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SUMMARY

Presently a Professor at the University of California Irvine with a primary appointment in the Department of Environmental & Occupational Health in the program in Public Health with secondary appointments in the Department of Pharmaceutical Sciences in the UCI School of Pharmacy & Pharmaceutical Sciences as well as an appointment in the Department of Neurology, UCI School of Medicine. Outside of UCI I have a research appointment in the Research Service of the Veterans Administration Healthcare System at the Long Beach VA. Formerly an Associate Dean in the UC Irvine School of Medicine of Innovation and Clinical Trials as well as an adjunct Professor in Neurology and a Director in the UCI Center for Clinical Research. Prior to returning to academia in 2019 was a senior pharmaceutical executive with wide-ranging experience in Fortune 100, mid-size, and start-up companies. Has extensive international development experience as a member of European, Japanese and U.S. pharmaceutical companies. Management as well as consulting expertise includes both pre-clinical and clinical research and development in pharmaceuticals, biologicals, vaccines, and medical devices. Initiated twenty plus clinical development programs in U.S. and Europe in neurology, psychiatry, obesity, gastroenterology, and infectious diseases. Oversaw all aspects of clinical development from Phases I - IV with hands on experience managing over three dozen studies with in-patient and outpatient clinics, Contract Research Organizations (CROs), and multinational pharmaceutical companies. Patent holder and author of two-dozen published scientific articles; invited speaker on research and clinical development issues.

EDUCATION

Visiting Post-Doc Fellow, National Institutes of Mental Health, Bethesda, MD, 1984
Advanced Biomedical Diploma, Albert Einstein College of Medicine, 1982
Ph.D., Biopsychology in Department of Psychology, **Syracuse University**, 1979
Graduate Courses, SUNY Upstate Medical Center, 1974 - 1976
B. S., Biology & Psychology (double major), **Syracuse University**, 1974

U.S. PATENTS

4,774,967; October 4, 1988: Zanakis, M.F., Albala, B.J., Femano, P.A. "Method and apparatus for mammalian nerve regeneration"
5,197,490; March 30, 1997: Steiner, S.S., Albala, B.J., Feldstein, R. "Information processing system for counting coughs or evaluating other activities of a patient."

PROFESSIONAL EXPERIENCE

UCI School of Pharmacy & Pharmaceutical Sciences **July 01, 2023 - Present**
Professor (Adjunct)
Department of Pharmaceutical Sciences, Irvine, CA
Assisting with the newly created PharmD program in the School of Pharmacy & Pharmaceutical Sciences. Course instructor for a new elective course on **"Clinical Trial Design (PHMD-281)**." Available to teach and mentor students in the PharmD program on clinical research, both domestically and globally, for the research and development of new therapeutic pharmaceutical agents, including biologicals and small chemical entities.

Veterans Administration Healthcare System **May 2023 - Present**
Research Associate
Research Service
Tibor Rubin VA Medical Center, Long Beach, CA
Co-Investigator on a multi-center clinical research trial being conducted at the Long Beach, CA, Salt Lake City, UT and Miami, FL Veterans Administration Medical Centers. The study is a **"Microbiome Targeted Oral Butyrate Therapy in Gulf War Multi-Symptom Illness"** with Dr. S. Chatterjee of UCI serving as the overall PI.

University of California Irvine **Dec. 2023 – Present**
Professor (Adjunct)
Department of Environmental & Occupational Health
UCI Public Health, Irvine, CA
Primary appointment in the Department of Environmental & Occupational Health in the program of Public Health.

- Responsibilities include teaching graduate level course PH-293 "**Foundations of Clinical and Translational Science"** which is a 4-credit course in Public Health.
- Serves as a Co-Investigator on ServeOC which is a community based, longitudinal, family focused study in Latino and Vietnamese communities in Orange County, California where people are evaluated using the American Heart Association (AHA) Life Essential 8 (LE-8) algorithm. Participants are followed over several years with both in-clinic visits as well as remote monitoring (e.g., home-based B.P. and Heart Rate) and those families randomized to interventional support work with Community Health Workers (CHWs) to achieve agreed to LE-8 goals of normalizing BP.
- Serves as a Co-Investigator on the multi-center (US & Canada) long running Alzheimer's Disease Neuro Imaging (ADNI) 4 grant. Helped to design web-based, cognitive testing systems for both recruitment and longitudinal monitoring of up to 20,000 people with concerns or suspected Alzheimer's disease.

University of California Irvine, School of Medicine Dec. 2019 – Present
Adjunct Professor of Neurology,

- As an adjunct professor in the UCI SoM Department of Neurology I continued to focus my work on Alzheimer's disease (AD) and other related neurodegenerative cognitive disorders. I have been actively engaged in AD clinical research for most of the last 35 years having conducted or supervised clinical research studies with numerous investigational compounds targeting different stages of the condition.

