NALZHEIMER'S ASSOCIATION

Business Consortium

Quarter 3 2023 Newsletter

Mission of AABC

The mission of the Alzheimer's Association[®] Business Consortium (AABC) is to advance Alzheimer's disease research and innovation in small- and medium-size biotechnology, diagnostics, medical device and contract research organizations.

AABC members work in areas of common interest pre-competitively to advance both the field of Alzheimer's research and the goals of member organizations. They provide leadership and direction to the group's areas of focus, which include, but are not limited to, collaborations, recognition and visibility, and knowledge and information sharing. AABC welcomes new member organizations who are aligned in their commitment to research and innovation. To express interest in joining, please email Dr. Jacob Donoghue (jake@beacon.bio), co-chair, Dr. Ornit Chiba-Falek (ornit.chibafalek@clairigene.com), co-chair, or Dr. Christopher Weber (cweber@alz.org), facilitator.

Welcome to our New Members

AABC is growing! Welcome to:

» Lenny Kristal, Paul Slowey, Rory Stear, Mike O'Donnell

Baseline Bioscience has patented technology which will analyze saliva for a broad range of medical conditions, such as Alzheimer's disease, and that analysis is almost immediate and is non-invasive, resulting in no patient reluctance to undergo the analysis. Saliva is a proven carrier of analytes, such as proteins, that are known to be indicative of various medical conditions. The purpose of the device is to identify those analytes for chosen significant medical conditions and to develop accurate, rapid, easy-to-use devices to assess for those analytes. This means that more patients will get assessed for their potential medical conditions sooner, and they will, therefore, be more likely to start treatment sooner. In some cases, earlier diagnosis and treatment can be more convenient for the patient; in other cases, earlier diagnosis and treatment can be absolutely critical in the life of the patient.

» Sergi Navarro I Guimera, Raphael Certain

Clairity Technologies is a healthcare company developing a digital clinic for neurological diseases, with a primary focus on Alzheimer's. Our first solution is a non-invasive neurostimulation device consisting of a virtual reality (VR) headset with brain activity sensors and a precision medicine platform designed to slow down the progression of Alzheimer's. Clarity's unique closed-loop neuromodulation approach, where the VR environment and stimulation delivery are tailored to the patient's brain activity, opens the door to precise, personalized, and engaging sensory stimulation that can be accessed from the comfort of people's homes.

» Yoon Kim, Jinwoo Kim, Shahid Azam

HAII is a Seoul-based digital therapeutics company that specializes in providing precise diagnostic and customized treatments for central nervous system (CNS) diseases. Their flagship product has the ability to accurately diagnose dementia and mild cognitive impairment (MCI), and personalized treatment plans based on the diagnosis are currently under development. The company's technology is supported by a growing body of clinical evidence and AI-driven data analytics. Further, their platform is easily accessible from anywhere through a standard smartphone or a simple web interface. HAII is actively pursuing clinical and strategic pharma partnerships for trials and publications. For further information, <u>click here</u>.

» Nathan Intrator

Neurosteer[®] has developed an innovative solution for the early detection of Alzheimer's and Parkinson's diseases. Its noninvasive FDA-cleared single-channel EEG consists of a forehead-only adhesive electrode strip and a cloud-based system that provides real-time monitoring and assessment of brain activity. When paired with simultaneous auditory stimulation, it delivers the neurological equivalent of a cardiac stress test for the brain. Neurosteer is currently undertaking rigorous clinical trials to validate our solution's efficacy. This also includes patient screening and longitudinal monitoring to streamline pharma inclusion and ensure the success of clinical trials.

» Keiji Asada, Kimunobu Sugaya, Christian Friese, Scott Kahn

Progenicyte Therapeutics, Inc. is a Chicago-based early-stage start-up company focused on developing small molecule compound drug-based stem cell therapies in neurodegenerative diseases. Our lead product is for the treatment of Alzheimer's

disease, and our mechanism is based on increasing endogenous stem cells through our small molecule compound, KS 217, and increasing neurogenesis by the combination of KS 217 and APP signaling inhibitor. We have successfully conducted in-vitro and in-vivo studies and planning to initially develop an orphan drug for acute regression with Down Syndrome, which is a human model of Alzheimer's disease (extra Amyloid Precursor Protein), prior to moving forward with Alzheimer's disease IND. Our technology was originally developed by renowned neuroscience professor, Dr. Kiminobu Sugaya, out of University of Central Florida. Dr. Sugaya has published over 15 publications related to stem cell research.

» Fernando Johann, Adolfo Garcia

TELL is an AI-based automated speech analysis tool granting users agency on their brain health. Our intuitive platform allows collecting, encrypting, analyzing, downloading, and visualizing speech and language data for research and clinical aims. It encompasses a linguistic profile survey and several tasks with varying motoric and cognitive demands, all proven to elicit discriminate verbal behavior in diverse neurodegenerative disorders. TELL's online platform aids researchers and physicians while democratizing early diagnosis and data based treatment for neurodegenerative diseases.

News from AABC Members

bioExpert

bioExpert produced the international Neuro4D 2023 meeting May 15-16, 2023 in Mainz Germany. This fourth event was focused on Alzheimer's dementia and the recent success of new amyloidbeta soluble aggregate directed antibodies. The Neuro4D is an international conference on Neuro Degenerative Disease Drug Discovery bringing together drug discovery companies, service and technology providers, and academic innovators in the field of proteopathic neurodegenerative diseases in the most interactive format.

