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Eisai Co., Ltd.

EISAI PRESENTS RESEARCH EVALUATING CORRELATION OF HIGHLY-PRECISELY MEASURED AMYLOID BETA IN PLASMA AND CEREBROSPINAL FLUID WITH NEWLY DEVELOPED AUTOMATED PROTEIN ASSAY SYSTEM AT ALZHEIMER'S ASSOCIATION INTERNATIONAL CONFERENCE (AAIC) 2019

Eisai Co.,Ltd.(Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced its latest research on evaluation about correlation of amyloid beta (Aβ) in plasma and in cerebrospinal fluid (CSF) by high precision measurement with the newly developed automated protein assay system, jointly developed with Sysmex Corporation (Headquarters: Hyogo, Chairman and CEO: Hisashi Ietsugu, "Sysmex"), using full-automated immunoassay system HISCL™*1 series for creating the simplified diagnosis of Alzheimer's disease (AD) with blood was presented at the Alzheimer's Association International Conference (AAIC) held in Los Angeles, California, United States, from July 14 to 18, 2019. (Poster Presentation No.: P4-548)

Aβ is a peptide consisting of amino acid residues, which is generated by excision from the amyloid precursor protein. $Aβ_{1-40}$ consisting of 40 residues is dominant substance, and $Aβ_{1-40}$ does not significantly fluctuate with progression of AD. On the other hand, as for the $Aβ_{1-42}$ consisting of 42 residues, the aggregability is high and the reduction in $Aβ_{1-42}$ is detected from the early stage of AD. The absolute value of Aβ has individual differences and intra individual variabilities, therefore, $Aβ_{1-42}/Aβ_{1-40}$ ratio in CSF is used for the diagnosis of amyloid positive or negative.

In this research, the correlation between $Aβ_{1-42}/Aβ_{1-40}$ ratio in plasma and $Aβ_{1-42}/Aβ_{1-40}$ in CSF were investigated for creating a simple blood diagnostic for AD by the automated protein assay system using full-automated immunoassay system HISCL™ series. This assay system enables the automated immune assay in 17 minutes with small volume samples such as 10-30μL, and Aβ assay in plasmas is possible with enough sensitivity and the high reliability. The samples from elderly person with normal cognition and patients with mild cognitive impairment (MCI) and AD were used for investigation with HISCL™ series. Results show a correlation (Spearman's rank correlation coefficient (r_s) *2 =0.502, $p<0.001$) between $Aβ_{1-42}/Aβ_{1-4}$ ratio in plasma and $Aβ_{1-42}/Aβ_{1-40}$ ratio in CSF; therefore, it may be possible to understand the pathological processes in the brain condition by measuring $Aβ_{1-42}/Aβ_{1-40}$ ratio in plasma. To further assess clinical utility, Eisai and Sysmex aim to check the correlation between $Aβ_{1-42}/Aβ_{1-40}$ ratio in plasma and amyloid PET.

Eisai aims to realize the prevention and cure of dementia including establishment of new diagnostics by multi-dimensional and holistic approach with a foundation of over 35 years of experience of drug discovery activities in the area of Alzheimer's disease and dementia. Eisai strives further contribute to addressing the unmet medical needs of, as well as increasing the benefits provided to, patients and their families.

*1 HISCL™ is a trademark of Sysmex Corporation.

*2 The correlation coefficient indicates the strength of the relationship between the two data from the two quantitative data distributions. In this analysis, Spearman's rank correlation coefficient (r_s) which is an index of correlation obtained from rank data is calculated.

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[Notes to editors]

1. About collaboration between Eisai and Sysmex

Eisai and Sysmex have entered into a comprehensive non-exclusive collaboration agreement aimed at the creation of new diagnostics in the field of dementia in February, 2016. Leveraging each other's technologies and knowledge, the two companies aim to discover next-generation diagnostics that will enable early diagnosis, selection of treatment options and the regular monitoring of the effects of treatment for dementia.