University of California School of Medicine, Irvine, CA Dec. 2019 – Dec. 2022
Associate Dean, Innovation & Clinical Trials,
Director, UCI Center for Clinical Research,
University of California at Irvine, School of Medicine (SoM) is the leading academic medical center and only medical school based in Orange County California with a diverse population of over 3.2 million people.

- As the Associate Dean at the medical school for Innovation I interacted with both the medical faculty and the private sector to bring new ideas and procedures forward to commercialization. I shared my many years of experience in the commercial sector with a large group of excellent clinical scientists and physicians.
- As Associate Dean for Clinical Trials I brought my over 35 years of experience to UCI as a former clinical investigator, director of a contract research organization (CRO) and my many years of supervising large and diverse studies in the clinical research divisions of a number of U.S. and international pharmaceutical companies.
- As a Director in the UCI Center for Clinical Research (CCR) I helped oversee and advised on the selection, start-up, and conduct of investigator-initiated trials (IITs), consortium supported multi-center trials and industry sponsored clinical studies.
- Another role that I oversaw in the CCR was the design and setup of new clinical research space both at the UCI School of Medicine's Irvine campus as well as at the UCI Medical Center and hospital in Orange, CA. As a former director and owner of a Phase I inpatient unit I helped to establish a new self-contained early clinical trial unit within UCI where special phase I studies and early phase II clinical trials can be conducted.

Eisai Inc., Woodcliff Lake, NJ **2010 - 2019**
Executive Director & International Project Team Leader and Clinical Leader, Neuroscience Clinical Development, Neurology Business Group
Eisai is one of the leading Japanese pharmaceutical companies with its headquarters in Tokyo, Japan and with major clinical and research facilities in the U.S. and Europe. Eisai quickly became one of the leaders in the treatment of Alzheimer's disease (AD) with the global introduction of its novel acetyl cholinesterase inhibitor donepezil (Aricept®).

- Serves as an Executive Director in the Neuroscience Clinical Department of the Neurology Business Group which is responsible within Eisai for the R&D efforts of all CNS active compounds.
- Key area of focus is on the portfolio and research in the area of both symptomatic treatment and disease modification of AD and the related dementias.
- Appointed as the International Project Team Leader (IPTL) for one of the internally developed disease modifying strategies for the treatment of AD.
- As IPTL sets the strategy and oversees both pre-clinical and clinical development for the lead compound as well as the backup strategy.
- Responsible for opening an IND for a first in class disease modifying therapy for AD and developing the global development program.
- Also serves as the Clinical Leader for the AD program which includes design and implementation of all of the required global clinical studies.

Manages a large global Team of experts in the U.S., Japan and Europe with expertise in all of the disciplines of pharmaceutical R&D including but not limited to: DMPK, pharmacology, toxicology, pharmacovigilance, clinical operations, data management, regulatory, etc. Responsible for setting and overseeing budgets in the tens of millions as well as the corresponding timelines. Key contact with global experts in the area of AD.

SHIONOGI USA, INC., Florham Park, NJ **2002 - 2009**
Vice President Clinical Development & Head CNS Program
Shionogi is one of the oldest and largest pharmaceutical companies in Japan. It was an equal partner in a joint venture (JV) with GlaxoSmithKline, Inc. (GSK) that was committed to jointly developing novel compounds in the U.S. and European markets.

- As V.P. of Clinical Development and Head of the CNS Program set strategy and oversaw both pre-clinical and clinical development in all of the neurological areas, including: analgesia, ataxias, Alzheimer's/other dementias, Parkinson's disease, hemorrhagic and ischemic stroke, and a CNS active obesity compound.
- Responsibilities included interacting with regulatory authorities, creating clinical development plans, establishing and overseeing all CNS budgets.
- Responsible for opening an IND for obesity in the US and initiating eight different clinical trials in a little more than three years. The clinical trials included novel designs for multiple center proof of concept (PoC) study for weight loss and control as well as two Phase II/III trials with over 80 sites and two thousand patients.
- Strong hands-on clinical operational skills. Including directly leading both in-house and consulting clinical staff and selecting and negotiating with CROs including production and packaging of clinical supplies, central ECG and central lab services, clinical and medical monitoring, data entry and statistical analyses, report generation and QA audits. This extended to review and selection of clinical investigators.

CNS BIO SERVICES, NY / CA **1999 – Present**
President & Lead Consultant
A pharmaceutical and healthcare consulting company specializing in research and development of products for the central nervous system. Generates research and development plans, study designs and program implementations worldwide. Has provided consultative services for over a dozen multinational pharmaceutical / healthcare companies. Key strength in working with CROs and Phase I units – including selection, contract negotiation and oversight.

