News Release

June 30, 2022
Sysmex Corporation

Sysmex Files for Manufacturing and Marketing Approval for Genetic Panel Testing System for Inherited Retinal Dystrophy

Sysmex Corporation (HQ: Kobe, Japan; Chairman and CEO: Hisashi Ietsugu) announces that it submitted an application on June 30, 2022 for manufacturing and marketing approval to the Pharmaceuticals and Medical Devices Agency (PMDA) for a genetic panel testing system (the "testing system") for inherited retinal dystrophy[1] that uses a next-generation sequencer[2] to detect and analyze information on multiple genetic mutations in target genes taken from the blood of patients with inherited retinal dystrophy. This testing system is designed ultimately to assist in the planning of treatment and low vision care[3] tailored to the causative genes as well as molecular evidence-based genetic counseling.

Inherited retinal dystrophy (IRD) is a generic term for a series of inherited progressive diseases in which retinal dysfunction is caused by genetic mutations, and with most common IRD, retinitis pigmentosa, a designated intractable disease. Many IRD patients experience symptoms beginning at a young age such as difficulty seeing in dim light or a narrowing of their visual field, with some cases leading to blindness. More than 300 genes have been reported to cause IRD, and its symptoms and severity vary depending on the causative genes. For this reason, more personalized diagnostics based on causative gene information is becoming increasingly important in complementing the conventional methods based on clinical findings.
If the causative genes of IRD can be identified, it will be possible to determine a treatment plan based on the causative gene, but also map out support plans for low vision care as well as molecular evidence-based genetic counseling. Such an improved situation is expected to greatly contribute to improving the quality of life (QOL) of patients by clarifying the risk of developing IRD and prediction of symptom progression, such as preparing for schooling/employment and family planning.
Although IRD has been thought to have no fundamental treatment, recent years have seen gene therapy[4] techniques targeting the causative genes developed and approved in Europe and the United States as well as developments in Japan. Thus, pathways to new treatment strategies are becoming more accessible.

Sysmex has recently completed the development of the testing system (reagent kits and analysis program) and submitted an application for approval to manufacture and market this as a combination medical device.[5] Its approval will mark Japan's first gene panel testing system for IRD.
In order to expand opportunities for patients to receive this testing, we will also work to have relevant IRD clinical flows covered by national health insurance.

Sysmex aims to contribute to improving the QOL of patients and their families through the clinical implementation of genomic medicine to treat inherited retinal dystrophy.

Reference

March 5, 2020 press release entitled "Sysmex and the Kobe City Eye Hospital Sign a Comprehensive Collaboration Agreement -Reinforcing Collaboration toward the Realization of Genomic Medicine in the Area of Ophthalmic Disorders-"
https://www.sysmex.co.jp/en/news/2020/pdf/200305_01_e.pdf

September 3, 2021 press release entitled "Approval of 'Genetic Diagnosis and Counseling for Inherited Retinal Dystrophy' Using Gene Panel Testing System for Advanced Medical Care B"
https://www.sysmex.co.jp/en/news/2021/pdf/210903.pdf

Terminology

1 Inherited Retinal Dystrophy (IRD):
A hereditary progressive disease presumably caused by a gene mutation. Several diseases that present similar symptoms are collectively referred to as IRD. Its main symptoms include night blindness (difficulty seeing in dim light), tunnel vision (a narrowing field of vision), and progressive loss of vision, which can lead to a complete loss of vision in severe cases. It is estimated that one out of every 4,000 to 8,000 people develops an IRD. The most common IRD subtype is Retinitis Pigmentosa (a designated intractable disease, Notification No: 90).
Disease explanations, Japan Intractable Diseases Information Center (Japanese only):
https://www.nanbyou.or.jp/entry/196

2 Next-generation sequencer:
An analyzer for reading large volumes of DNA base sequences.

3 Low vision care:
To those who experience any difficulty in their daily lives due to vision problems, a wide variety of support is offered, including the provision of advice or medical devices to improve QOL, provision of various counseling and information services on careers and employment, and use of welfare programs.

4 Gene therapy:
A treatment method for diseases caused by genes that are defective or do not function normally in which therapeutic genes are introduced into patient cells to be expressed in the cells, supplementing defective genes with normal genes and thereby achieving therapeutic effects (*in vivo* gene therapy).

5 Combination medical device:
A combination of two or more types of items (pharmaceuticals, medical devices or regenerative medicines) constituting a medical device to be manufactured and marketed.

Sysmex's Materiality

Sysmex has identified "Resolution of medical issues through products and services" as one of the issues that we prioritize (materiality) as we work to develop and supply products with high clinical value. Leveraging our proprietary technology and the global network that we have

cultivated thus far, we continue to strive to contribute to the development of healthcare and the healthy lives of people.

The purpose of this press release is to communicate our business activities to our stakeholders. It may or may not include information about Sysmex's products or their research and development, but this is not intended for promotion, advertising or medical advice. The information contained in this press release is current as of the date of the announcement but may be subject to change without prior notice.