed, A. McDonald, B. Jessen: Atopy as a Cause of Delayed Maturation of the Immune System. American Academy Allergy, Asthma and Immunology meeting (AAAAI), 2006.
37. I. Melamed, A. McDonald, M. Gonzalez: Autism as a Neuroimmune Disease: The Benefit Effect of IVIG. American Academy Allergy, Asthma and Immunology meeting (AAAAI), 2006.

38. I. Melamed, S. Kelley, A. McDonald, D. Bar-Or: The Immunomodulatory Effect of IVIG in Parvovirus B-19 Induced Neuroimmune Disease. American Academy Allergy, Asthma and Immunology meeting (AAAAI), 2006.
39. I. Melamed, A. Smith, F. Accurso: The Benefit of IVIG in Children with Chronic Sinus Disease Secondary to Single Mutation in the Cystic Fibrosis Transmembrane Regulatory Gene. American Academy Allergy, Asthma and Immunology (AAAAI) meeting, 2006.
40. I. Melamed, D. Bar-Or, R. Shimonkevitz: 605 The Immune modulating Effect of Pimecrolimus in Atopic Dermatitis. American Academy of Dermatology annual meeting, 2008.
41. I. Melamed, M. R. Stein, R. L. Wasserman, H. Leibl, W. Engle, R. C. Yocum, R. I. Schiff: Recombinant Human Hyaluronidase Facilitates Dispersion of Subcutaneously Administered Gammagard Liquid and Enables Administration of a Full Monthly Dose in a Single Site to Patients with Immunodeficiency Diseases: American Academy Allergy, Asthma and Immunology meeting (AAAAI), 2008.
42. I. Melamed: Atopy as a Linkage to Autoimmune Diseases. Presentation given at: International Conference Dedicated to a Centenary of Elie Metchnikoff and Paul Ehrlich Nobel Prize Award; September 15, 2008; Moscow, Russia.
43. I. Melamed: The Metabolic Syndrome as an Immune-related Disease. Presentation given at: Colorado Society of Osteopathic Medicine Annual Meeting; February 23, 2008; Keystone, CO.
44. I. Melamed: The Immunomodulatory Role of IVIg in Viral Induced Neuro-immune Disorders — The Potential Role of Anti-myelin Antibodies as a Biomarker: Poster presentation given at: 6th International Immunoglobulin Symposium; March 2009 Interlaken, Switzerland.
45. I. Melamed, M. R. Stein, R. L. Wasserman, H. Leibl, W. Engle, R. C. Yocum, R. I. Schiff: Use of Recombinant Human Hyaluronidase to Facilitate Dispersion, Absorption, and Bioavailability of IVIG. Presented at: American Academy of Neurology Focus Group; April 27, 2009; Seattle, WA.
46. I. Melamed: The Role of the Immune System in Autoimmune Diseases. Presentation given at Hospital Punta Pacifica, May 5, 2009; Panama City, Panama.
47. I. Melamed: Phase 3 Clinical Trial on the Use of IVIG, 10% Plus Recombinant Human Hyaluronidase: Overview and Updates. Presentation given at: Federation of Clinical Immunology Societies (FOCIS) FOCUS Group Dinner, June 10, 2009; San Francisco, CA.



48. I. Melamed: The role of Zyraltin in neuro-inflammatory diseases – Nerve growth factor as a possible link between the nervous and the immune system. Presentation at: 45th Annual Drug Information Association (DIA) Poster Session 2009; June 23, 2009; San Diego, CA.
49. I. Melamed: The Immunomodulatory of Role of IVIg in Viral Induced Neuro-immune Disorders. Poster presentations at: International Forum on Immunoglobulin Research (IFIR) 2009; November 19, 2009; Ft. Lauderdale, FL.
50. I. Melamed: Attention Deficit Disorder and Allergic Rhinitis – Are They Related? The Benefit of Using Cetirizine in Children with Comorbid Disease (ADHD and Allergy). American College of Allergy Asthma & Immunology Annual Meeting (ACAAI), 2009.
51. I. Melamed, Robinson L, Heffron M: The Benefit of Montelukast in Atopic Dermatitis Induced by Food Allergies. American Academy of Allergy Asthma & Immunology Annual Meeting, 2010.
52. I. Melamed: The immunomodulatory role of IVIg in viral induced neuroimmune disorders – The potential role of anti-myelin antibodies as a biomarker. VI Georgian Congress of Allergology & Immunology, Keynote Speaker, October 1, 2010, Tbilisi, Georgia
53. I. Melamed: The role of vitamin D in autoimmune disease. VI Georgian Congress of Allergology & Immunology Annual Meeting, October 1, 2010, Tbilisi, Georgia.
54. I. Melamed, A. Neff, A. McDonald, A. Beck: An analysis of safety and tolerability data on 10%, 16%, and 20% formulations of subcutaneous immunoglobulins (IGSC Poster presentation at Academy of Allergy, Asthma and Immunology annual meeting (AAAAI), March 17 – 21, 2011, San Francisco, CA.
55. I. Melamed. An analysis of safety and tolerability data on 10%, 16%, and 20% formulations of subcutaneous immunoglobulins (IGSC). Focus group presentation at Academy of Allergy, Asthma and Immunology annual meeting (AAAAI), March 17 – 21, 2011, San Francisco, CA.
56. I. Melamed, A. Neff, A. McDonald. Subcutaneous immunoglobulins: Product characteristics and their role in primary immunodeficiency disease. Poster presentation at Clinical Immunology Society annual meeting (CIS), May 18 - 21, 2011, Chicago, IL.
57. I. Melamed, M. R. Stein, R. L. Wasserman, H. Leibl, W. Engle, R. C. Yocum, R. I. Schiff: Safety and Pharmacokinetics of Facilitated-Subcutaneous Infusion of Immune Globulin (Human), 10% and Recombinant Human Hyaluronidase (IGHy) in a Phase III Extension Study in Patients

with Primary Immunodeficiency Disease (PID). Presentation given at: American Academy of Allergy, Asthma and Immunology Annual Meeting (AAAAI), March 2-6, 2012, Orlando, FL.

58. I. Melamed, A. Testori: The Benefit of Intravenous Immunoglobulin in Sarcoidosis. Presented at: 3rd International Forum in Immunoglobulin Research (IFIR), October 3-6, 2013, Miami, Florida.
59. I. Melamed: Benefits of Gammalex 5% IVIG for Patients Experiencing Adverse Events on 10% IVIG. Presentation given at: First International Primary Immunodeficiencies Congress (IPIC), November 7-9, 2013, Estoril, Portugal.
60. I. Melamed, R.L. Wasserman, M. Stein, A. Rubenstein, J. Puck, S. Gupta, et. al. Long-Term Safety/Pharmacokinetics of Facilitated-Subcutaneous Infusion of Human Immune Globulin G 10%, and Recombinant Human Hyaluronidase in Primary Immunodeficiencies: An Extension Study. First International Primary Immunodeficiencies Congress Annual Meeting (IPIC), November 7-9, 2013, Estoril, Portugal.
61. I. Melamed, R.L. Wasserman, M. Stein, A. Rubenstein, J.M. Puck, S. Gupta, W. Engl, H. Leibl, et. al.: Long-Term Tolerability and Safety of Facilitated-Subcutaneous Infusion of Human Immune Globulin G (IgG), 10%, and Recombinant Human Hyaluronidase (rHuPH20) (IGHy): A Phase 3 Extension Study in Patients with Primary Immunodeficiencies (PIs). American Academy of Allergy, Asthma and Immunology annual meeting (AAAAI), February 27 – March 3, 2014, San Diego, CA.
62. I. Melamed, R. L. Wasserman, M. Stein, A. Rubinstein, J. Puck, S. Gupta, et. al.: Long Term Safety, Efficacy, Tolerability, and Pharmacokinetics of Recombinant Human Hyaluronidase-Facilitated Subcutaneous Infusion of Immunoglobulin G: A Phase 3 Extension Study in Patients with Primary Immunodeficiencies. 100th J Project Meeting, March 12 – 15, 2014, Antalya, Turkey.
63. I. Melamed, R.L. Wasserman, M. Stein, A. Rubinstein, J. Puck, S. Gupta, et. al: Long-Term Tolerability and Safety of Facilitated-Subcutaneous Infusion of Human Immunoglobulin G, 10%, and Recombinant Human Hyaluronidase: A Phase 3 Extension Study in Patients With Primary Immunodeficiencies. Clinical Immunology Society Annual Meeting (CIS), April 10 – 14, 2014, Baltimore, MD.
64. I. Melamed, R.L. Wasserman, M. Stein, A. Rubinstein, J. Puck, S. Gupta, et.al.: Long Term Safety, Efficacy, Tolerability, and Pharmacokinetics of Recombinant Human Hyaluronidase-Facilitated Subcutaneous Infusion of Immunoglobulin G: A Phase 3 Extension Study in

Patients with Primary Immunodeficiencies. Immunoglobulin Nursing Society Annual Meeting (IgNS), September 19 – 20, 2014, Las Vegas, NV.

