



Press Release

**Astellas and Roche Diabetes Care Japan ink partnership agreement to develop and commercialize integrated diabetes self-management solution with BlueStar®**

- Accu-Chek® Guide Me glucose meter to be paired with *BlueStar®* in Japan, which is being jointly developed by Astellas and Welldoc -
- Initiation of clinical trial planned for fiscal year 2023 -

**TOKYO and Columbia, Maryland, March 29, 2023** - Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., “Astellas”) today announced that it has entered into an agreement (“the Agreement”) with Roche Diabetes Care Japan Co., Ltd. (Country Manager: Noriko Hattori, “Roche Diabetes Care Japan”) for the development and commercialization of Roche Diabetes Care’s world-renowned Accu-Chek® Guide Me blood glucose monitoring system with advanced accuracy as a combined medical product with BlueStar®<sup>1</sup>. BlueStar is an FDA-cleared digital health solution for diabetes patients, developed by Welldoc, Inc. (President, CEO: Kevin McRaith, “Welldoc”) and is currently marketed in the U.S. and Canada. Astellas and Welldoc are jointly developing BlueStar in Japan. In the future, Astellas will aim to obtain regulatory approval and reimbursement as a combined medical product.



Image of Roche Diabetes Care’s world-renowned Accu-Chek® Guide Me blood glucose meter (right) and Welldoc’s BlueStar (app)

The combined medical product solution, which is being developed in Japan, is expected to support patients with managing their diabetes by capturing, storing, and transmitting blood glucose data which is obtained from Roche Diabetes Care's Accu-Chek® Guide Me system and track medication, diet, activity and exercise in Welldoc's BlueStar(app). It is also expected to support patients' diabetes self-management with a unique algorithm designed using AI, and personalized digital coaching messages, focused on building better habits over time. Astellas is responsible for the clinical trials of the combined medical product, which are scheduled to start during 2023.

In Japan, the number of people with diabetes and the number of people with prediabetes is estimated to be approximately 10 million respectively<sup>1</sup>, and there is a substantial unmet medical need in this area. In addition to existing treatments, the development of novel digital solutions that support patients and healthcare professionals in managing these conditions is gaining traction.

"Under our [Corporate Strategic Plan 2021](#), "Advance the [Rx+](#)® businesses" is one of the strategic goals Astellas is committed to." said Naoki Okamura, Chief Strategy Officer of Astellas. "We hope that we can deliver greater VALUE to patients by expanding our partnership with Welldoc through BlueStar and connected insights with Roche Diabetes Care's glucose meters."

"Together with Astellas, Roche Diabetes Care is making innovations in diabetes care more accessible through connected devices and digital products, to bring true relief for people living with diabetes," said Noriko Hattori, Country Manager of Roche Diabetes Care Japan. "We are creating patient-centered value by enabling access to relevant data insights for informed diabetes therapy management, facilitating clinical development and regulatory and reimbursement decisions."

"BlueStar empowers individuals living with diabetes to take control of their health, manage complexities associated with their condition and connect with their care teams," said Kevin McRaith, CEO of Welldoc. "At Welldoc, we are driving new possibilities for people living with chronic conditions with one, comprehensive, scalable digital health solution. We are proud of our partnership with Astellas, which aims to bring a new standard of care in diabetes to a broader population in Asia."

Astellas, Roche Diabetes Care Japan, and Welldoc aim to provide new treatment options and contribute to patients suffering from diabetes by developing Roche Diabetes Care's Accu-Chek® Guide Me blood glucose monitoring system as a combined medical product with BlueStar® in Japan.

\*1 **BlueStar®**: Welldoc's U.S. Food and Drug Administration (FDA)-cleared BlueStar®\* Mobile Digital Health Application is for adults living with type 1 or type 2 diabetes. BlueStar delivers personalized, AI - driven digital coaching and insights to individuals so that they are able to better self-manage their conditions and build better habits throughout their journey. These insights are also easily shared with care teams to support data-driven interventions and clinical decisions. The solution currently has non-prescription and prescription based features for complex diabetes management, such as insulin management capabilities and a basal/bolus insulin calculator. BlueStar currently holds 9 FDA clearances for diabetes management capabilities and is currently marketed in the U.S and Canada. Astellas and Welldoc entered a strategic agreement in November 2019 for co-development and co-commercialization of BlueStar in Japan and certain Asian markets.

\*2 **A combined medical product**: Combination of medical equipment needed for diagnosis or treatment, which is subject to regulatory oversight.

#### **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 Roche Diabetes Care**

Roche Diabetes Care has been pioneering innovative diabetes technologies and services for more than 40 years. More than 5,000 employees in over 100 markets worldwide work every day to support people with diabetes and those at risk to achieve more time in their target ranges and experience true relief from the daily therapy routines.

Being a global leader in integrated Personalised Diabetes Management (iPDM), Roche Diabetes Care collaborates with thought leaders around the globe, including people with diabetes, caregivers, healthcare providers and payers. Roche Diabetes Care aims to transform and advance care provision and foster sustainable care structures. Under the brands RocheDiabetes, Accu-Chek® and mySugr®, comprising glucose monitoring, insulin delivery systems and digital solutions, Roche Diabetes Care unites with its partners to create patient-centred value. By building and collaborating in an open ecosystem, connecting devices and digital solutions as well as contextualise relevant data points, Roche Diabetes Care enables deeper insights and a better understanding of the disease, leading to personalised and effective therapy adjustments. For better outcomes and true relief.

For more information, please visit [rochediabetes.com](http://rochediabetes.com), [accu-chek.com](http://accu-chek.com) and [mysugr.com](http://mysugr.com)

#### **About Welldoc**

Welldoc®, a digital health leader revolutionizing chronic care, is integrating personalized, real-time and actionable insights into the daily lives of individuals living with chronic conditions, enabling improved

health and outcomes. Welldoc's comprehensive chronic care platform provides multi-condition support across diabetes, hypertension, heart failure and behavioral health. Welldoc partners with health plans, health systems and employers with the goal of extending care, improving health and reducing costs. For more information, visit [www.welldoc.com](http://www.welldoc.com). Follow us on [LinkedIn](#) and [Twitter](#).

**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: The National Health and Nutrition Survey 2016 conducted by the Ministry of Health, Labour, and Welfare