



Press Release

Begun Providing Holter ECG Analysis Service using AI

*-Jointly Developed by Astellas and M. Heart-
-Implementing MYHOLTER II into M.Heart's cloud-type
Holter ECG Analysis service-*

TOKYO and Iwate, July 16, 2021 - Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., "Astellas") and M. Heart Co., Ltd. (Headquarters: Iwate, President and CEO: Yoshimi Mizunuma, "M. Heart") launched "MYHOLTER II", a software for the holter analyzer that the two company jointly developed, on July 15. MYHOLTER II is a program that uses artificial intelligence (AI) to analyze data obtained from Holter electrocardiography and provided to healthcare professionals through M.Heart's cloud-type Holter ECG*¹ analysis service.

Astellas entered into an exclusive license agreement for MYHOLTER II in Japan with M. Heart in May. Based on the license agreement, Astellas will receive a portion of the sales of the cloud-type Holter ECG analysis service using MYHOLTER II by M. Heart. This collaboration, which has been pursued as part of the Rx+[®] program*², is one of the ways Astellas is striving to prevent chronic diseases from becoming severe*³. This is the first full-scale commercialized program in Rx+[®] program.

Astellas and M. Heart have jointly developed MYHOLTER II since December 2019 for the purpose of early detection of atrial fibrillation, which is estimated to affect approximately 700,000 patients in Japan¹. In March 2021, M. Heart obtained certification for MYHOLTER II as a medical device (Class II) software from a certifying body registered by the Minister of Health, Labour and Welfare.

Medical costs for heart diseases and other cardiovascular diseases in Japan exceed 6 trillion yen per year—the highest of any disease category². Of particular concern is cardiogenic cerebral embolism, which occurs when a thrombus that formed in the heart blocks an artery in the brain or neck. This has a high mortality rate (20%) and often results in severe sequelae such as a bedridden state (40%)¹. Atrial fibrillation is said to be the cause of cardiogenic cerebral embolism in 3 out of 4 cases¹. Early detection of atrial fibrillation is an important social issue.

The number of heart beats that are analysed by the Holter ECG amount to 100,000. This is a significant labour burden for healthcare professionals who have to analyze this large amount of data. In addition, there was also the issue of the accuracy of

automatic ECG analysis that had to be addressed. To resolve these issues, Astellas and M. Heart have succeeded in developing an efficient and accurate process for the automatic analysis of ECG data with MYHOLTER II by using an AI-assisted algorithm. This web-based cloud service allows healthcare professionals to conduct ECG data analysis from anywhere. Furthermore, by adopting the international standard, i.e., Medical waveform Format Encoding Rule (MFER^{*4}) compliant data format for the system, an open environment in which many electrocardiograph device manufactures are able to adopt the program is provided. By making ECG examinations "more familiar and easier", we are hoping that this will contribute to the prolongation of healthy life expectancy by promoting early detection and appropriate treatment of atrial fibrillation. Both companies will continue to enhance its AI to improve its diagnostic accuracy using more ECG data obtained from clinical research.

*1 Holter ECG: An exam that continuously records ECGs, 24 hours a day. An electrode is attached to the chest and ECGs are continuously recorded on a small portable recorder to detect pulse irregularities.

*2 Rx+[®] business: A business that leverages the expertise and knowledge of Astellas, which has been cultivated through its prescription drug (Rx) business, integrates innovative medical technology with cutting-edge technology in different fields, contributes to patients through Patient Journey (overall medical care, including diagnostic, preventive, therapeutic, and prognostic care), and creates new revenue streams separate from Astellas' core Rx products. For more information, please visit <https://www.astellas.com/en/partnering/rx-plus>



*3 Astellas Rx+[®] Day (Media Seminar) [March 25, 021] <https://www.astellas.com/jp/en/news/news-library>

*4 MFER: ISO 22077-1:2015 Health informatics - Medical waveform format - Part 1: Encoding rules

About Astellas

Astellas Pharma Inc. is a pharmaceutical company conducting business in more than 70 countries around the world. We are promoting the Focus Area Approach that is designed to identify opportunities for the continuous creation of new drugs to address diseases with high unmet medical needs by focusing on Biology and Modality. Furthermore, we are also looking beyond our foundational Rx focus to create Rx+[®] healthcare solutions that combine our expertise and knowledge with cutting-edge technology in different fields of external partners. Through these efforts, Astellas stands on the forefront of healthcare change to turn innovative science into value for patients. For more information, please visit our website at <https://www.astellas.com/en>.

About M. Heart

M.Heart is a MedTech venture that provides the cloud-type Holter ECG analysis service to medical institutions nationwide using the program "My holter".

Since the data to be analyzed complies with the international standard MFER, it enables collaboration with domestic and overseas electrocardiograph manufacturers and system manufacturers.

Our staff includes doctors, clinical laboratory engineers, IT engineers, marketers, and pharmaceutical consultants, and we will realize business transformation of medical services with innovative technology and diverse imagination.

For more information on M-Heart, please visit our website at <https://www.emheart.co.jp/>

Cautionary Notes (Astellas)

In this press release, statements made with respect to current plans, estimates, strategies and beliefs and other statements that are not historical facts are forward-looking statements about the future performance of Astellas. These statements are based on management's current assumptions and beliefs in light of the information currently available to it and involve known and unknown risks and uncertainties. A number of factors could cause actual results to differ materially from those discussed in the forward-looking statements. Such factors include, but are not limited to: (i) changes in general economic conditions and in laws and regulations, relating to pharmaceutical markets, (ii) currency exchange rate fluctuations, (iii) delays in new product launches, (iv) the inability of Astellas to market existing and new products effectively, (v) the inability of Astellas to continue to effectively research and develop products accepted by customers in highly competitive markets, and (vi) infringements of Astellas' intellectual property rights by third parties.

Information about pharmaceutical products (including products currently in development) which is included in this press release is not intended to constitute an advertisement or medical advice.

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- 1: From Japan Stroke Association, Japanese Heart Rhythm Society, Atrial Fibrillation Weekly Website
- 2: Ministry of Health, Labour and Welfare, 2018 Summary of National Medical Care Expenditures