65. I. Melamed, R.L. Wasserman, M. Stein, A. Rubinstein, J. Puck, S. Gupta, et. al.: Long Term Safety, Efficacy, Tolerability, and Pharmacokinetics (PK) of HyQvia<sup>®</sup> (IGHy): A Phase III Extension Study in Patients With Primary Immunodeficiencies. German, Austrian and Swiss Societies of Haematology and Oncology Annual Meeting (DGHO), October 10 – 14, 2014, Hamburg, Germany.
66. I. Melamed, R. L. Wasserman, M. Stein, A. Rubinstein, J. Puck, S. Gupta, et. al. Long Term Safety, Efficacy, Tolerability, and Pharmacokinetics of Recombinant Human Hyaluronidase-Facilitated Subcutaneous Infusion of Immunoglobulin G: A Phase 3 Extension Study in Patients with Primary Immunodeficiencies. American College of Clinical Pharmacy Annual Meeting (ACCP), October 12 – 15, 2014, Austin, TX.
67. I. Melamed, A. Testori. The Role of C1 Esterase Inhibitor in CVID. European Society for Immunodeficiencies Annual Meeting (ESID), October 29 – November 1, 2014, Prague, Czech Republic.
68. I. Melamed. Pharmacokinetics of RI-002, an investigational IGIV preparation. American Academy of Allergy, Asthma & Immunology annual meeting (AAAAI), February 20 – 24, 2015, Houston, TX.
69. I. Melamed. Gammaplex<sup>®</sup> 5% in Children and Adolescents with Primary Immunodeficiency Diseases. Clinical Immunology Society annual meeting (CIS), April 9 – 12, 2015, Houston, TX.
70. I. Melamed. The Benefit of IVIG in Treating Children with Autism Spectrum Disorder. Immunoglobulin Nursing Society (IgNS), September 17 – 20, 2015, Washington D.C.
71. I. Melamed, S. Gupta, M.S. Bobbitt, K. Gillander, N. Hyland, J.N. Moy. Efficacy and Safety of Gammaplex<sup>®</sup> in Children and Adolescents with Primary Immunodeficiency Diseases. Immunoglobulin Nursing Society (IgNS), September 17 – 20, 2015, Washington D.C.
72. I. Melamed. In a Developing World of Novel 10% Intravenous Immunoglobulin Products, the Original 5% Solutions Still Have an Important Role & Why. International Primary Immunodeficiency Congress, November 5 – 6, 2015, Budapest, Hungary.

## PUBLICATIONS

1. Zelikovski, I. Melamed, I. Kott, M. Manoach, I. Urca. The "Lymphapress" - a new pneumatic device for the treatment of lymphedema: clinical trial and results. *Folia Angiology* 1980; 28:165-169.
2. I. Melamed, I. Romem: Is bicarbonate needed in shock treatment? *Harefuah* 1980; 11:397-9.
3. I. Melamed, Y. Romem, G. Keren, Y. Epstein and E. Dolev. March myoglobinemia - A hazard to renal function. *Archives of Internal Medicine* 1982; 142:1277-9.
4. I. Melamed, V. Zakuth, E. Tzechoval, Z. Spirer. Suppressor T cell activity in splenectomized subjects. *Journal of Clinical & Laboratory Immunology* 1982; 7(3):173-7.
5. I. Melamed, Z. Spirer. Aging and immunity. *Harefuah* 1982; 102(1):31-3.
6. I. Melamed, Y. Bujanover, J. Hammer, Z. Spirer. Hepatoblastoma in an infant born to a mother after hormonal treatment for sterility. *New England Journal of Medicine* 10/1982; 307(13):820. DOI:10.1056/NEJM198209233071313. PMID: 6287262.
7. I. Melamed, Y. Romem, T. Shimoni, Y. Pereck, E. Dolev. Overdose of booster tetanus toxoid given in error: A clinical study. *Scandinavian Journal of Infectious Disease* 1983; 15(3):303-6. PMID: 6359374.
8. I. Melamed, Y. Bujanover, Y.S. Igra, D. Schwartz, V. Zakuth, Z. Spirer. *Campylobacter* enteritis in normal and immunodeficient children. *American Journal of Diseases of Children* (1960) 1983; 137(8):752-3. PMID: 6869333.
9. I. Melamed, S. Shemer, V. Zakuth, E. Tzechoval, M. Pras, Z. Spirer. The immune system in familial Mediterranean fever. *Clinical & Experimental Immunology* 1983; 53(3):659-62. PMID: 6225577.
10. I. Melamed, M. Djaldetti, H. Joshua, U. Seligson: Association of the hemophila A carrier state and hemorrhagic thrombocytopeny with dilatation of platelet membrane complex. *Acta Haematologica* 1984; 71(6):381-7. DOI:10.1159/000206623. PMID: 6433619.
11. I. Melamed, Y. Bujanover and Z. Spirer. Neurologic complication in *Campylobacter jejuni* enteritis. *Harefuah* 1984; 106(10):455. PMID: 6469104.
12. I. Melamed, D. Chitayat, V. Zakuth and Z. Spirer. Incomplete transient immunodeficiency in children. *Harefuah* 1984; 106:350-2.

13. I. Melamed, A. Aviram, A. Rubinstein, V. Zakuth, G. Pereschansky, Z. Spierer. Inhibition of lymphocyte response to mitogens by dipyridamole: preliminary findings. *European Journal of Clinical Pharmacology* 1985; 28(3):263-5. DOI:10.1007/BF00543321. PMID: 4007031.
14. I. Melamed, Y. Bujanover, Y. Siegman-Igra, V. Zakuth and Z. Spierer: *Campylobacter enteritis in normal and immunodeficient children*. *Campylobacter II*, Ed., A.D. Pearson, M.B. Skirrow, B. Bowe, J.R. Davis, D.M. Jones, 1985.
15. I. Melamed, V. Zakuth, D. Schwartz and Z. Spierer: The immune response to campylobacter infection. *Campylobacter III*, Ed., A.D. Pearson, M.B. Skirrow, B. Bowe, J.R. Davis, D.M. Jones, 1987.
16. I. Melamed, V. Zakuth, J.O. Kark, Z. Spierer. The immune system in isolated IgA deficiency. *Journal of Clinical & Laboratory Immunology* 1985; 17(4):163-6.
17. I. Melamed, Y. Bujanover, Z. Spierer, D. Schwartz, N. Conforty. Polymicrobial infection in campylobacter enteritis. *British Medical Journal (Clinical research ed.)* 1985; 291(6496):633-4. DOI:10.1136/bjm.291.6496.633. PMID: 3928058.
18. I. Melamed, S. Diamant, A. Fattal, Z. Spierer. Kawasaki disease with serologic evidence of streptococcal infection. *Infection* 1989;14(2):91-2. DOI:10.1007/BF01644453.
19. I. Melamed, J.D. Kark, V. Zakuth, G. Margalit, Z. Spierer. Serum immunoglobulin A levels and ethnicity in an Israeli population sample. *Clinical Immunology and Immunopathology* 1987; 42(3):259-64. DOI:10.1016/0090-1229(87)90013-4. PMID: 3829450.
20. Y. Bujanover, I. Melamed and D. Branski: *Campylobacter jejuni enteritis in normal and immunodeficient children*. *Front Gastrointestinal Research* 1986; 13:343-354.
21. Z. Spierer, M. Holtzman, I. Melamed, I. Shalit. Age distribution of anginose mononucleosis. *Archives of Disease in Childhood* 07/1987; 62(6):617-619. DOI:10.1136/adc.62.6.617. PMID: 3619480.
22. I. Melamed, Y. Bujanover, D. Schwartz, M. Rogol, V. Zakuth, Z. Spierer. Persistent campylobacteriosis in an immune deficient child. *Journal of Diarrhoeal Diseases Research* 1987; 5(3):188. PMID: 3507430.
23. I. Melamed, V. Zakuth, D. Schwartz, Z. Spierer. The immune system response to campylobacter infection. *Microbiology and Immunology* 1988; 32(1):75-82. PMID: 3374406.

