



Press Release

Astellas and Welldoc Enter into Strategic Alliance for Digital Therapeutics

- Develop and commercialize digital health solutions globally for multiple therapeutic areas, including in Japan for diabetes patients -

TOKYO and Columbia, Maryland, November 20, 2019 - Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., “Astellas”) and Welldoc, Inc. (President, CEO: Kevin McRaith, “Welldoc”) today announced that the companies have entered into a collaboration and license agreement directed toward the development and commercialization of digital health solutions. Under the agreement, Astellas and Welldoc will jointly develop and commercialize BlueStar^{®(1)} in Japan and certain other Asian markets for patients with diabetes, collaborate to broaden the adoption of BlueStar[®] in the U.S. market, and jointly develop and commercialize digital therapeutics in other therapeutic areas globally.

BlueStar[®] is a digital health solution that is cleared by the U.S. Food and Drug Administration (FDA)- in the United States for use by healthcare providers and their patients aged 18 years and older who have type 1 or type 2 diabetes. BlueStar[®] not only assists patients in managing their disease by capturing, storing, and transmitting blood glucose data and tracking medication, diet, activity and exercise, but also uses individual patient treatment data and machine learning to provide tailored motivational, behavioral, and educational coaching messages to aid in diabetes self-management.

FDA initially cleared BlueStar[®] in 2010 and since then Welldoc has received 6 additional 510(k) clearances from the FDA. In the United States, BlueStar[®] is marketed as both a prescription and non-prescription digital health solutions for diabetes. BlueStar[®] is currently marketed in the U.S. and Canada.

Under the terms of the agreement, Astellas will make an upfront payment of \$15 million to Welldoc. In addition, the agreement includes development and commercialization milestones as well as royalties on any future product sales.

“Welldoc is excited to collaborate with Astellas as part of our evolution as a digital health company with a commitment to help improve the health of those living with chronic disease,” said Kevin McRaith, President and CEO of Welldoc. “Astellas is a

critical partner as Welldoc looks to broaden our platform into other disease areas as well as expand into other global markets.”

“Under our Strategic Plan 2018, Astellas is committed to developing Rx+™⁽²⁾ programs, which aim to create new, clinically relevant healthcare solutions (Rx+™) that combine expertise gained from its prescription drug (Rx) business with technology and knowledge from different fields. Our alliance with Welldoc, a pioneer in the digital therapeutics field, is part of this commitment,” said Naoki Okamura, Representative Director Corporate Executive Vice President, Chief Strategy Officer and Chief Financial Officer, Astellas. “Advances in digital technology are bringing dynamic innovations to the healthcare field. Astellas is proactively investing in this field to take advantage of these advances.”

The impact of this alliance on Astellas’ financial results in the fiscal year ending March 31, 2020 is expected to be limited.

(1)BlueStar®: BlueStar® is a digital health solution that is cleared by FDA for use by adults with type 1 or type 2 diabetes. In addition to assisting patients in managing their disease in line with the guidelines compiled by the American Association of Diabetes Educators (AADE), namely, taking medication, eating well, and being active, it offers a management method for individual patients’ blood glucose levels made possible by machine learning and artificial intelligence that uses compiled treatment data to provide tailored coaching messages to aid in diabetes self-management. BlueStar® also comes with a diagnosis support system for physicians, which allows patients to share data on blood glucose levels, medication, and physical conditions, as well as the status of progress, with physicians before examination.

(2)Astellas’ Rx+™ Business: A business that leverages the expertise and knowledge of Astellas, which have 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.

About Astellas

Astellas Pharma Inc., based in Tokyo, Japan, is a company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. For more information, please visit our website at <https://www.astellas.com/en>

About Welldoc

Welldoc® is a leading digital health company revolutionizing chronic disease management to help transform lives. BlueStar® helps guide individuals through the complicated journey of living with chronic diseases, with a goal of helping them self-manage their conditions, while connecting them to their own healthcare team. For more information, please visit us at <https://www.welldoc.com/>

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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