- Designed and implemented a small and affordable dozen patient study in three very prestigious academic medical centers with experts in the disease area and secured federal funding for the program. Interim analyses showed that the new chemical entity was efficacious with a reasonable safety profile and little in the way of drug interactions. This data helped the client enter an attractive licensing agreement with a large international pharmaceutical company that will bring the drug to market.
- Researched and designed a multinational pharmaceutical project in a controversial area that involved several different medical disciplines. Successfully assembled and guided a team of experts to provide a plan that was acceptable to all parties.
- Directed the clinical aspects of a management team that was transferring a licensed drug to a new corporate partner so that the transition was not disruptive to the clinical program or the established timelines.
- Negotiated and implemented "win – win" contracts that established accountable CRO performance that ensured quality work being produced on time.

MEDEVA, PLC, Westport, CT; Wayne, PA & Leatherhead, UK **1996-1999**
Medeva was a multinational pharmaceutical company with annual sales of $500 million and is now part of Celltech Group, plc.
Vice President, Worldwide - Clinical Operations,
Controlled a $12 million annual clinical budget supervising all operations of staff in the U.S. and Europe. Negotiated and oversaw all contracts with clinical subcontractors.

- Led a major project and explored possibilities of conducting studies in Central and Eastern Europe, forming a consortium of contractors. Traveled to the targeted countries to meet with local subcontractors, visited the hospitals and talked to research staff. These centers in Bulgaria, Czech Republic and Poland started the study on time and accounted for over 80% of the enrollment and at only a fraction of the cost of a comparable U.S. or Western European study.
- Consolidated regional clinical research groups into a single global operations department that worked to the same standards and used integrated Standard Operating Procedures (SOPs). Projects flowed seamlessly across the world stage with support from different parts of the company, resulting in integrated programs that were executed much more efficiently and met or exceeded ambitious timelines.

CTA BIO SERVICES, INC., Elmsford, NY and New York, NY **1991-1995**
President & CEO,
Phase I-IV clinical trial center conducting outpatient studies in two dedicated facilities and pharmacokinetic, sleep and specialty studies in a 33-bed inpatient unit. Specialized in psychiatric and neurological disorders. Managed physicians, psychologists, nurses, research coordinators and other clinical and research staff.

EMISPHERE TECHNOLOGIES, INC., Elmsford, NY 1989-1991
Vice President & Director Clinical Research & Head of CRO Business Unit
Public company (NASDAQ; formerly Clinical Technologies Associates) developing drug delivery systems. Headed the separate Contract Research Organization (CRO) business unit that specialized in conducting psychiatric and neurological trials.

AMERICAN BIOINTERFACE, CORPORATION, New York, NY 1986-1989
Vice President, Scientific Affairs
Company dedicated to implantable medical devices, which were designed to repair the damaged peripheral and central nervous systems. Wrote and received research grants from NIH. Designed and initiated both preclinical and clinical trials. Planned regulatory strategies and worked directly with the FDA, NIH and other governmental agencies.

AYERST LABORATORIES of American Home Products, NY, NY 1984-1986
Clinical Research Monitor
Designed clinical development plans, protocols and investigator brochures. Worked with Investigators, "Thought-leaders", and monitoring staff to implement large clinical trials. Emphasis was in CNS with responsibility for clinical trials in anxiety, dementias, depression and neuropathies.

NEW YORK STATE, DEPARMENT OF MENTAL HEALTH 1983-1984
Member of the Program Evaluation & Research Department
Collected and analyzed census and demographic data, diagnostic classification, pharmaceutical and therapeutic interventions, and patient outcomes, including length of stay and final patient placement.

UCI LEADERSHIP ACTIVITIES

- Conflict of Interest Official (SoM)
- CRAFT (SoM)
- Medical Innovation Working Group (SoM)
- COVID Biorepository Committee (SoM & UCI Health)
- Research Governance & IT Committee (UCI Health & SoM)
- UCI Health Vision (UCI Health & SoM)
- Collaboration for Data in Health & Wellness (UCI Collaboratory)
- Conflict of Interest Oversite Committee- voting member (UCI)
- CRAFT COVID Grant Review Committee (UCI)
- Innovation & Entrepreneurship Collaborators Network (UCI)
- ICTS Steering Committee (UCI)

PROFESSIONAL SERVICE ACTIVITIES & MEMBERSHIPS

Committees

- Co-Chair Clinical Endpoints Working Group (CEWG) of the Alzheimer's Disease Neuroimaging Initiative (ADNI) - Private Partner Scientific Board (PPSB)
- Co-Leader of Digital (Cognitive) Biomarkers for the ADNI4 Planning Committee
- Member Alzheimer's Association BACE Safety Task Force

Memberships

- American Academy of Neurology, 2002 - Present
- ISTAART, 2008 – Present
- American Public Health Association, (APHA), 2023 – Present
- American Schools & Programs in Public Health, (ASPPH), 2023 – Present
- American Heart Association (AHA), 2023 - Present