24. I. Melamed, S. Kabili, V. Zakuth, Z. Spierer. The immune system in familial Mediterranean fever. *Journal of Clinical & Laboratory Immunology* 1988; 26(3):125-8. PMID: 2976426.
25. Z. Spierer, V. Zakuth, E. Tzechoval, S. Dagan, M. Friedkin, A. Golander, I. Melamed. Tuftsin stimulates IL-1 production by human mononuclear cells, human spleen cells and mouse spleen cells in vitro. *Journal of Clinical & Laboratory Immunology* 1989; 28(1):27-31. PMID: 2786082.
26. I. Melamed. Pneumovax vaccine: new aspects. *Harefuah* 1989; 116:166-8.
27. Z. Spierer, V. Zakuth, E. Tzechoval, S. Dagan, B. Lev, A. Golander, I. Melamed. Decreased interleukin 1 and interleukin 2 production in splenectomized patients. *Harefuah*. 1994; 126(7):374-7. PMID: 8200582.
28. I. Melamed, J. Kark, Z. Spierer. Coffee and the immune system. *International Journal of Immunopharmacology* 1990; 12(1):129-34. DOI:10.1016/0192-056(90)90076-Y. PMID: 2303315.
29. D. Schwartz, I. Melamed, D. Cohen, N. Konforti, J. Goldhar. ELISA for *Campylobacter jejuni* antibodies in Israeli children with diarrhea and in healthy soldiers. *Israel Journal of Medical Sciences* 1990; 26(6):319-24. PMID: 2380033.
30. I. Melamed, G. Downey and C.M. Roifman. Cytoskeletal changes associated with B cell activation. *FASEB* 1990; J 4, A640.
31. I. Melamed, S. Pheanny, P. Shermann, C.M. Roifman. Benefit of ketotifen in eosinophilic gastroenteritis. *The American Journal of Medicine* 1991; 90(3):310-4. DOI:10.1016/0002-9343(91)80010-J. PMID: 2003512.
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112. R.L. Wasserman, M. Stein, I. Melamed, L. Kobrynski, A. Grant, S. Gupta, et. al. Recombinant Human Hyaluronidase [rHuPH20] – Facilitated Subcutaneous (SC) Infusion of Immunoglobulin G (IgG) (HyQvia; IGHy) in Patients Aged  $\geq 16$  Years with Primary Immunodeficiencies (PI): Long Term Safety, Efficacy, and Tolerability. American College of Allergy, Asthma & Immunology (ACAAI), November 6 – 10, 2014, Atlanta, GA.
113. J.J. Mond, C. Cunningham-Rundles, A.R. Falsey, L.R. Forbes, A.S. Grossman, J. Harris, K.M. Kestenber, A.L. Kobayashi, R. H. Kobayashi, R.J. Levy, W.R. Lumry, I. Melamed, M.R. Stein, R.L. Wasserman. Pharmacokinetics of RI-002, an Investigational Igiv Preparation. Journal of Allergy and Clinical Immunology 2015; 135(2):AB89. DOI:10.1016/j.jaci.2014.12.1224.
114. D. Suez, I. Melamed, I. Hussain, M. Stein, S. Gupta, K. Paris, et. al. Efficacy, Safety and Tolerability of Human Immune Globulin Subcutaneous, 20% (IGSC 20%): Interim Analysis of a



Phase 2/3 Study in Patients with Primary Immunodeficiencies (PID) in North America. Clinical Immunology Society (CIS), April 9 – 12, 2015, Houston, TX.

115. R.L. Wasserman, I. Melamed, M. Stein, L. Kobrynski, J. Puck, S. Gupta, et. al. Long Term Safety, Efficacy and Tolerability of Recombinant Human Hyaluronidase [RHUPH20]-Facilitated Subcutaneous (SC) Infusion of Immunoglobulin G (IGG) (HYQVIA; IGHY) in Pediatric Patients Aged <16 Years with Primary Immunodeficiencies (PID). Clinical Immunology Society (CIS), April 9 – 12, 2015, Houston, TX.
116. Melamed, M. Heffron, S. McGee, L. Ullate, A. Testori. A New Subset of Common Variable Immune Deficiency Characterized by Reduced C1 Esterase Inhibitor Levels. Letters/Ann Allergy Asthma Immunol. 2015; 115:69-85.
117. T.C. Theoharides, J. M. Stewart, S. Panagiotidou, I. Melamed. Mast cells, brain inflammation and autism. Eur J Pharmacol. 2015 May 1. pii: S0014-2999(15)00398-2. doi: 10.1016/j.ejphar.2015.03.086. [Epub ahead of print]
118. D. Suez, I. Melamed, I. Hussain, B. McCoy, L. Yel. Efficacy, Safety, and Tolerability of Human Immune Globulin Subcutaneous, 20%: Interim Analysis of a Phase 2/3 Study in Patients with Primary Immunodeficiencies in North America. Immunoglobulin Nursing Society (IgNS), September 17 – 20, 2015, Washington D.C.
119. D. Suez, I. Melamed, I. Hussain, B. McCoy, L. Yel. Efficacy, Safety, and Tolerability of Human Immune Globulin Subcutaneous, 20%: Interim Analysis of a Phase 2/3 Study in Patients with Primary Immunodeficiencies in North America. International Primary Immunodeficiency Congress, November 5 – 6, 2015, Budapest, Hungary.
120. D. Suez, I. Melamed, I. Hussain, B. McCoy, L. Yel. Efficacy, Safety, and Tolerability of Human Immune Globulin Subcutaneous, 20%: Interim Analysis of a Phase 2/3 Study in Patients with Primary Immunodeficiencies in North America. American Society of Health-Systems Pharmacists (ASHP), December 1 – 6, 2015, New Orleans, LA.
121. I. Melamed, S. Gupta, M. Stratford Bobbitt, N. Hyland, J. N. Moy. Efficacy and safety of Gammaplex<sup>®</sup> 5% in children and adolescents with primary immunodeficiency diseases. Clin Ex Immunol. [Submitted]
122. J. Heimall, J.A. Church, R. Griffin, T. Lennon, I. Melamed, G. I. Kleiner. Pharmacokinetics, Safety, and Tolerability of Subcutaneous Immune Globulin Injection (Human), 10% Caprylate/Chromatography Purified (GAMUNEX<sup>®</sup>-C) in Pediatric Patients with Primary Immunodeficiency Disease. J. Clin Immunol [Submitted]

## BOOKS AND REVIEWS

I. Melamed, Y. Romem, G. Keren, Y. Epstein and E. Dolev: Myoglobinemia A Hazard to Renal Function. 1984 Year Book of Emergency Medicine.

