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EISAI INC. COLLABORATES WITH C₂N TO BUILD AWARENESS AND REAL-WORLD EVIDENCE FOR BLOOD-BASED ASSAYS IN THE DIAGNOSIS OF PEOPLE LIVING WITH COGNITIVE IMPAIRMENT IN CLINICAL PRACTICE IN THE U.S. OUTSIDE OF CLINICAL TRIAL SETTINGS

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that its U.S. subsidiary Eisai Inc. has entered into a memorandum of understanding with C₂N Diagnostics ("C₂N") that will seek to build awareness about how blood-based assays in the diagnosis for people living with cognitive impairment, including Alzheimer's disease (AD), may help patients receive a timely diagnosis and appropriate treatment. Collaborating with C₂N, Eisai Inc. will work to build awareness and develop real-world evidence to support the use of blood-based assays in people living with cognitive impairment in clinical practice outside of clinical trial settings in the U.S. Blood-based assays could result in the development of new standards in clinical care that may enable timely and accurate diagnoses for people living with cognitive impairment.

The number of people with dementia is growing substantially; more than 55 million people worldwide are living with dementia, and this number is expected to increase to 78 million by 2030. Accurate diagnosis remains a barrier to early and proper care management; research reviews estimate that between 40 and 60 percent of adults with probable dementia are undiagnosed. Importantly, blood-based assays may be able to help identify which patients may benefit from therapy, and therefore may help streamline care and reduce healthcare spending. Early detection, diagnosis and treatment of dementia protects individuals against risks from delayed or missed diagnosis and allows individuals, their families and their caregivers to plan for the future as the condition progresses.

The development and adoption of blood-based assays as simple diagnostic tools, in every day clinical practice is an important step in improving care for people in remote and underserved communities where access to the traditional diagnostic tools of positron emission tomography (PET) and lumbar punctures are not a viable option.

In collaboration with various partners, Eisai will engage in practical application of simple and less invasive diagnostic technologies and diagnostics for dementia, including blood tests, and will work to improve the medical environment in which people with dementia can receive appropriate treatment, thereby contributing to relieving anxieties of people living with dementia and their families around the world.

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[Notes to editors]

1. About C₂N Diagnostics and Its Blood-Based Biomarkers for Cognition Health

C₂N Diagnostics ("C2N") is a specialty diagnostics company with a vision to bring Clarity Through Innovation™. C₂N strives to provide exceptional laboratory services and products in the field of brain health. C₂N's biomarker services and products are used for: clinical decision making to improve patient care, including diagnosis and treatment monitoring; maximizing the quality and efficiency of clinical trials that test novel treatments for neurodegeneration; and providing innovative tools to help healthcare researchers better understand novel mechanisms of disease, identify new treatment targets, and conduct important epidemiologic studies to improve global public health. Its PrecivityAD™ blood test is an innovative new blood test intended for use in patients with cognitive impairment. Accurate quantification of Aβ42/40 ratio and ApoE prototyping in blood using its mass spectrometry platform helps healthcare providers determine the presence or absence of amyloid plaques in the brain, a hallmark sign of Alzheimer's disease. In addition, the P-tau Multi-Analyte Assay (P-tau MAA), which simultaneously measures four types of tau217 and tau181 phosphorylated and non-phosphorylated forms in blood sample, is now available for research use only (ROU). The assay is expected to aid in screening for clinical studies, better understanding of disease biology, as well as investigational drug research. For more information visit www.C2N.com

- 1. Alzheimer's Disease International. World Alzheimer Report 2021, Journey through the diagnosis of dementia.
- 2. The Milken Institute. Building Workforce Capacity to Improve Detection and Diagnosis of Dementia 2021.