TEACHING & MENTORING EXPERIENCE

Institution	Course title	Level	Role	Credit Hours	Year(s) Taught
UCI – UCI School of Pharmacy & Pharmaceutical Sciences	Clinical Trial Design (PHMD-281)	Graduate	Instructor	2	2023
UCI – University California Irvine, Program in Public Health	Foundations of Clinical & Translational Science (PH-293)	Graduate	Instructor	4	2023
UCI University California Irvine, Program in Public Health, Irvine, Ca	Public Health MPH Practicum Site: Center for Clinical Research: Directed field practice with a focus on trial participant recruitment and under-representation among Hispanic and Chinese Communities	Graduate Students	MPH Practicum Site Director	4	2022
Beall Applied Innovations and UCI School of Medicine, Irvine, Ca	Medical Innovation	Faculty, Post - Doctoral / medical residents	Co-Course Director – 10-week certification		Fall 2021
NYU College of Global Public Health, NY, NY	Course Title: Bioethical Issues in Clinical Research Lecture title: Ethical Issues in Alzheimer's Disease Trial Design	Graduate	Course lecturer	3	2017
NYU College of Global Public Health, NY, NY	Course Title Lecture - Global Burden of Alzheimer's Disease	Honors Undergraduate	Course lecturer	3	2016
Eisai Pharma, Woodcliff Lake, NJ	High School Summer Research Program Student – Sam Johnson	Honors High School	Research Mentor	NA	2010-2012
Eisai Pharma, Woodcliff Lake, NJ	Clinical Forum faculty for professional development Topics: Clinical trial design; Assessment and capture of adverse events; Dementia and Alzheimer's Disease: Diagnosis, background and differences.	Professional Workshops	Lecturer	NA	2010-2019
Shionogi Pharma, Florham Park, NJ	Faculty lecturer as part of professional staff development workshops. Topics: Obesity and clinical trial interventions; Clinical Trial Design; Neuropeptide Y and Obesity.	Professional Workshops	Lecturer	NA	2002-2009
The Cooper Union, New York, NY	Bioengineering Honors Research	Undergraduate	Honors site Directors	1-3	1986-89
Hunter College, City University of New York, NY	Behavioral Pharmacology	Undergraduate	Course Director	3	1980-83
Syracuse University, Syracuse, NY	Introductory Psychology	Undergraduate	Course Director	3	1978-79
Syracuse Univ., Syracuse, NY	Drugs and Behavior	Undergraduate	Co-Course Director	3	1976-78

RESEARCH GRANTS

Sponsor, Mechanism	Grant #	Role	Duration	Title	Total Annual Costs (Directs and Indirects)
Veterans Administration		Co-I	01/01/2023-12/31/2027	Microbiome Targeted Oral Butyrate Therapy in Gulf War Multi-Symptom Illness	
NIH-NIA	2U19AG024904-16	Co-I	9/01/2023 18/31/2028	Alzheimer's Disease Neuroimaging Initiative (ADNI4)	$30,144,100
NIH NINDS		Co-I	2020-2025	Neuro-Next – NIH Network for Excellence in Neuroscience Clinical Trials	
NIH NIMHD P50	20215747-06	Co-I	9/24/2021-6/30/2022	Skills-based Educational strategies for Reduction of Vascular Events in Orange County (SERVE OC)	$ 740,940
NIH NIMHD P50	20215747-05	Co-I	9/24/2021-6/30/2022	UCLA-UCI Center for Eliminating Cardio-Metabolic Disparities in Multi-Ethnic Populations (UC END-DISPARITIES)	$ 131,856
FEMA	*Population-based Seroprevalence Surveillance Study of COVID-19 in Orange County.*	PI	05/20-05/21	This is a county wide study to detect the prevalence of antibodies through-out Orange County, CA.	$4,375,000
US CARES ACT	Santa Ana Cares	Co-I	09/20-02/21	Surveillance student to assess COVID-19 Prevalence in City of Santa Ana, CA	$1,738,601

PUBLICATIONS

Palfai, T. and **Albala, B. J.** Pentylenetetrazole-induced amnesia: a case for overt seizures. *Psychopharmacology* **48:** 19-23, 1976.

Palfai, T. and **Albala, B. J.** Time-dependent performance impairments produced by Metrazol: amnesia or non-specific drug-effect? *Behavioral Biology* **17:** 453-461, 1976.

Palfai, T., Walsh, T., **Albala, B. J.,** and Brown, O. M. Effects of l-dihydroxyphenylalanine (l-dopa) and d, l, 5-hydroxytryptophan (d,l, 5-HTP) on reserpine induced amnesia. *Psychopharmacology* **53:** 269-276, 1977.

Albala, B. J. and McDonald, R. D. Current use of antiparkinsonian agents with psychiatric inpatients. *Current Therapeutic Research* **25:** 695-701, 1979.

Moshé, S. L. and **Albala, B. J.** Kindling in developing rats: Persistence of seizures into adulthood. *Developmental Brain Research* **4:** 67-71, 1982.