## OTHER PUBLICATIONS

I. Melamed and V. Steiner: Herpes simplex labialis. I.D.F. Bulletin 1:25, 1980.

I. Melamed: Dopamine. I.D.F. Bulletin 1:29, 1980.

## **CLINICAL RESEARCH EXPERIENCE**

### **Allergic Rhinitis**

2010: A Randomized, Double Blind, Placebo-Controlled, Parallel-Group Study to Assess the Efficacy, Tolerability and Safety of 0.05% Low-Dose XXX Intranasal Spray in Adults with Allergic Rhinitis

2010: A Randomized, Double Blind, Placebo-Controlled, Parallel-Group Study to Assess the Efficacy, Tolerability and Safety of 0.1% XXX Intranasal Spray in Adults with Allergic Rhinitis

2010: A 12-Week Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Safety and Efficacy Study of XXX Nasal Aerosol 37 mcg and 74 mcg in Subjects 6-11 Years with Perennial Allergic Rhinitis

2009: A Randomized, Multicenter, Double-Blind, Placebo-Controlled, Parallel Group Study of the 12 Month Effect of Treatment with Once Daily XXX (XXX Nasal Spray XXX micrograms) on the Growth Velocity of Children, 3 to 9 Years of Age, with Perennial Allergic Rhinitis (PAR)

2007: A study evaluating the safety and efficacy of nasal spray in 6-11 year old patients with Seasonal Allergic Rhinitis

2006: Pediatric (6 to 14 yrs) study to evaluate the clinical effect of oral XXX versus placebo in persistent asthma which is also active during allergy seasons in pediatric patients with seasonal aeroallergen sensitivity

- 2005: Adult (18 yrs and up) study to evaluate the relationship and impact of clinical symptoms of allergic rhinitis, on key patient reported outcomes in addition to establishing a minimally important difference in overall symptoms of allergic rhinitis, with particular regard to nasal congestion and morning allergy symptoms
- 2005: Pediatric (6–11 yrs) study comparing the safety and efficacy of an investigational nasal spray drug in patients with seasonal allergic rhinitis.
- 2005: Pediatric (2–11 yrs) study evaluating the efficacy and safety of once daily, investigational nasal spray drug in patients with seasonal allergic rhinitis

## **Asthma**

- 2015: A phase IIa, randomized, double-blind, placebo controlled, parallel group study to assess the safety and efficacy of subcutaneously administered XXX as add-on therapy over 24 weeks in patients with severe persistent asthma
- 2015: A Multicentre, Randomized, Parallel Group, Phase 3 Safety Extension Study to Evaluate the Safety and Tolerability of XXX in Asthmatic Adults and Adolescents on Inhaled Corticosteroid Plus Long-acting $\beta$ 2 Agonist
- 2015: A 52-Week, Multicentre, Randomized, Double-Blind, Parallel Group, Placebo Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of XXX in Adults and Adolescents with Asthma Inadequately Controlled on Inhaled Corticosteroid Plus Long-Acting  $\beta$ 2-Agonist
- 2015: A Randomized, Double-Blind, Double Dummy, Parallel Group Study to Determine the Local Equivalence of Multiple Doses of XXX To XXX Administered via Oral Inhalation in Adult Asthma Patients.
- 2014: A Three-Week, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Chronic-Dose Safety and Efficacy Study of XXX relative to Placebo in Pediatric Asthmatics
- 2014: A 12-Week, Double-Blind, Placebo-Controlled, Efficacy and Safety Study of XXX Compared with XXX in Adolescent and Adult Patients with Persistent Asthma Symptomatic Despite Low-dose Inhaled Corticosteroid Therapy.
- 2014: A Randomized, Double-Blind, Double-Dummy, Placebo-Controlled, Parallel-Group, 12-Week Clinical Study to Assess the Efficacy and Safety of 320 or 640 mcg/Day of XXX XXX 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

- 2014: A Randomized, Double Blind, Double Dummy, Placebo Controlled, Parallel Group, 12 Week Clinical Study to Assess the Efficacy and Safety of 80 or 160 mcg/Day of XXX XXX Delivered via Breath Actuated Inhaler (BAI) or Metered Dose Inhaler (MDI) in Pediatric Patients 5 Through 11 Years of Age with Persistent Asthma
- 2014: A Multicenter, Randomized, Double-blind, Parallel Group, Placebo-controlled, Phase 3 Efficacy and Safety Study of XXX (MEDI-563) to Reduce Oral Corticosteroid Use in Patients with Uncontrolled Asthma on High Dose Inhaled Corticosteroid plus Long-acting  $\beta$ 2 Agonist and Chronic Oral Corticosteroid Therapy
- 2013: A Multicenter, Randomized, Double-Blind, Parallel Group, Placebo-Controlled, Phase 3 Efficacy and Safety Study of XXX Added to Medium-Dose Inhaled Corticosteroid Plus Long-Acting B2 Agonist in Patients with Uncontrolled Asthma
- 2013: A Multicenter, Randomized, Double-Blind, Parallel Group, Placebo-Controlled, Phase III Efficacy and Safety Study of XXX Added to High-Dose Inhaled Corticosteroid Plus Long-Acting B2 Agonist in Patients with Uncontrolled Asthma
- 2013: 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<sup>®</sup>, a Fixed Combination of Inhaled Corticosteroid (ICS) (XXX) and a Long Acting B2 Agonist (LABA) (XXX) as Compared to Treatment with ICS (XXX) Alone in Adult and Adolescent ( $\geq$ 12 Years of Age) Patients with Asthma
- 2013: A Phase 3, Randomized, Double-blind, Placebo-Controlled Study to Assess the Efficacy and Safety of XXX in Patients Using Corticosteroids and a Second Controller Medication
- 2013: A Phase III, Randomized, Double-blind, Placebo-Controlled Study to Assess the Efficacy, Safety, and Tolerability of XXX in Adolescent Patients with Uncontrolled Asthma who are on Inhaled Corticosteroids and a Second Controller Medication
- 2013: A Phase III, Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy, Safety, and Tolerability of xxx in Adolescent Patients with Uncontrolled Asthma who are on Inhaled Corticosteroids and a Second Controller Medication

- 2012: A Safety and Efficacy Study of XXX Combination versus XXX in the Treatment of Adolescent and Adult Subjects with Asthma Phase IV
- 2012: A Phase IIb, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Dosing Regimens of XXX in Adults with Allergic Asthma who are Inadequately Controlled on Inhaled Corticosteroids and a Second Controller
- 2012: A Phase 2 Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter Study to Evaluate the Efficacy and Safety of XXX in Adults with Persistent Asthma
- 2011: A 12-Week Dose-ranging Study to Evaluate the Efficacy and Safety of XXX Administered Twice Daily compared with Placebo in Adolescent and Adult Subjects with Persistent Asthma Uncontrolled on Non-Steroidal Therapy
- 2011: A 12-Week Dose-ranging Study to Evaluate the Efficacy of XXX Administered Twice Daily compared with Placebo in Adolescent and Adult Subjects with Severe Persistent Asthma Uncontrolled on High Dose Inhaled Corticosteroid Therapy
- 2011: A Phase III, Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of XXX in Patients with Uncontrolled Asthma who are on Inhaled Corticosteroids and a Second controller Medication
- 2011: 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 XXX, a Fixed Combination of Inhaled Corticosteroid (ICS) (XXX) and a Long Acting  $\beta$ 2 -Agonist (LABA) (XXX) as Compared to Treatment with ICS (XXX) Alone in Adult and Adolescent ( $\geq 12$  years of age) Patients with Asthma
- 2011: A Safety and Benefit Study of Inhaled XXX/XXX Combination Versus Inhaled Fluticasone Propionate in the Treatment of Adolescents and Adults with Asthma
- 2011: A 6-Month Safety and Benefit Study of Inhaled XXX/XXX Combination Versus Inhaled xxx xxx in the Treatment of 6,200 Pediatric Subjects 4-11 Years Old with Persistent Asthma
- 2010: A Phase 2, Double-Blind, Randomized, Parallel-Group, Placebo-Controlled, Multicenter Study, Comparing XXX 160  $\mu$ g bid with placebo: a 6-week efficacy and

safety study in children aged 6 to <12 years with asthma

- 2010: A Phase 2b, Randomized, Double-Blind Study to Evaluate the Efficacy of XXX in Adults with Uncontrolled, Severe Asthma
- 2010: A Safety, Efficacy, and Tolerability Study of Daily Dosing with XXX MDI and Placebo in Subjects Aged Birth to <48 Months with Asthma
- 2009: An Efficacy and Safety Study of XXX (XXX) in the Treatment of Poorly Controlled Asthma in Subjects with Eosinophilic Airway Inflammation
- 2009: A Phase 2b, Randomized Study to Evaluate the Efficacy and Safety of Subcutaneous XXX in Adults with Uncontrolled Asthma
- 2009: A Prospective, Randomized, Double-Blind Study of the Efficacy of XXX in Atopic Asthmatics With Good Lung Capacity Who Remain Difficult to Treat
- 2008: A 12-week, randomized, double-blind, double dummy, multi-center, phase IV study comparing the efficacy and safety of XXX XXX/XX µg x 2 actuations twice daily versus XXX XXX µg x 2 inhalations twice daily, in adult and adolescent (≥12 years) African American subjects with asthma
- 2008: A 2-Year Prospective, Multi-center, Observational and Epidemiologic Outcomes Study of the Disease Course and Unmet Needs in Children with Symptomatic Moderate to Severe Allergic Asthma
- 2007: A study of the therapeutic equivalency of inhalers in corticosteroid-dependent subjects with moderate asthma
- 2007: A phase III clinical trial comparing the safety and efficacy of a combination inhaler to using the components separately or placebo in adolescent and adult patients with mild to moderate asthma
- 2007: An open label, single arm study to assess the safety and immunogenicity of a study medication administered subcutaneously over a period of 6 months to male and female adolescents and adults with moderate to severe persistent allergic asthma
- 2007: A study evaluating the effects of an investigational study drug in patients with mild to moderate asthma

