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Clinical Trial Explores the Effects of Health Coaching on Cognitive Function in Patients with Early-Stage Alzheimer's

Study will also assess multi-omic data to understand transitions related to cognitive decline

SEATTLE, Feb. 1, 2018 – Institute for Systems Biology (ISB) is among several organizations conducting a clinical trial testing how health coaching affects the cognitive function of patients with early-stage Alzheimer's disease and analyzing longitudinal, multi-omic data to explore transitions in cognitive function over time.

Participants in the Coaching for Cognition in Alzheimer's (COCOA) trial will be randomly assigned to two groups: The control group will receive only regular care. The other group will receive lifestyle coaching from Arivale in addition to regular medical care. All study participants will be given the opportunity for a genetic assessment, as well as mental and functional ability assessments. In addition, they will receive basic health questionnaires and submit frequent samples for longitudinal, integrated biological data analyses (multi-omic analyses). Those not in the control group will also receive coaching sessions by phone.

"These multi-omic analyses of Alzheimer's patients will provide deep insights into the progression and reversal of this disease," said Leroy Hood, M.D., Ph.D., chief science officer and senior vice president of Providence St. Joseph Health and chief strategy officer and co-founder of ISB.

The trial is being funded by Providence St. Joseph Health, and was designed by researchers at ISB and Arivale in Seattle, and the Pickup Family Neurosciences Institute at Hoag and Shankle Clinic in Southern California.

"Previous studies have shown that multi-domain lifestyle interventions can slow the progression of cognitive decline," said Jennifer Lovejoy, Ph.D., Arivales's chief translational science officer. "This study provides a unique opportunity to apply multi-omic data and coaching in individuals in the early stages of cognitive decline."

The COCOA trial will enroll 200 participants – 100 for each study group – who will be monitored for two years.

"Clinical trials are a critical tool in our ongoing efforts to help those with Alzheimer's disease," said William R. Shankle, M.S., M.D., F.A.C.P. program director of the Memory and Cognitive Disorders program at the Pickup Family Neurosciences Institute at Hoag. "We know that individuals benefit from early detection and treatment. Now we are testing multi-domain, lifestyle coaching – including diet, exercise, and cognitive training – which may provide novel insights and approaches into future detection and treatment."

"With the COCOA trial, and programs such as the Orange County Vital Brain Aging Program, Hoag is committed to achieving breakthroughs in the detection of cognitive impairment at its earliest possible stage," said Michael Brant-Zawadzki, M.D, F.A.C.R., senior physician executive and the Ron & Sandi Simon Executive Medical Director Endowed Chair of the Pickup Family Neurosciences Institute, Hoag. "Research continues to prove that this is the best opportunity we have to provide optimal care and management to patients with Alzheimer's. This month's editorial in the Journal of the American Medical Association suggested the importance of lifestyle and behavioral modification in slowing the progression of this disease. Our trial aims to verify that active 'coaching' can significantly slow progression of Alzheimer's symptoms."

Alzheimer's disease, the most common form of dementia, has no cure. The Alzheimer's Association estimates that every 66 seconds someone in the U.S. develops the disease, projecting that by 2050 as many as 16 million Americans may be living with Alzheimer's with costs for care rising as high as \$1.1 trillion.

ABOUT INSTITUTE FOR SYSTEMS BIOLOGY

The Institute for Systems Biology is a nonprofit biomedical research organization based in Seattle. It was founded in 2000 by systems biologist Leroy Hood, immunologist Alan Aderem, and protein chemist Reudi Aebersold. ISB was established on the belief that the conventional models for exploring and funding breakthrough science have not caught up with the real potential of what is possible today. ISB serves as the ultimate environment where scientific collaboration stretches across disciplines and across academic and industrial organizations, where our researchers have the intellectual freedom to challenge the status quo, and where grand visions for breakthroughs in human health inspire a collective drive to achieve the seemingly impossible. Our core values ensure that we always keep our focus on the big ideas that eventually will have the largest impact on human health. ISB is an affiliate of Providence St. Joseph Health, one of the largest not-for-profit health care systems in the United States.

