Press Release

Astellas Announces FDA Listing of DIGITIVA™ for the Management of Heart Failure

- New digital health solution for heart failure management puts patients at the center of their care by providing ability for at-home disease monitoring -

TOKYO, September 18, 2024 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Naoki Okamura, "Astellas") today announced that DIGITIVA™, a non-invasive digital health solution for heart failure management, has been listed with the U.S. Food and Drug Administration (FDA). DIGITIVA is classified as a Class I Software as a Medical Device (SaMD) and is exempt from 510(k) premarket submission*. DIGITIVA is the first digital health offering from Astellas in the U.S.

DIGITIVA is designed to place patients impacted by heart failure at the center of their care, allowing them to take a more active role in managing their health while working in partnership with their care team. DIGITIVA is comprised of three components: the CORE 500™ Digital Stethoscope developed by Eko Health Inc., a smartphone app designed for heart failure patients and built on the Welldoc, Inc. platform, bolstered by educational content from the American Heart Association, and a dedicated clinical review team. The DIGITIVA clinical review team triages patient data, including previously elusive biomarkers specific to heart failure, and notifies the patient's treating physician when certain signals are present that may indicate the patient would benefit from intervention, with the goal of impacting clinical outcomes such as acute decompensation events and re-hospitalizations.

Richard Cassidy, Head of Rx+ Business Accelerator, Astellas
"We believe DIGITIVA has the potential to help patients and their physicians better manage heart failure by providing patients with a new option that facilitates disease monitoring from home, enabling physician intervention, as needed. DIGITIVA was developed within the Astellas Rx+ Business Accelerator and exemplifies our commitment to pioneering digital health technologies that provide personalized and accessible care with the goal of improving health outcomes. This achievement marks a significant milestone for Astellas as we integrate innovative technology with tailored patient support."

Heart failure is a global health issue affecting more than 64 million people worldwide[1]. In the U.S., the prevalence of heart failure is 6.9 million (2020 estimate) and is expected to increase by 24% to nearly 8.5 million by 2030 due to the aging and growth of the U.S. population[2,3,4].

Connor Landgraf, Co-founder and CEO, Eko Health
"The realization of DIGITIVA is a remarkable stride toward transforming the landscape of tools available to manage heart health by bridging the gap between home and clinic care. By joining forces with Astellas, we have seamlessly integrated our cutting-edge CORE 500 Digital Stethoscope and AI technology with a highly engaging DTx app with the goal of moving us toward a future where heart failure is actively managed rather than treated reactively."

Kevin McRaith, President and CEO, Welldoc
"DIGITIVA embodies the potential of digital health by equipping patients with the information, support and resources they need to manage their heart health from the comfort of home. By integrating Welldoc's platform, DIGITIVA provides patients with AI-driven real-time and personalized feedback that can help promote positive lifestyle changes, while also offering physicians data-driven insights for tailored clinical decision-making."

Astellas has already reflected the impact from the FDA listing in its financial forecast of the current fiscal year ending March 31, 2025.

For additional information, the DIGITIVA™ Instructions for Use are linked here[5] and the CORE 500™ Digital Stethoscope Instructions for Use are linked here[6].

*FDA classifies medical devices into three different classes based on the device's safety and effectiveness. Class I includes those devices with the lowest risk, and Class III includes those devices with the greatest risk such as life-supporting or life-sustaining devices. Most Class I and some Class II devices are exempt from FDA's 510(k) premarket review. Virtually all Class III devices require premarket approval (or a PMA) that must be supported by valid scientific evidence (often well-controlled clinical studies) to demonstrate the device is safe and effective for its intended use.

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 Eko Health
Eko Health is a leading digital health company advancing how healthcare professionals detect and monitor heart and lung disease with its portfolio of digital stethoscopes, patient and provider software, and AI-powered analysis. Its FDA-cleared platform, used by over 500,000 healthcare professionals worldwide, allows them to detect earlier and with higher accuracy, diagnose with more confidence, manage treatment effectively, and ultimately give their patients the best care possible. Eko Health is headquartered in Emeryville, California, with over $165 million in funding from ARTIS Ventures, DigiTx Partners, Double Point Ventures, EDBI, Highland Capital Partners, LG Technology Ventures, Mayo Clinic, Morningside Technology Ventures Limited, NTTVC, Questa Capital, and others.

About Welldoc
Welldoc®, a digital health leader revolutionizing cardiometabolic care, is integrating personalized, real-time and actionable insights into the daily lives of individuals living with cardiometabolic conditions, enabling improved health and outcomes. Welldoc's comprehensive digital health platform provides AI-powered digital coaching across pre-diabetes, diabetes, hypertension, heart failure and weight and obesity management, with integrated mental wellbeing and sleep support. Welldoc's flagship product, BlueStar®, is an FDA-cleared digital health solution that guides individuals through the complicated journey of living with diabetes by enabling them to self-manage their care while enhancing connections to their healthcare team. These capabilities are now integrated into the Welldoc platform, providing comprehensive and flexible support across conditions. The company partners with health plans, health systems and employers with the goal of extending care, improving health and reducing costs.

Welldoc has achieved 11510(k) clearances for diabetes functionality within its digital health platform, and an IP portfolio of 45 patents for its advanced AI and first-in-class tech. With over 80 clinical publications, Welldoc has also built an extensive library of clinical research, including many publications focused on the value of combining CGM with AI-powered digital health solutions. Welldoc is an industry thought leader and has been showcased in prestigious conferences and publications, including South by Southwest, the Wall Street Journal and the Economist. The company has been named the "Best Overall Digital Health Company" by MedTech Breakthrough for the past two years, and is regularly recognized for AI innovation. Most recently, Welldoc was awarded the 2024 Innovation Award from the Business Intelligence Group and the 2024 Healthcare AI Impact award by MDRN Leader.

Cautionary Notes
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 and medical device 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 and medical device 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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Contacts for inquiries or additional information:

Astellas Rx+ Business Accelerator Communications
Carly Marcus
+1-310-570-8475
carly.marcus@astellas.com

Astellas Pharma Inc.
Corporate Communications
+81-3-3244-3201

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[3] Heidenreich PA, Albert NM, Allen LA, Bluemke DA, Butler J, Fonarow GC, et al. Forecasting the impact of heart failure in the United States: a policy statement from the American Heart Association. Circ Heart Fail. 2013 May;6(3):606-19.
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[5] DIGITIVA™ Instructions for Use: https://www.astellas.com/en/system/files/1539a14805/digitiva_instructions_for_use.pdf
[6] CORE 500™ Digital Stethoscope Instructions for Use: https://cdn.shopify.com/s/files/1/0715/6111/files/LBL-0002512_CORE_500_IFU_Rev_2.0.pdf?v=1718204855