- 2007: A pediatric study to assess the systemic exposure to investigational study medication in patients with Infant Wheezing
- 2006: Pediatric (6 to 14 yrs of age) A study to evaluate the efficacy and safety of chewable XXX when initiated at the start of the school year in pediatric patients with asthma
- 2005: Pediatric (6 to 14 yrs) study comparing the clinical effects of intravenous XXX with placebo in pediatric patients (ages 6 to 14 years) with acute asthma
- 2005: Pediatric (6-<12 years) study evaluating the efficacy, safety, pharmacokinetics and pharmacodynamics of XXX (XXX) in children with moderate-severe, persistent, inadequately controlled allergic asthma
- 2005: Adult (15 and up) study comparing the clinical effects of an investigational intravenous drug in patients with acute asthma.
- 2005: Phase three, pediatric (6–14 yrs) study comparing the clinical effects of an investigational intravenous drug in patients with acute asthma
- 2005: Pediatric (6–11) study evaluating the efficacy, safety, pharmacokinetics and pharmacodynamics of an investigational drug in children with moderate-severe, persistent, inadequately controlled allergic asthma
- 2004: Patients (age 4–11 years) to compare XXX vs. XXX in patients with activity induced bronchospasm
- 2004: Patients (age 12 years) evaluating the clinical effectiveness and long-term safety of XXX (XXX) in patients with moderate to severe asthma
- 2003: Patients (age 15–65 years) to evaluate the efficacy and safety of XXX vs. Placebo in patients with seasonal allergic rhinitis and concomitant asthma
- 2003: Patients (age 18–75 years) to test the safety and effectiveness of a new medication which is expected to reduce or diminish the inflammation of the airway in asthma patients

- 2003: Male patients (age 18–50) to assess the safety and efficacy of a non steroidal oral medication for mild to moderate asthma
- 2002: Patients (age 6–15) to assess the efficacy of a fixed combination metered dose inhaler product containing XXX and XXX
- 2002: Patients (age 6–11 years) to assess the efficacy of a fixed combination metered-dose inhaler product containing XXX and XXX
- 2002: Pediatrics (age 4-11) asthma study examined the efficacy and safety of an inhaled environmental safe propellant to be combined with XXX
- 2002: Pediatrics (age 4-11) asthma study examined the efficacy and safety of XXX to XXX propionate discus
- 2001: Pediatric asthma study compared a treatment period of XXX to a treatment period of XXX on the average rate of linear growth
- 2001: Pediatric asthma study examined the efficacy and safety of an inhaled corticosteroid (XXX) in the form of a nebulized treatment
- 2001: Pediatric patients enrolled into this study in order to test the use of XX medication
- 2001: Pediatric and Adolescent patients enrolled into this study in order to evaluate the natural history and epidemiology of asthma in patients with severe asthma
- 2000: Study compared the use of XXX and XXX in pediatric patients with mild to moderate asthma
- 1999: Study on asthmatic adolescents and adults in the long term use of XXX
- 1999: Study on asthmatic children ages 6–47 months using XXX
- 1999: Treatment of asthmatic adolescents with XXX

### **Attention Deficit/Hyperactive Disorder (ADHD)**

- 2012: A Phase 3, Double-Blind, Randomized, Multi-center, Placebo-Controlled, Dose-optimization Study Evaluating the Safety, Efficacy, and Tolerability of Once-daily Dosing with Extended-Release XXX in Adolescents Aged 13-17 years Diagnosed With Attention Deficit / Hyperactivity Disorder (ADHD)



- 2001: Child/Adolescent Attention Deficit Hyperactivity Disorder (ADHD) patients who also suffer from Allergic Rhinitis enrolled in order to examine the correlation between ADHD and Allergic Rhinitis
- 2001: Adolescent Attention Deficit Hyperactivity Disorder patients enrolled in order to test the effectiveness of an extended-release psycho-stimulant medication

## **Atopic Dermatitis**

- 2015: An Open-Label, Drug-Drug Interaction Study to Examine the Effects of XXX on the Pharmacokinetics of Selected Cytochrome P450 Substrates in Adult Patients with Moderate to Severe Atopic Dermatitis
- 2009: A Multi-Center, Double-Blind, Randomized, Vehicle-Controlled, Parallel-Group Study Comparing XXX Ointment 0.1% To XXX (XXX) Ointment 0.1% And Both Active Treatments To a Vehicle Control in the Treatment of Atopic Dermatitis
- 2004: Patients (age 3–35 mo) to evaluate the safety of a topical corticosteroid cream in children with atopic dermatitis
- 2004: Patients (age 3 mo–5 yrs 11 mo) to assess the potential of XXX cream and ointment in children with moderate to severe atopic dermatitis

## **Autism**

- 2013: A Phase IV, Multicenter, Open-Label Study to Evaluate the Efficacy of High-Dose XXX in children on the Autism Spectrum (Investigator Initiated)
- 2013: A Multicenter, Randomized, Double-Blind, 12 Week, Parallel-Group, Placebo-controlled Proof of Concept Study to Investigate the Efficacy and Safety of XXX in Individuals with Autism Spectrum Disorders
- 2012: A Double Blind, Placebo-Controlled, Randomized Withdrawal Study of the Safety and Efficacy of XXX in Pediatric Patients with Autism, Asperger's Disorder, or Pervasive Developmental Disorder Not Otherwise Specified (PDD-NOS) Previously Treated with XXX
- 2012: An Open-Label Extension of the Safety and Tolerability of XXX in Pediatric Patients with Autism, Asperger's Disorder or Pervasive Developmental Disorder Not Otherwise Specified (PDD-NOS)

2012: An Open-Label study of the Safety and Tolerability of XXX in Pediatric Patients with Asperger’s Disorder or Pervasive Developmental Disorder Not Otherwise Specified (PDD-NOS)

## **Cancer**

2015: A Multicenter, Double-blind, Placebo-controlled, Adaptive Phase 3 Trial of XXX Polyvalent Melanoma Vaccine in Post-resection Melanoma Patients with a High Risk of Recurrence

2010: A Randomized, Controlled Phase III Study Investigating XXX Muropeptide Cancer Vaccine in Patients Receiving XXX as First-line Therapy for Advanced/Metastatic Renal Cell Carcinoma

1998: United States Department of Defense grant—The role of Cdk6 in integration of cell signaling and cell cycle networks in human breast cancer cells

1998: NIH R21—“Cdk6: mediator of cell signaling, growth and death.”