All chairmen (Rakez Kayed, Neil Cashman, Knut Biber and Oliver Peters) gave comprehensive introductions into their chaired session subject, before the individual presentations. The focus on the second day was diagnosis and clinical treatments of AD and other neurodegenerative diseases. Presentations on biomarkers determined from serum, CSF, but interestingly also from nasal secretion preceded the clinical session with presentations of Eisai, Priavoid, Grifols and Roche. Views on the recent clinical progress were optimistic, and the benefit of recent antibodies Lecanemab and more recently Donanemab is encouraging. However, antibody treatments clearly have limitations and important although thankfully rare side effects. Priavoid's approach using specific D-peptide catalyzed refolding mechanisms for misfolded pathogenic peptide forms again impressed many delegates and we are very keen to see Phase II clinical study results in the future. There was much interest in the clinical progress and the patient and caretaker-perceived effects on patients' activity of daily living during the last clinical sessions and discussion panel.

The Neuro4D 2023 poster for the best presented approach in neurodegenerative disease drug discovery was selected by all participants and awarded to Janine Kutzsche from Dieter Willbold's groups in Jülich and at the University of Düsseldorf, for: "A New Mode of Action for the Treatment of Alzheimer's Dementia" (see: www.neuro4d.com).

Neuro4D 2024 will be held May 27-28, 2024 in the Atrium Hotel in Mainz. The focus of this meeting will be on PD and other non-AD neurodegenerations. We have already started to look for exhibitors and presenters for this event.



ImmunoBrain Checkpoint Inc. (IBC), a biopharmaceutical company developing innovative diseasemodifying immune therapies to combat neurodegenerative diseases, announced in May that it has dosed the first two patients in the Phase 1b IBC-01-01 clinical trial investigating IBC's lead program, IBC-Ab002 for patients with early Alzheimer's disease. IBC-Ab002 is a novel, fully human anti-PD-L1 monoclonal antibody designed to harness the peripheral immune system to help the brain overcome the multiple pathological factors that contribute to the cognitive manifestation and progression of neurodegenerative diseases, including local brain inflammation, amyloid beta, tau pathologies and neuronal loss.



Established in 2015, IBC builds on over 20 years of research by Professor Michal Schwartz's team at the Weizmann Institute of Science, which pioneered the concept that the brain relies on the immune system for maintenance and repair, with this communication compromised in aging and Alzheimer's disease.

IBC-01-01 [NCT05551741] is a randomized, double-blind, placebo-controlled, first-in-human Phase 1b clinical trial designed to evaluate safety, tolerability, pharmacokinetics and exploratory markers of efficacy of IBC-Ab002 in patients with early Alzheimer's disease. The study features single and multiple ascending doses, administered intravenously across up to five cohorts, with a 3:1 patient randomization for IBC-Ab002 or placebo. Conducted in Israel, the UK, and the Netherlands, IBC plans to enroll 40 participants.



Neuronascent Inc., a clinical stage biopharmaceutical company, with first-in-class neuron regenerative therapeutics announced its abstract titled, "Clinical Stage Alzheimer's therapy, NNI-362 Promotes TH+ Neurons Associated with a Reversal of Motor Deficits in AAV-Alpha Synuclein Model, Leaving Alpha Synuclein Unchanged" was presented at AAIC[®] in Amsterdam, Holland, on July 19, 2023. Neuronascent has also learned that they have been awarded a U01 grant from NIA to support the non-clinical long-term GLP safety and further GMP manufacturing to support NNI-362 into Phase 2 proof-of-concept trials in patients.

AAIC AABC Meeting

Alzheimer's Association International Conference[®] (AAIC) 2023 took place in Amsterdam, Netherlands July 16-20, with over 11,000 attendees, including over 7,000 in-person! We had more than over 600 podium presentations, more than 4,000 posters and 171 exhibit booths representing 102 companies, sharing the latest advancements in dementia science. During AAIC, the AABC hosted an in-person luncheon on July 16th, providing attendees with a unique opportunity for networking, exploring common areas of interest and discussing new areas of collaboration, recognition and visibility for the membership. The luncheon featured a presentation by Dr. Sudhir Sivakumaran (<u>ssivakumaran@c-path.org</u>), Executive Director, Critical Path for Alzheimer's Disease (CPAD) and a panel discussion titled "Developing and Commercializing Precision Medicine: Partnerships and Emerging Biomarkers & Treatments." Conversations and exchanges such as those that occurred at AAIC help to advance our collective efforts in Alzheimer's disease. AAIC 2024 will be held in Philadelphia, PA. Please visit <u>aaic.alz.org</u> to keep an eye out for updates, abstract submission deadlines and the option to sign up to receive conference alerts, program announcements and registration information.

in Social Media

Follow our LinkedIn page! We use this page to foster partnerships and communications.

Join our Slack channel! We launched a Slack channel in 2022 to encourage open and direct communications between all members. If interested in joining, please reach out to Ashley Hansen (<u>ahansen@alz.org</u>).

🔍 Get Involved

To help us grow AABC, please continue to introduce new members and companies to our group. We also welcome ideas or events for this newsletter. Please send your suggestions to Ashley Hansen at (ahansen@alz.org).

