Media & Investor Release

Roche receives CE Mark for its AI-enabled continuous glucose monitoring solution offering critical predictions to people living with diabetes

- **The Accu-Chek® SmartGuide CGM solution provides 14 days of accurate[1] real-time glucose values for adults living with type 1 and type 2 diabetes on flexible insulin therapy.**
- **The built-in AI-trained algorithms will empower users to proactively intervene when their glucose levels require attention and before a complication can even occur.**
- **The solution is set to launch in selected European markets in the coming months.**

Basel, 09 July 2024 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that it has received the CE Mark for its Accu-Chek SmartGuide® continuous glucose monitoring (CGM) solution. This significant milestone paves the way for the solution to be made available to people living with type 1 and type 2 diabetes over the age of 18 on flexible insulin therapy.

“Maintaining optimal blood glucose levels and preventing adverse glycaemic episodes remains a complex task for people living with diabetes, often necessitating up to 180 therapy decisions a day[2],” said Matt Sause, CEO of Roche Diagnostics. “Our novel CGM solution with its predictive algorithms will help address significant unmet needs associated with diabetes management, empowering users to take control of their condition and live better and healthier lives.”

Despite CGM technology's demonstrated positive impact on glycaemic control,[3] a significant proportion of people living with diabetes still do not meet glycaemic targets - even when using a CGM system.[4] Moreover, they typically encounter an average of two hypoglycaemic episodes a week, with 1-2 of these being severe enough to require medical intervention each year.[5] Notably, nighttime hypoglycaemia is associated with reduced quality of life, increased anxiety, and fear. The persistent fear of hypoglycaemia, hypoglycaemia unawareness, sleep disruption, and diabetes-related distress among CGM users frequently correlates with elevated glucose levels.[6]

The Accu-Chek SmartGuide CGM solution aims to address those critical unmet needs. Every five minutes, the Accu-Chek SmartGuide CGM sensor sends glucose values measured in real time to the Accu-Chek SmartGuide app. The Accu-Chek SmartGuide Predict app then utilises those glucose values and other available information to detect glucose patterns and predict future glucose levels. Its integrated AI-enabled predictive algorithms indicate hypoglycaemia

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risk within the next 30 minutes, continuously forecast how glucose levels will develop within the next two hours, and estimate the risk of nocturnal hypoglycaemia. As such, Roche's new CGM solution is designed to alleviate people living with diabetes' and caregivers' concerns about nighttime hypoglycaemia and lower its risk. It aims to support informed therapy self-management decisions, enabling proactive intervention before glucose levels require immediate attention.

Clinical evaluations have demonstrated the new CGM solution's high system accuracy, with an overall mean absolute relative difference (MARD) of 9.2% and 99.8% of measured glucose values falling within zones A and B on the Parkes Error Grid.[7] The evaluation of the predictive capabilities showed that all advanced predictive features exceeded high performance requirements as e.g. accuracy, sensitivity, specificity, and events detected.[1]

About the Accu-Chek SmartGuide CGM solution

Accu-Chek SmartGuide is a continuous glucose monitoring (CGM) solution developed by Roche providing accurate real-time glucose readings and predictions for different timeframes. The solution includes 3 elements: the Accu-Chek SmartGuide CGM sensor, the Accu-Chek SmartGuide App and the Accu-Chek SmartGuide Predict App. With an all-in-one applicator and 14-day wear time, Accu-Chek SmartGuide is designed for people living with diabetes type 1 and type 2 on flexible insulin therapy, 18 years of age and older. It aims at empowering people living with diabetes to be prepared for the future course of glucose levels and take preventive action by making the appropriate therapy adjustments in good time.

The Accu-Chek SmartGuide solution seamlessly integrates with the Accu-Chek® Care platform, offering healthcare professionals (HCP) access to comprehensive and accurate therapy-relevant data provided by the CGM solution. This integration allows HCPs to analyse together with their patients how lifestyle and therapy impact their glucose levels and make more informed decisions. Such personalised care can lead to improved outcomes.that

About Roche

Founded in 1896 in Basel, Switzerland, as one of the first industrial manufacturers of branded medicines, Roche has grown into the world's largest biotechnology company and the global leader in in-vitro diagnostics. The company pursues scientific excellence to discover and develop medicines and diagnostics for improving and saving the lives of people around the world. We are a pioneer in personalised healthcare and want to further transform how healthcare is delivered to have an even greater impact. To provide the best care for each person we partner with many stakeholders and combine our strengths in Diagnostics and Pharma with data insights from the clinical practice.

In recognising our endeavour to pursue a long-term perspective in all we do, Roche has been named one of the most sustainable companies in the pharmaceuticals industry by the Dow Jones Sustainability Indices for the fifteenth consecutive year. This distinction also reflects our efforts to improve access to healthcare together with local partners in every country we work.

Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan.

For more information, please visit www.roche.com.

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Calibration required for insulin dosing as requested by the Accu-Chek SmartGuide app

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