1997: Susan G. Komen Breast Cancer Foundation grant entitled “The role of D-type cyclins in human cancer”

## **Cardiovascular**

2012: A Multicenter, Randomized, Double-blind, Placebo-Controlled, 8-Week Study to Evaluate the Safety and Efficacy of XXX and XXX Given as a Fixed- Dose Combination in Patients with Stage 1 or 2 Essential Hypertension

## **Chronic Obstructive Pulmonary Disease**

2015: A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter, Efficacy and Safety Trial of 12 Weeks of Treatment with XXX in Patients with COPD

2015: A Randomized, Double-Blind, Parallel Group 24 Week Placebo-Controlled Efficacy and Safety Study with a 28 Week Long Term Extension, of Nebulized XXX (FP) /XXX (FF) Combination Compared with FP and FF Monotherapy in Patients with COPD

2015: A Phase 3, 12-week, Randomized, Double-Blind Placebo-Controlled Parallel Group Study of XXX in Subjects with Chronic Obstructive Pulmonary Disease

2013: Double-Blind, Randomized, Placebo-Controlled, Parallel-Group, Phase IV Study to Evaluate the Effect of XXX on Long-Term Cardiovascular Safety and COPD Exacerbations in Patients with Moderate to Severe COPD

- 2009: A Randomized, Double-Blind, Controlled, Parallel-Group, 12-Week Treatment Study to Compare the Efficacy and Safety of the Combination of XXX XX µg Once Daily with Open Label XXX XXµg Once Daily Versus Open Label XXX XXµg Once Daily in Patients with Moderate-to-Severe Chronic Obstructive Pulmonary Disease
- 2009: A 52-week Efficacy and Safety Study to Compare the Effect of Three Dosage Strengths of XXX/XXX Inhalation Powder with XXX on the Annual Rate of Exacerbations in Subjects with Chronic Obstructive Pulmonary Disease (COPD)
- 2007: A phase IIIb exacerbation clinical trial to compare the effect of two inhaled medications given twice-daily in COPD patients
- 2006: Adult (18 yrs and up) study to assess the efficacy and safety study of an investigational asthma inhaler compared to XXX & placebo in COPD patients

### **Chronic Idiopathic Demyelinating Polyneuropathy**

- 2013: Randomized, Multicenter, Double-Blind, Placebo-Controlled, Parallel-Group Phase III Study to Investigate the Efficacy, Safety, and Tolerability of 2 Different Doses of XXX (Subcutaneous Immunoglobulin) for the Treatment of Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

### **Chronic Idiopathic Urticaria**

- 2015: A Phase IV, Multicenter, Randomized, Double-Blind Placebo-Controlled Study to Evaluate the Efficacy and Safety of xxx Through 48 Weeks in Patients with Chronic Idiopathic Urticaria

### **Depression**

- 2012: A Double Blind, Randomized, Placebo-Controlled, Parallel Group Dose Frequency Study of XXX in subjects with Treatment-Resistant Depression. (Phase 1)

### **Dermatology**

- 2004: Patients (age 18 years and above) to compare the efficacy of continuous vs intermittent XXX therapy in subjects with psoriasis
- 2004: Patients (age 13–17 years) to compare the efficacy and safety of topical application treatment with oral XXX in patients with secondarily infected skin lesion

## **Device**

- 2013: Phase 1B, Multicenter, Randomized, Open-Label, Parallel-Group Study to Characterize the Pharmacokinetics of a Single Dose of XXX 125 mg Administered Subcutaneously Using the XXX or the XXX
- 2013: A Study of the Clinical Accuracy of the Braun XXX Thermometer to Show Substantial Equivalency of the XXX XXX Thermometer with XXX When Compared to XXX XXX Thermometer
- 2009: A Multicenter Study Conducted to Support CLIA Waiver for the XXX Influenza A&B Test Using Nasal Swabs

## **Diabetes**

- 2013: A Randomized, Placebo-Controlled Dose-Escalation Study to Assess the Safety and Tolerability of a Single Intravenous Infusion of XXX in Patients with Type 2 Diabetes Sub-optimally Controlled on XXX
- 2012: A Randomized, Placebo-Controlled Dose-Escalation Study to Assess the Safety and Tolerability of a Single Intravenous Infusion of XXX in Patients with Type 2 Diabetes
- 2009: A Randomized Double-Blind, Placebo-Controlled Clinical Trial to Assess the Effects of XXX (XXX) on Cardiovascular Outcomes in Subjects with Inadequately Controlled Type 2 Diabetes and Established Cardiovascular Disease
- 2007: A clinical trial of evaluating a medication for C-reactive protein reduction in early treatment of Type 2 Diabetes

## **Ear/Nose/Throat**

- 2007: A phase II clinical trial to evaluate the safety of an inhaled solution in post-surgical subjects with Chronic Sinusitis
- 2006: Adult (18 yrs and up) A Qualitative Study of the Cardinal Symptoms in Patients with Chronic Sinusitis
- 2006: Pediatric (6-18 years) study of a nasal spray used for the treatment of nasal polyps
- 2004: Pediatric study comparing the safety of two investigational drugs in the treatment of children with tinea capitis

- 2003: Patients (age 6 months–5 years) to evaluate the clinical response at the end of therapy in infants and children who have recurrent and/ or persistent acute otitis media
- 2002: Subjects 1 year and older tested the effectiveness and safety of an antibiotics ophthalmic solution for treatment of pink eye
- 2002: Patient age 6 years and under, evaluated the effectiveness of an antibiotic otic solution in the treatment of mucus and pus like ear infections in children with ear tubes

## **Gastroenterology**

- 2012: A Phase 2 Open-Label, Multicenter, 4-Week Study to Assess the Safety and Effectiveness of Daily Oral Administration of XXX Delayed-Release Capsules for Relief of Heartburn, in Adolescent Subjects Aged 12 to 17 Years With Symptomatic Non-Erosive Gastroesophageal Reflux Disease
- 2012: A Phase 2 Multicenter, 36-Week Study to Assess the Safety and Effectiveness of Daily Oral Administration of XXX Delayed-Release Capsules for Healing of Erosive Esophagitis and Maintenance of Healed Erosive Esophagitis and Relief of Heartburn, in Adolescent Subjects Aged 12 to 17 Years
- 2009: An Efficacy and Safety Study of XXX (XXX) in the Treatment of Eosinophilic Esophagitis in Subjects Aged 5 to 18 Years
- 2009: An Open-Label Safety and Efficacy Study of XXX (XXX) for the Treatment of Pediatric Subjects with Eosinophilic Esophagitis Who Completed Study XXX
- 2009: A Multicenter, Double-blind, Randomized, Placebo-controlled, Parallel Group, Withdrawal Study to Evaluate the Safety and Efficacy of Delayed-Release XXX in 1 to 11 Month Old Pediatric Subjects with Symptomatic/Erosive Gastroesophageal Reflux Disease
- 2009: A Multi-Center, Double-Blind, Parallel-Group Study to Evaluate Short-Term Safety and Efficacy and Long-term Maintenance of Two Dose Levels of XXX Delayed-Release Pediatric Bead Formulation in 1- to 11-Year-Old Pediatric Subjects with Endoscopically Proven GERD
- 2009: A Pharmacokinetic, Pharmacodynamic and Safety Study of Single and Multiple Doses of XXX in Pediatric Subjects with GERD 1 to 11 Months Old, Inclusive

2003: Female patients (age 18–65) to assess the safety and efficacy in the treatment of female subjects with severe diarrhea irritable bowel syndrome

## **Hereditary Angioedema**

2015: A Multicenter, Randomized, Double-Blind, Placebo-Controlled Efficacy and Safety Study to Evaluate XXX For Long-Term Prophylaxis Against Acute Attacks of Hereditary Angioedema (HAE)

2015: A Phase 3, Randomized, Double-blind, Placebo-controlled, Two-period, Three-sequence, Partial Crossover Study to Evaluate the Efficacy and Safety of Subcutaneous Administration of xxx U of xxx for Injection for the Prevention of Angioedema Attacks in Adolescents and Adults with Hereditary Angioedema

## **Infectious Disease**

2015: A Randomized Double-Blind Phase 2 Study Comparing the Efficacy, Safety, and Tolerability of Combination Antivirals (XXX) versus XXX for the Treatment of Influenza in Adults at Risk for Complications

2014: A Multi-Center, Double-Blind, Randomized Vehicle-Controlled, Parallel-Group Study to Compare XXX XXX, X% with XXX (XXX) Cream X% and both Active Treatments to a Vehicle Control In treatment of Recurrent Herpes Simplex Labialis

2013: A Phase III, Stratified, Randomized, Double-Blind, Multicenter, Non-Inferiority Study to Evaluate Safety and Immunogenicity of Cell-Based XXX Influenza Virus Vaccine and XXX Influenza Virus Vaccines in Subjects  $\geq$ 4 Years to  $<$ 18 Years