Moshé, S. L., **Albala, B. J.,** Ackermann, R. F., and Engel, J. R. Increased seizure susceptibility of the immature brain. *Developmental Brain Research* **7:** 81-85, 1983.

Moshé, S. L. and **Albala, B. J.** Maturational changes in postictal refractoriness and seizure susceptibility in developing rats. *Annals of Neurology* **13:** 552-557, 1983.

Albala, B. J., Moshé, S. L., and Okada, R. Kainic acid induced seizures: A developmental study. *Developmental Brain Research* **13:** 139-148, 1984.

Holmes, G. L., **Albala, B. J.,** and Moshé, S. L. Effect of single brief seizure on subsequent seizure susceptibility in the immature rat. *Archives of Neurology* **41:** 853-855, 1984.

Moshé, S. L. and **Albala, B. J.** Nigral muscimol infusions facilitate the development of seizures in immature rats. *Developmental Brain Research* **13:** 305-308, 1984.

Okada, R., Moshé, S. L. and **Albala, B. J.** Infantile status epilepticus and future seizure susceptibility in the rat. *Developmental Brain Research* **15:** 177-183, 1984.

Moshé, S. L. and **Albala, B. J.** Perinatal hypoxia and subsequent development of seizures. *Physiology & Behavior* **35:** 819-823, 1985.

Moshé, S. L., Okada, R. and **Albala, B. J.** Ventromedial thalamic lesions and seizure susceptibility. *Brain Research* **337:** 368-372, 1985.

Okada, R., Moshé, S. L., Ono, K. and **Albala, B. J.** Unidirectional interaction between flurothyl seizures and amygdala kindling. *Brain Research* 344**:** 103-108, 1985.

Albala, B. J., Moshé, S. L., Cubells, J. F., Sharpless, N. S. and Makman, M. H. Unilateral peri-substantia nigra catecholaminergic lesion and amygdala kindling. *Brain Research* **370:** 388-392, 1986.

Moshé, S. L., Ackermann, R. F., **Albala, B. J.,** and Okada, R. The role of substantia nigra in seizures of developing animals. In KINDLING 3 J. A. Wada (ed), Raven Press, 1986.

Politis, M. J., Zanakis, M. F. and **Albala, B. J.** Facilitated regeneration in the rat peripheral nervous system using applied electric fields. *Journal of Trauma* **28:** 1375-1381, 1988.

Politis, M. J., Zanakis, M. F. and **Albala, B. J.** Mammalian optic nerve regeneration following the application of electric fields. *Journal of Trauma* **28:** 1548-1552, 1988.

Ackermann, R. F., Moshé, S. L., and Albala, B. J. Restriction of enhanced ^{14}C-2-deoxyglucose utilization to rhinencephalic structures in immature amygdala-kindled rats. *Experimental Neurology* **104:** 73-81, 1989.

Gillin, J.C., Rapaport, M., Erman, M.K., Winokur, A., **Albala, B.J.** A comparison of nefazodone and fluoxetine on mood and on objective, subjective, and clinician-rated measures of sleep in depressed patients: a double-blind, 8-week, clinical trial. *Journal of Clinical Psychiatry*, **58:** 185-192, 1997.

Rush, A.J., Armitage, R., Gillin, J.C., Yonkers, K.A., Winokur, Moldofsky, H., Vogel, G.W., Kaplita, S.B., Fleming, J.B., Montplaisir, J., Erman, M.K., **Albala, B.J.,** McQuade, R.D. Comparative effects of nefazodone and fluoxetine on sleep in outpatients with major depressive disorder. *Biological Psychiatry* **44:** 3-14, 1998.

Rogers, S.L., Farlow, M.R., Doody, R.S., Mohs, R., Friedhoff, L.T. & the Donepezil Study Group (**Bruce Albala**, etc.). A 24-week, double-blind, placebo-controlled trial of donepezil in patients with Alzheimer's disease. *Neurology* **50:** 136-145, 1998.

Zhang, R.L., Zhang, C., Zhang, L., Roberts, C., Lu, M., Kapke, A., Cui, Y., Ninomiya, M., Nagafuji, T., **Albala, B.,** Zhang, Z.G., and Chopp, M. Synergistic effect of an endothelin type A receptor antagonist, S-0139, with rtPA on the neuroprotection after embolic stroke. *Stroke* **39**: 2830-2836, 2008.

Lunnon, M.W., Wallace, S.M.L., Palmer, J.E., Francis-Lang, A., Laurijssens, B.E., Mistry, P., **Albala, B.,** Nagafuji, T., Wilkinson, I.B., and Maltby, K. Prolonged pharmacodynamic effects of S-0139, an intravenously administered endothelin A (ET_A) antagonist, in the human forearm blood flow model. *Br J Clin Pharmacol* : **69**: 252-261, 2010.

