HemeSight®, the First-in-Japan Comprehensive Genomic Profiling Assay for Hematological Malignancies, Receives Its First Regulatory Approval

HemeSight® hematological malignancies gene panel test approved in Japan

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Otsuka Pharmaceutical Co., Ltd. (Tokyo); The National Cancer Center Japan (Tokyo); Kyushu University (Fukuoka); Kyoto University (Kyoto); Nagoya Medical Center (Aichi); Advanced Clinical Research Center, The Institute of Medical Science at The University of Tokyo (Tokyo); and Keio University School of Medicine (Tokyo) announce today that Otsuka Pharmaceutical has received approval to manufacture and market HemeSight®, hematological malignancies gene panel test, in Japan. Otsuka will proceed on procedures to qualify HemeSight for health insurance reimbursement and will start marketing the test as soon as launch preparations are completed.

HemeSight was developed jointly by Otsuka Pharmaceutical and the National Cancer Center, and its performance has been verified by a research consortium[*1] comprising the National Cancer Center, Kyushu University, Kyoto University, and the Nagoya Medical Center.

Insurance coverage for the cancer gene panel test for solid tumors already exists in Japan. However there was no approved gene panel test for hematological malignancies, and cancer genome medicine has not yet been covered by health insurance reimbursement.

This product is the first gene panel test for hematological malignancies and related diseases to be designated as a product subject to the “review system for designated world-first products” [*2] by Japan’s Ministry of Health, Labour and Welfare[*3] and approved for manufacture and marketing in Japan. The product consists of the in vitro diagnostic product HemeSight In Vitro Diagnostics and the medical device program HemeSight Analysis Program.

In recent years, diagnosis and treatment guidelines for hematological malignancies proposed by the World

Health Organization (WHO) and other organizations recommend medical treatment based on genome information, and it is becoming increasingly difficult to make an appropriate diagnosis and treatment without using genome information.

In Japan, the Japanese Society of Hematology has issued guidelines for genomic testing of hematological malignancies[*4], which provide recommendations for gene panel testing for each disease and stage, including leukemia, malignant lymphoma, and multiple myeloma. HemeSight is designed to comprehensively test for the genetic abnormalities of hematological malignancies listed in the guidelines, and is expected to enable diagnosis, treatment selection, and prognosis prediction based on genetic abnormalities.

The approval of the hematological malignancies gene panel test HemeSight is expected to greatly advance personalized medicine in the field of hematopoietic oncology in Japan and contribute to better medical care.

Professor Koichi Akashi, Department of Pathology and Restorative Medicine, Graduate School of Medicine, Kyushu University, commented, “In recent years, cancer genome medicine has made rapid progress since the gene panel tests for solid tumors have become covered by insurance. A hematological malignancies genome test guideline was issued with the aim of implementing cancer genome medicine, but there was no gene panel test that could be used for hematological malignancies. With the approval of the hematological malignancies gene panel test, we hope that cancer genomic medicine will advance in hematological malignancies as well, enabling optimal treatment for each individual patient. ”

Tatsuaki Ohashi, general manager of the Diagnostics Division of Otsuka Pharmaceutical, said, “HemeSight is the first hematological malignancies gene panel test in Japan. We would like to thank all the medical professionals who participated in the joint research consortium and all the patients and stakeholders who were involved in its development. Otsuka Pharmaceutical has been manufacturing and marketing in vitro diagnostics for genetic testing for acute leukemia. With the enactment of the Genomic Medicine Promotion Act, we are very pleased to add HemeSight for hematological malignancies and related diseases to our new product lineup. Hematological malignancies are the most common pediatric cancer, and the number of adults with this disease is also increasing. We look forward to contributing to personalized medicine for all patients with hematological malignancies, both adult and pediatric, who need it.”

Gretchen Weightman, Illumina’s senior vice president, Asia-Pacific, Middle East & Africa, who also signed the development and commercialization agreement for this product[*5] on behalf of Illumina, said: “We are very pleased with the approval of HemeSight in Japan. As Otsuka Pharmaceutical’s technology partner for genomic sequencing, we are proud to support Otsuka and healthcare organizations in providing comprehensive genomic profiling for patients with hematological malignancies. ”

*1 Consists of an in vitro diagnostic product for hematological malignancies gene panel testing and its program.

*2 Development of the first comprehensive genomic profiling assay for hematologic malignancies in Japan (https://www.otsuka.co.jp/en/company/newsreleases/2020/20200326_2.html)

*3 Act on Comprehensive and Systematic Promotion of Measures to Ensure that the Public is Securely Able to Receive High-Quality and Appropriate Genomic Medicine (Act No. 57 of 2023)

*4 Japanese Society of Hematology Guidelines for Genomic Testing of Hematological Malignancies, 2021 Partially Revised Edition（http://www.jshem.or.jp/genomgl/home.html）

*5 Otsuka and Illumina Announce Agreement on Development and Commercialization of IVD Test Kit for Patients in Japan with Blood Cancer（https://www.otsuka.co.jp/en/company/newsreleases/2021/20210203_1.html）