2013: Influenza A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study Evaluating the Safety and Efficacy of XXX in Adult Subjects with Uncomplicated Influenza

2013: A Phase III Randomized, Double-Blind, Placebo-Controlled Trial to Evaluate the Efficacy and Safety of XXX and XXX Plus XXX in the Treatment of Acute Uncomplicated Influenza

2011: A Phase III, Double-Blind, Randomized Study to Evaluate the Immunogenicity and Safety of XXX Influenza Vaccine Candidate, XXX (XXX), Compared to XXX Influenza Vaccine XXX Administered Intramuscularly to Children 3 to 17 Years of Age; and to Describe the Safety and Immunogenicity of XXX in Children 6-35 Months of Age

- 2009: A Pivotal Randomized, Single-Blind, Dose-Finding Study to Evaluate Immunogenicity, Safety and Tolerability of Different Formulations of an XXX and XXX, Inactivated Novel Swine Origin A/H1N1 Monovalent Subunit Influenza Virus Vaccine in Healthy Pediatric Subjects 3 to < 9 Years of Age
- 2008: A Phase II, Multicenter, Randomized, Placebo-Controlled Study To Evaluate The Efficacy and Safety Of Intramuscular XXX 600 mg In Subjects With Uncomplicated Acute Influenza
- 2007: An observational follow-up study of pediatric patients who participated in a previous Respiratory Syncytial Virus (RSV) – Induced Bronchiolitis study
- 2006: Pediatric (6months to 13 yrs of age) comparative study to evaluate the efficacy and safety of an investigative oral suspension antibiotic versus XXX oral solution, in children with Streptococcus pyogenes tonsillitis/ pharyngitis
- 2006: Adolescent/Adult (13 yrs and up) comparative study to evaluate the efficacy and safety of an investigative antibiotic, versus XXX, in patients with Streptococcus pyogenes tonsillitis/pharyngitis
- 2006: Adult (18 yrs and up) study comparing clinical outcomes of 2 antibiotics in patients with Community Acquired Lower Respiratory Tract Infections
- 2004: Phase III pediatric (3–24 mos) study comparing the effects of 2 doses of an investigational drug and placebo in the treatment of respiratory symptoms associated with respiratory syncytial virus- induced bronchiolitis
- 2004: Phase III adolescent/adult study, evaluating the safety and efficacy of an investigational drug versus XXX in the treatment of patients with tonsillitis and/or pharyngitis secondary to streptococcus pyogenes.
- 2004: Patients (age 12 years and older) to assess the efficacy and safety of XXX administered either fixed or adjustable vs a fixed regimen of XXX
- 2002: Toddlers (age 1–3) asthma study examining the efficacy and safety of an inhaled environmental safe propellant to be combined with XXX
- 2002: Pediatrics (age 6-18 months) investigational influenza vaccine trial as a nasal spray administration product

- 2001: Adolescent (age 7-12) study evaluated the clinical efficacy of an investigational medication in the treatment of viral respiratory infection
- 2001: Pediatric (age 1-6) study evaluated the clinical efficacy of an investigational medication in the treatment of viral respiratory infections
- 2000: Pediatric and Adolescent observational study of XXX in patients with various infections
- 1999: Influenza study in healthy adolescent and adult patients
- 1998: Influenza study—healthy pediatric patients
- 1998: Influenza study—pediatric patients with asthma

## **Lupus Nephritis**

- 2012: A First-In-Human, Ascending-Dose Study To Assess the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of XXX After Single and Multiple Dose Administration in Subjects with Stable Proliferative Lupus Nephritis and Persistent Proteinuria (Phase 1)

## **Migraine**

- 2015: A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study of XXX in Patients with Episodic Migraine
- 2011: A Multicenter, Double-blind, Randomized, Placebo-controlled, 4-Armed Parallel Group Study to Evaluate the Efficacy of XXX X-, X- and X-mg Nasal Spray in the Treatment of Acute Migraine Headache in Adolescents
- 2010: A Worldwide, Randomized, Double Blind, Placebo-Controlled, Parallel Group Clinical Trial to Evaluate the Safety and Efficacy of XXX for the Acute Treatment of Migraine in Children and Adolescents
- 2010: A Worldwide, Open Label, Clinical Trial to Examine the Long Term Safety and Tolerability of XXX in Pediatric Migraineurs for the Treatment of Migraine With or Without Aura
- 2005: Adolescent (12–17) long-term study to determine the safety of an investigational study drug in the treatment of migraines



- 2005: Adolescent (12–17) study comparing the safety and efficacy of an investigational drug in migraine prophylaxis
- 2003: Adolescents (age 12–18) to assess the safety and effectiveness of an already approved medication for the use in adolescents who suffer from migraines

### **Multifocal Motor Neuropathy**

- 2009: A Randomized, Double-Blind, Placebo Controlled, Cross-over Study of the Effectiveness of Immune Globulin Intravenous (Human), XX% (XXX%) for the Treatment of Multifocal Motor Neuropathy

### **Multiple Sclerosis**

- 2013: A Double-Blind, Placebo-Controlled, Single Ascending Intravenous Infusion Study of XXX in Patients with Multiple Sclerosis (Phase 1)
- 2013: A multinational, multicenter, randomized, double-blind, parallel-group, placebo controlled study followed by an active treatment period, to evaluate the efficacy, safety and tolerability of two doses of oral administration of xxx (x mg/day or x mg/day) in subjects with relapsing remitting multiple sclerosis (RRMS).
- 2012: A Phase 1/2 Randomized, Dose-finding Study of XXX in Subjects with Relapsing-Remitting Multiple Sclerosis
- 2011: A Multicenter, Single-Arm, Open-Label, Study to Evaluate the Immunogenicity and Pharmacokinetics of XXX High Yield Process (DAC HYP), Prefilled Syringe Administered by Subcutaneous Injection in Subjects With Relapsing-Remitting Multiple Sclerosis
- 2010: A Randomized, Blinded, Placebo-Controlled, Serial Cohort, Multiple Ascending Dose Study of the Safety, Tolerability, and Pharmacokinetics of XXX in subjects with Multiple Sclerosis (Phase 1).
- 2010: A multinational, multicenter, randomized, parallel-group study performed in subjects with Relapsing-Remitting Multiple Sclerosis (RRMS) to assess the efficacy, safety and tolerability of XXX injection 40 mg/ml administered three times a week compared to placebo in a double-blind design
- 2007: A multinational, multicenter, randomized, double-blind, parallel-group, placebo-controlled study, to evaluate the safety, tolerability and efficacy of daily oral

administration of XXX X mg in subjects with relapsing remitting multiple sclerosis (RRMS)

## Primary Immunodeficiency Disorders

- 2015: An Investigator Driven Observational Study to Determine the Benefit of XXX 5% for Treatment of Patients Diagnosed with Primary Immunodeficiency Disorders (PID) on IntraVenous ImmunoGlobulin (IVIG) Therapy that Experience Adverse Events (AEs) on Any 10% IVIG Preparation
- 2015: A Two Cohort, Open-Label, Prospective, Multicenter Study of the Safety, Tolerability, efficacy and Pharmacokinetics of XXX 10% in Subjects with Primary Immunodeficiency Diseases
- 2014: Clinical study to evaluate the efficacy, pharmacokinetics, and Safety of Immunglobulin intravenous (human) 10% (xxx) in patients with primary immunodeficiency diseases. Non-interventional 2 armed study to evaluate the safety of xxx immune globulin intravenous (human) 5% Liquid preparation, with a special emphasis on monitoring, analysis and reporting of thromboembolic events (TEEs)
- 2014: A Phase III, Multicenter, Open-label, Randomized, Two-Period, Crossover Bioequivalence Study to Evaluate the Pharmacokinetics, Safety, and Tolerability of XXX and XXX in Primary Immunodeficiency Diseases.
- 2013: Non-Interventional 2 Armed Study to Evaluate the Safety of XXX with a Special Emphasis on Monitoring, Analysis and Reporting of Thromboembolic Events (TEEs)
- 2013: Clinical Phase III Study to Evaluate the Pharmacokinetics, Efficacy, Tolerability and Safety of Subcutaneous Human Immunoglobulin (XXX 16.5%) in Patients with Primary Immunodeficiency Diseases
- 2013: An Open Label, Multicenter Study to Evaluate the Pharmacokinetics, Efficacy and Safety of XXX (IVIG) in Subjects with Primary Immunodeficiency (PID)
- 2013: A Clinical Study of Immune Globulin Subcutaneous (Human), XX% Solution (IGSC, XX%) for the Evaluation of the Efficacy, Safety, Tolerability, and Pharmacokinetics, in Subjects with PID