Vellas, B., Hampel, H., Rougé-Bugat, M.E., Grundman, M., Andrieu, S., Abu-Shakra, S., Bateman, R., Berman, R., Black, R., Carrillo, M., Donohue, M., Mintun, M., Morris, J., Petersen, R., Thomas, R.G., Suhy, J., Schneider, L., Seely, L., Tariot, P., Touchon, J., Weiner, M., Sampaio, C., Aisen, P.; Task Force Participants (**Albala, B.J.,** et al.). Alzheimer's disease therapeutic trials: EU/US Task Force report on recruitment, retention, and methodology. *J Nutr Health Aging* **16(4)**: 339-45, 2012.

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Hampel H, Vassar R, De Strooper B, Hardy J, Willem M, Singh N, Zhou J, Yan R, Vanmechelen E, De Vos A, Nisticò R, Corbo M, Imbimbo BP, Streffer J, Voytyuk I, Timmers M, Tahami Monfared AA, Irizarry M, **Albala B,** Koyama A, Watanabe N, Kimura T, Yarenis L, Lista S, Kramer L, Vergallo A. The β-Secretase BACE1 in Alzheimer's Disease. *Biol Psychiatry*. **89(8)**:745-756, 2021.

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RECENT ABSTRACTS

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Albala B., Kaplow J., Lai R., Matijevic M., Aluri J. and Satlin A. CSF Amyloid Lowering in Human Volunteers after 14 days Oral Administration of the Novel BACE1 Inhibitor E2609. ***AAIC 2012.***

Lai R., Albala B., Kaplow J, Majid O., Matijevic M., Aluri J and Satlin A. Novel BACE1 Inhibitor E2609 Reduces Plasma and CSF Amyloid in Healthy Subjects after 14 days Oral Administration. ***AD/PD 2013.***

Matijevic M., Desmond H., Watanabe H., Kaplow J., Lai R. and Albala B. Novel BACE1 Inhibitor E2609 Reduces Multiple CSF Amyloid-Beta Isoforms in Daily Dosing of Human Subjects: An IP-MS Analysis. ***AD/PD 2013.***

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Albala B, Hurt S., Maruff P., Jaeger J., Gee M., and Satlin A, Brief Online Computerized Cognitive Battery as a Screening Tool for Clinical Trials in MCI and Mild Dementia Due to AD. ***CTAD 2013.***

Hurt S., Albala B. and Maruff P. Efficient Screening for Mild Cognitive Impairment Due to AD for Clinical Trial Enrollment. ***CTAD 2013.***

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CLINICAL TRIALS ADDENDUM (Prior to UCI)

DIRECTOR OF SINGLE AND MULTI-CENTER CLINICAL TRIALS:

CCC in the Treatment of Multi-Infarct Dementia.

Efficacy and Safety of VVV in the Treatment of Multi-Infarct Dementia.

FFF for the Treatment of Major Depressive Disorders.

A Double-blind, Placebo-controlled, Parallel Group, Multicenter Study to Demonstrate the Efficacy of SSS compound and the Contribution of the Individual Ingredients (CCC; AAA) to the Overall Effect of the Combination in the Treatment of Acute Painful Musculoskeletal Conditions of the Lower Back.

A Multicenter, Double-blind Study of DDD (12.5 Mg), PPP (30 mg), DDD (15 mg) as Compared to DDD (12.5 mg), PPP (30 mg); DDD (15 mg), PPP (30 mg); PPP (30 mg) in Cough and Cold.

Open-Label Comparison of the Effects of Antiepileptic Drug (AED) Treatment with FFF, CCC, or PPP Monotherapy, or a Combination of CCC and PPP on the Performance of a Computerized Test Battery (CTB) in Adult Subjects with Epilepsy.

A Double-Blind, Placebo-Controlled, Parallel Study to Determine the Efficacy and Safety of 72 and 96 mg of BBB (bbb Hydrochloride) Compared to Placebo in Patients with Keratoconjunctivitis Sicca (KCS) Associated with Sjogren's Syndrome.

Multicenter clinical trials of the Hepatitis B Vaccine HHH in the US & Europe.

Multicenter clinical trials of the safety and efficacy of HHH in the treatment of chronic Hepatitis B infection in the US, Europe and Africa.

Multicenter clinical trials of a new formulation of MMM in children with Attention-Deficit/Hyperactivity Disorder.

Phase I studies of a proprietary investigational compound for the treatment of gastro-intestinal disorders.

Clinical trials of a proprietary yellow fever vaccine.

Initiation of a U.S. clinical program for the development of HHH (HHH 234037) a novel antiepileptic drug.

Early clinical studies of the novel antiepileptic compound HHH for the treatment of status epilepticus.

An international study of two marketed antiepileptic drugs and their effect on Polycystic Ovarian Syndrome (PCOS).

A randomized placebo-controlled study to investigate the duration of pharmacodynamic effects of the ETa antagonist XXX as measured by effect upon attenuation of ET-1 mediated vasoconstriction in the human forearm blood flow model and by effect upon cerebral blood flow.