ABOUT PROVIDENCE ST. JOSEPH HEALTH

Providence St. Joseph Health is committed to improving the health of the communities it serves, especially those who are poor and vulnerable. With 50 hospitals, 829 physician clinics, senior services, supportive housing and many other health and educational services, the health system and its partners employ more than 111,000 caregivers (employees) serving communities across seven states – Alaska, California, Montana, New Mexico, Oregon, Texas and Washington. With system offices based in Renton, Wash. and Irvine, Calif., the Providence St. Joseph Health family of organizations works together to meet the needs of its communities, both today and into the future.

ABOUT ARIVALE

Arivale is the Scientific Wellness® company that combines personalized data and tailored coaching, supported by a clinical team, to help individuals optimize their wellness and avoid disease. The Arivale program evaluates genetics, blood markers, microbiome, and lifestyle data to deliver unique actionable recommendations to members. Arivale has created a unique, longitudinal, multi-omic dataset and partners with leading healthcare institutions and companies to discover new ways for individuals to optimize their wellness and avoid disease. To learn more, visit www.arivale.com and follow us on Twitter and Facebook.

ABOUT THE PICKUP FAMILY NEUROSCIENCES INSTITUTE

Delivering a personalized, integrated approach using best-practice guidelines, the most advanced technology, and integration of medical specialists in the most appropriate facilities, the Pickup Family Neurosciences Institute (PFNI) at Hoag provides the highest quality care for patients with brain and spine disorders including stroke, aneurysms and vascular malformations, brain tumors, epilepsy, movement disorders, memory and cognitive disorders, pain, minimally invasive spine surgery, multiple sclerosis, addiction medicine and sleep disorders, as well as the mind-body interface of behavioral health. Several of Hoag's PFNI programs have received high acclaim, including the stroke program at Hoag, which was the first hospital in Orange County and the second in California to be named a Certified Comprehensive Stroke Center by DNV GL Healthcare. It was awarded the American Stroke Association's Get With The Guidelines Stroke Gold Plus Performance Achievement for stroke care. And as one of the first centers in the U.S. to offer the most advanced radiosurgical treatment system available, Leksell Gamma Knife® Perfexion™, Hoag's brain tumor program is the largest in Orange County and is also among the top volume programs in the western United States. The epilepsy program is an accredited Level 3 center. The PFNI's memory and cognitive disorders program is nationally recognized.

ABOUT HOAG MEMORIAL HOSPITAL PRESBYTERIAN

Hoag is an approximately \$1 billion nonprofit, regional health care delivery network in Orange County, California, that treats more than 30,000 inpatients and 425,000 outpatients annually. Hoag consists of two acute-care hospitals - Hoag Hospital Newport Beach, which opened in 1952, and Hoag Hospital Irvine, which opened in 2010 - in addition to seven health centers and ten urgent care centers. Hoag is a designated Magnet® hospital by the American Nurses Credentialing Center (ANCC). Hoag offers a comprehensive blend of health care services that includes five institutes providing specialized services in the following areas: cancer, heart and vascular, neurosciences, women's health, and orthopedics through Hoag's affiliate, Hoag Orthopedic Institute, which consists of an orthopedic hospital and two ambulatory surgical centers. In 2013, Hoag entered into an alliance with St. Joseph Health to further expand health care services in the Orange County community, known as St. Joseph Hoag Health. Hoag has been named one of the Best Regional Hospitals in the 2017 - 2018 U.S. News & World Report, and Becker's Hospital Review named Hoag as one of the 2016 "100 Great Hospitals in America" – a designation Hoag has received four times. For an unprecedented 22 years, residents of Orange County have chosen Hoag as one of the county's best hospitals in a local newspaper survey. Visit www.hoag.org for more information.

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