- 2012: A Phase IV, Multicenter, Open-Label Study to Evaluate the Efficacy, Safety and Pharmacokinetics of XXX in Primary Immunodeficiency Diseases in Children and Adolescents
- 2012: An Open-label, Single-Sequence, Crossover Study to Evaluate the Steady-State Trough IgG Concentration, Safety and Tolerability of Subcutaneous XXX in Pediatric Subjects with Primary Immunodeficiency
- 2011: Tolerability, Safety and Administration Mode Evaluation of XXX Facilitated Subcutaneous Treatment with Immune Globulin Infusion (Human), 10% in Subjects with Primary Immunodeficiency Diseases – A Study in North America
- 2011: A Phase IV, Multicenter, Open-Label Study to Evaluate the Efficacy, Safety and Pharmacokinetics of XXX in Primary Immunodeficiency Diseases (PID) in Children and Adolescents
- 2010: Long-Term Tolerability and Safety of Immune Globulin Subcutaneous (IGSC) Solution Administered Subcutaneously Following Administration of XXX (XXX) in Subjects with Primary Immunodeficiency Diseases
- 2009: Efficacy, tolerability and pharmacokinetic comparison of immune globulin intravenous (human), XXX% (XXX) administered intravenously or subcutaneously following administration of (XXX) in subjects with primary immunodeficiency diseases
- 2009: Clinical Study to Evaluate The Efficacy, Pharmacokinetics and Safety of Immunoglobulin Intravenous (Human) XX% (XXX) in Patients With Primary Immunodeficiency Diseases
- 2008: Tolerability and pharmacokinetic comparison of immune globulin intravenous (human), XX% (XXX%) administered intravenously or subcutaneously in subjects with primary immunodeficiency diseases
- 2008: Open Label, Phase III Safety, Efficacy, and Pharmacokinetic Study of XXX-IGIV XX% [Immune Globulin Intravenous (Human)] in Subjects with Primary Immune Deficiency Disorders (PIDD)
- 2007: Determination of the dose of investigational medication required enabling up to XXX mg/kg of IGIV, XX% to be administered subcutaneously in a single infusion site in patients with Primary Immunodeficiency Disease

- 2007 A phase III study of the efficacy, tolerability, safety, and pharmacokinetics of immune globulin subcutaneous in subjects with Primary Immunodeficiency (PID)
- 2006: A clinical study of the Pharmacokinetics, efficacy and safety of Immune Globulin Intravenous (Human) in patients (3-70 yrs) with P.I.D.
- 2006: An extended clinical research study to assess the safety and efficacy of immunoglobulin intravenous 10% in patients (3-70 yrs) with P.I.D.
- 2004: A clinical research study to assess the safety and efficacy of immunoglobulin intravenous 10% in patients (3–70 yrs) with P.I.D.
- 2004: A clinical research study to assess the safety and efficacy of immunoglobulin intravenous 12% in patients (3–70 yrs) with P.I.D.
- 2002: A study to assess the safety and efficacy of Immune Globulin Intravenous 10% in subjects >24 months of age with P.I.D.

## **Psychiatric Disorders**

- 2012: An Open-Label, Multicenter, Single and Multiple Ascending Dose Study to Evaluate Pharmacokinetics, Safety, and Tolerability of XXX in Subjects from 6 to 17 years old with Schizophrenia Spectrum, Bipolar Spectrum, Autistic Spectrum Disorder, or Other Psychiatric Disorders. (Phase 1).

## **Rheumatoid Arthritis**

- 2014: A Double-Blind, Randomized, Parallel-Group, Active-Control Study to Compare the Efficacy and Safety of XXX Versus XXX in Subjects With Rheumatoid Arthritis and Inadequate Response to Treatment With XXX

## **Urology**

- 2012: A Placebo and Active-Comparator Controlled Multiple-Dose Study to Evaluate the Pharmacokinetics and Pharmacodynamics of XXX in Patients with Overactive Bladder

## **Vaccine**

- 2014: A Phase I Randomized, Double-Blind, Placebo-Controlled, Dose-Escalation Study to Evaluate the Safety, Tolerability and Immunogenicity of the XXX Vaccine (XXX) in Healthy Adults
- 2011: Safety and Immunogenicity of XXX (Diphtheria and Tetanus Toxoids and Acellular

Pertussis Vaccine Adsorbed Combined with Inactivated Poliovirus Vaccine) Compared to XXX (Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed) + XXX (Poliovirus Vaccine Inactivated) as the 5th Dose in Children 4 to 6 Years of Age.

- 2009: A Phase 3b, Open-Label, Randomized, Parallel-Group, Multi-Center Study to Evaluate the Safety of XXX Vaccine when Administered with Routine Infant Vaccinations to Healthy Infants
- 2009: A Phase 1/2a, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety, Tolerability, Immunogenicity, and Viral Shedding of XXX, a Live Attenuated Intranasal Vaccine Against Respiratory Syncytial Virus in Healthy 1 to <24 Month-Old Children
- 2008: A Phase 3, Open-Label, Randomized, Multi-Center Study to Evaluate the Safety and Immunogenicity of XXX Vaccine When Administered Concomitantly with XXX Conjugate Vaccine to Healthy Toddlers
- 2008: A Multicenter Study Conducted during the 2008-2009 Respiratory Syncytial Virus Season to Evaluate XXX<sup>®</sup> RSV Test as a Qualitative Assay to aid in the Diagnosis of Respiratory Syncytial Virus Infection
- 2008: A Phase 3, Randomized, Observer-blind, Multi-Center Study to Compare the Safety and Immunogenicity of One Dose of XXX Conjugate Vaccine with One Dose of Licensed XXX Conjugate Vaccine (XXX) Administered to Healthy Children 2-10 Years of Age
- 2007: A phase III, randomized, active-control, double-blind trial evaluating the safety, tolerability and immunogenicity of a pediatric XXX vaccine in healthy infants given with routine pediatric immunizations in the United States
- 2006: Adolescent (11 to 18 yrs of age) A study to evaluate the safety and immunogenicity of an investigational vaccine co-administered intramuscularly with the XXX vaccine and/or XXX vaccine according to different dose schedule combinations as compared to the investigational vaccine, XXX or XXX alone in healthy female subjects aged 11- 18 years
- 2006: Pediatric (2months) study comparing safety, tolerability and immunologic noninferiority of an investigational vaccine, in conjunction with routine pediatric vaccinations in the United States

- 2005: Pediatric (4 to 6 yrs) study evaluating the safety and immunogenicity of XXX administered as a 5th dose in children previously immunized with XXX or XXX
- 2005: Pediatric (4–6 yrs) study to determine the safety and immunogenicity of an investigational combination vaccine, when administered as a 5th dose in this age group
- 2004: Patients (age 10–17 years) to evaluate the immunogenicity and safety of HSV vaccine in female subjects
- 2003: Patients (age 2 months) to study the safety of the rotavirus vaccine and the vaccine's ability to prevent the rotavirus disease
- 2003: Patients (age 2 weeks) to assess the safety and immunogenicity (the body's ability to develop immunity against a disease) of an investigational formulation of a XXX vaccine in healthy infants in their first 2 weeks of life
- 2003: Patients (age 15 months) evaluating the administration of XXX vaccine for the immunization of children against hepatitis A at 15 months of age
- 2001: Patients (age 12 months to 8 years) study evaluated rates of seroconversion following a XXX vaccine in infants/children treated with asthma therapy
- 2001: Healthy infants enrolled into an immunization study in order to test various combination vaccines
- 2001: Healthy Pediatric and Adolescent patients enrolled into this XXX vaccine study
- 2001: This study tested the efficacy and safety of a XXX vaccine for newborns