A double-blind, dose-rising study to assess the safety, tolerability and pharmacokinetics of (ETa Antagonist XXX) administered as a 12 and 24 hour continuous iv infusion in healthy young male and healthy elderly male and female volunteers

A double blind, placebo controlled, parallel group, dose escalation study to investigate the tolerability, pharmacodynamics and pharmacokinetics of repeated doses of (YYY GABA antagonist for Alzheimer's Disease) in healthy elderly male and female subjects.

A Phase I, Double-Blind, Placebo-Controlled, Ascending Oral Dose, Safety, Tolerability, and Pharmacokinetic Study of (NNN NPY antagonist) Administered as a Tablet with a Food-Effect Arm in Healthy Male and Female Volunteers.

Double-Blind, Placebo-Controlled, Ascending Multiple Oral Dose, Safety, Tolerability, Pharmacokinetic, and Pharmacodynamic Study of (NNN NPY antagonist) Administered qd for 14 Days or for 28 Days in Healthy Overweight or Healthy Obese Male and Female Volunteers.

Double-Blind, Placebo-Controlled, Ascending Multiple Oral Dose, Maximum Tolerated Dose Safety, Tolerability, and Pharmacokinetic Study of (NNN NPY antagonist) at Doses Up to 9600 mg/Day Administered QD Orally with an FDA High-Fat Caloric-Equivalent Breakfast For 7 Days in Healthy Overweight or Healthy Obese Males and Females.

Open-Label, Randomized, 4-Treatment Crossover, Food-Effect Study of (NNN NPY antagonist) Administered Orally as a 400-mg Tablet in a Fasted and 3 Additional Fed States in Normal, Overweight, and Obese Healthy Male and Female Volunteers.

A Phase I, Monosequence, Open-Label, Drug-Drug Interaction Study To Evaluate the Effect of Multiple-Dose, Steady-State Ketoconazole on the Single-Dose Safety, Tolerability, and Pharmacokinetic Profile of (NNN NPY antagonist) in Normal Healthy Male and Female Subjects.

A Phase I Study to Investigate the Absorption, Metabolism, and Excretion of [^{14}C]-NNN Following Oral Dose Administration in Healthy Male Subjects.

Double-Blind, Multi-Center, Randomized, Parallel-Group, 16 Week Study of 0, 400, or 1600 mg/day (NNN NPY antagonist) Administered Orally Once-A-Day with or without a Low-Calorie Diet Lead-in in Obese Males and Females.

Open-Label Extension of Initial 16-Week Proof-of-Concept Study to Continue Administration of (NNN NPY antagonist) Orally Once-A-Day for up to 12 Additional Months (i.e., 52-weeks) in Obese Males and Females.

A Double Blind, Multi-Center, Randomized, Parallel-Group, Yearlong Study to Assess the Efficacy and Safety of 0, 800 or 1600 mg/day of (NNN NPY antagonist) Administered Orally Once Daily with a Reduced Calorie Diet in Obese Males and Females.

A Double Blind, Multi-Center, Randomized, Parallel-Group, Yearlong Study to Assess the Efficacy and Safety of 0 or 1600 mg/day of (NNN NPY antagonist) Administered Orally Once Daily with an Initial 6-Week Low Calorie Diet in Obese Males and Females.

Open-Label Extension (OLE) Safety and Efficacy Study of (NNN NPY antagonist) Following the Year-Long Controlled Clinical Trials of (NNN NPY antagonist) in Obese Males and Females.

Single Ascending Dose Study of a BBB Inhibitor in Normal Healthy Volunteers as a Disease Modifying Treatment for Alzheimer's disease (AD).

Multiple Ascending Dose Study of a BBB Inhibitor in Older Healthy Volunteers as a Disease Modifying Treatment for Alzheimer's disease (AD).

A Randomized, Double-blind, Placebo-Controlled Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of Single Oral Doses of EEE in Subjects with Mild Cognitive Impairment or Mild Dementia Due to Alzheimer's Disease.

A 3-Part, Open-Label, Drug-Drug Interaction Study of Concomitant Administration of EEE with Itraconazole, Rifampin, Digoxin or Donepezil.

A Randomized, Double-Blind, Placebo- and Active-Controlled, Single Dose, 4-Treatment Crossover Study to Evaluate the Effects of EEE on QTc Interval in Healthy Adult Subjects.

An Open-Label, Single Dose Study to Determine the Metabolism and Elimination of ^{14}C-EEE in Healthy Male Subjects.

A Randomized, Double-Blind, Placebo-Controlled, Single Oral Dose Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of EEE in Healthy Adult Male Japanese and White Subjects.

A Randomized, Open-Label, 3-Treatment Crossover Study to Determine the Bioavailability of EEE Tablets Compared to Capsules and the Effect of Food on Absorption in Healthy Caucasian Male Adults.

