

January 5, 2022
Sysmex Corporation

Sysmex Files for Manufacturing and Marketing Approval for an Assay Kit that Assists in Identification of Amyloid Beta (A β) Accumulation in the Brain

- Measurement of Plasma A β Using Automated Immunoassay System HISCL™-5000/HISCL™-800 -

Sysmex Corporation (HQ: Kobe, Japan; Chairman and CEO: Hisashi Ietsugu) announced that it submitted an application on December 28, 2021 for manufacturing and marketing approval with the Pharmaceuticals and Medical Devices Agency (PMDA) for an assay kit to measure A β in the blood using its automated immunoassay system HISCL-5000/HISCL-800.

In recent years, there has been increased activity in the development of therapeutic drugs that can address the underlying pathology of Alzheimer's disease. In June 2021, the U.S. Food and Drug Administration (FDA) approved ADUHELM™ (aducanumab-avwa), and a new drug application for the same treatment was filed in Japan in December 2020. The appropriate use and dissemination of these therapeutic drugs requires technology to identify the accumulation of A β in the brain, but conventional testing methods have issues such as invasiveness and cost.

Sysmex has been developing a technology that can more readily identify accumulation of A β in the brain. In February 2016, Sysmex and Eisai Co., Ltd. entered into a comprehensive non-exclusive collaboration agreement for the creation of new diagnostic reagents in the field of dementia. Since then, we have been engaged in the development of next-generation diagnostic reagents that will enable early diagnosis, selection of treatment options, and the monitoring of the effects of treatment for dementia, by utilizing each company's technologies and knowledge.

Sysmex recently submitted an application for manufacturing and marketing approval of an assay kit to measure A β levels in blood to assist in identifying A β accumulation in the brain. This assay kit is used in conjunction with Sysmex's automated immunoassay system HISCL-5000/HISCL-800, both of which employ chemiluminescence enzyme immunoassay (CLEIA) as their measurement principle.

Sysmex has identified "Resolution of medical issues through products and services" as one of its priority objectives (materiality), and is working to solve medical issues through its business activities. Sysmex will continue its efforts to contribute to the development of healthcare and the healthy lives of people by leveraging its unique technologies and global network.

References

February 15, 2016 news release: “Sysmex and Eisai enter comprehensive agreement to create next-generation diagnostic reagents in the field of dementia”

<https://www.sysmex.co.jp/en/news/2016/160215.html>

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