An Open-Label Parallel-Group Study to Evaluate the Pharmacokinetics of EEE amd its Metabolites in Subjects with Mild and Moderate Hepatic Impairment Compared with Healthy Subjects.

A Placebo-Controlled, Double-Blind, Parallel-Group, Randomized, Proof-of-Concept, Dose-Finding Study to Evaluate Safety, Tolerability, and Efficacy of EEE in Subjects with Mild Cognitive Impairment Due to Alzheimer's Disease (Prodromal Alzheimer's disease) and Mild to Moderate Dementia Due to Alzheimer's Disease.

A Placebo-Controlled, Double-Blind, Parallel-Group, 24-Month Study with an Open-Label Extension Phase to Evaluate the Efficacy and Safety of EEE in Subjects with Early Alzheimer's Disease. (Phase III Study #1)

A Placebo-Controlled, Double-Blind, Parallel-Group, 24-Month Study with an Open-Label Extension Phase to Evaluate the Efficacy and Safety of EEE in Subjects with Early Alzheimer's Disease. (Phase III Study #2)

PRINCIPAL INVESTIGATOR:

A Double-Blind Trial Comparing NNN to FFF in Patients with Activation Side Effects Previously Demonstrated During Treatment with FFF for Major Depression.

A Double-blind Trial Comparing NNN to SSS in Patients with Previously Demonstrated Sexual Dysfunction During Treatment with SSS for Major Depression.

A Controlled Study of OOO in the Treatment of Alzheimer-Type Dementia (A three-month study).

A Controlled Study of OOO in the Treatment of Alzheimer-Type Dementia (A six-month study).

A Controlled Study of OOO in the Treatment of Alzheimer-Type Dementia (One Year Extension Phase).

Clinical Evaluation of SSS in the Treatment of Patients with Dementia of the Alzheimer Type.

Clinical Evaluation of Efficacy and Safety of SSS in the Treatment of Alzheimer's Disease: A One-Year Double-Blind, Placebo-Controlled Study.

Safety of SSS in the Long-Term Treatment of Alzheimer's Disease.

Multi-center, 36-week, Double-Blind, Parallel-Group Safety, Tolerance and Efficacy Comparison of Placebo and MMM (225 mg/d, 300 mg/d and 375 mg/d) in Outpatients with Alzheimer's Disease (NINCDS/ADRDA Criteria).
A Randomized, Double-Blind, Parallel, Single Dose Study Comparing the Effects of Placebo to Two Doses of DDD Hydrochloride in Sleep in Healthy Volunteers with Adjustment Sleep Disorder.

A Multi-Center Double-Blind Comparison of the Effects of NNN and FFF on Sleep Architecture and Quality of Sleep in Depressed Outpatients.

A 30-week, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Evaluation of the Safety and Efficacy of EEE in Patients with Alzheimer's Disease.
An Open-Label, Multicenter, Extended Evaluation of the Safety and Efficacy of EEE in Patients with Alzheimer's Disease.

A Comparison of the Effects and Duration of Action of DDD and Mentholated Lozenges in Patients with Chronic Cough.

A Comparison of the Effects of SSS (DDD HCl) and UUU (DDD Succinate) on Sleep Parameters and Morning After Performance in Subjects with Phase Shift Insomnia.

Double-Blind, Placebo Controlled Efficacy Study of Three Dose Levels of AAA in Outpatients with Non-Psychotic Anxiety.

Extension Study of AAA in Outpatients with Non-Psychotic Anxiety.

A Double-Blind, Placebo Controlled Study to Determine the Efficacy and Safety of FFF (0.5, 2 & 8 mg BID) in the Treatment of Secondary (Acquired) Male Erectile Disorder.

Dose Ranging Pilot Study Comparing the CNS Pharmacologic Effects of SSS to Placebo and Diazepam.

Delay in Nursing Home Placement of Alzheimer's Disease (AD) Patients Treated in the AAA Clinical Program.

SUB-INVESTIGATOR:

CCC, Single Blind, Multiple Oral Dose Safety Study.

A Randomized, Double-Blind, Placebo Controlled, Crossover Study to Evaluate the Safety and Efficacy of SSS Suppositories in the Acute Treatment of Three Migraine Attacks.

The Tolerance and Safety of Ascending RRR Dose-Titration Regimens in Normal Volunteers.

Pharmacokinetics of Sertraline and FFF when FFF (20 or 40 mg QD) Administration is Switched to SSS (50 mg QD) in Depressed Patients.

Consumer Test of LLL (lactase enzyme) Taken at Various Times.

Safety, Tolerance, and Pharmacokinetics of Single Doses of SSS (GGG, ggg) Administered Intravenously to Normal Male Volunteers: A Double-Blind Placebo-Controlled Ascending-Dose Study.

A Double-Blind, Single Dose Study Comparing the Safety and Efficacy of SSS and Acetaminophen to Placebo in the Treatment of Acute Back Pain.

CCC (ttt) Access Program (Treatment IND).