Roche

Roche presents positive topline CGM accuracy data at the 17th International Conference on Advanced Technologies and Treatments for Diabetes

- **At the 17th International Conference on Advanced Technologies and Treatments for Diabetes (ATTD) in Florence, Italy, Roche shared recent accuracy data for its new Accu-Chek SmartGuide solution for real-time continuous glucose monitoring (rtCGM).**
- **International experts discussed how a novel CGM solution using prediction capabilities can address unmet needs of people with diabetes at the Roche symposium.**
- **The presented study results underlined the accurate and safe performance of the solution.**

Basel, 7 March, 2024 - Roche (SIX: RO, ROG; OTCQX: RHHBY) presented the latest data on its novel solution for continuous glucose monitoring. The solution consists of a CGM sensor and two apps designed to display current glucose values and predictions over 30 minutes and two hours. In addition, it features a risk prediction for nocturnal hypoglycemia. Roche is currently working on obtaining CE mark for the Accu-Chek SmartGuide device and will start to launch the solution in selected European countries soon after the clearance.

During the company's symposium on the occasion of the 17th ATTD International Conference in Florence, Italy, chaired by Professor Chantal Mathieu, University of Leuven, Belgium and Professor Francesco Giorgino, University of Bari, Italy, recent accuracy and performance data of the new CGM solution were shared. Despite the advancements made in diabetes therapy and the increased uptake of technology over recent years, still only 55-60% of people with diabetes reach their therapy goals.[1,2] This underlines the many unmet needs and challenges people with diabetes have in the daily management of their condition. "Fear of hypoglycaemia or hypoglycaemia unawareness, sleep disruption, intrusion in daily life and distress caused by device alarms and alerts are just some examples of the many daily challenges a person with diabetes faces", highlighted Professor Pratik Choudhary, University of Leicester, United Kingdom.

The Accu-Chek SmartGuide CGM solution aims to address these unmet needs. Study evidence and participants' feedback presented by Professor Julia Mader, University of Graz, Austria, underscore the sound performance, accuracy and safety of the sensor. The study included 48 people with type 1 or type 2 diabetes wearing three sensors for a period of 14 days each. The study results showed a high system accuracy with an overall mean absolute relative deviation (MARD) of 9.2% and 99.8% of the measured glucose values in zones A and B on the Parkes Error Grid.[3] "The Accu-Chek SmartGuide solution is not only highly accurate and robust in its performance in a clinical setting, but also during routine day evaluation", illustrated Professor Mader, "In addition, 83% of our study participants liked

or very much liked the Accu-Chek SmartGuide CGM device and about 80% liked or very much liked the app design."

In the symposium, the Accu-Chek SmartGuide CGM solution was demonstrated to provide users with predictive insights ahead of time. Beyond the retrospective and current view on glucose values and trend estimations, it will indicate the risk of hypoglycemia in the next 30 minutes and continuously forecast how glucose will develop in the next two hours. In addition, it will estimate the risk of nocturnal hypoglycemia. "This empowers users to be in control and take preventive decisions to adjust their therapy and pre-empt complications", stated Professor Lutz Heinemann, Duesseldorf, Germany. "Using the potential of predictive algorithms contributes to less troubleshooting and unforeseen glucose excursions, less fear of hypoglycemia and less diabetes burden." The evaluation of the Accu-Chek SmartGuide Predict app showed that all advanced predictive features exceeded the high performance requirements.[3]

"We are very excited to present these positive study results of our innovative and differentiating Accu-Chek SmartGuide CGM device for the first time", says Dr. Marcel Gmuender, Global Head of Roche Diabetes Care. "Providing users with predictive capabilities will empower them to proactively adapt their therapy so they can maintain optimal glycemic control and prevent dangerous short and long term complications." He concluded, "We know from recent research that glucose predictions provide people with diabetes with invaluable insights to navigate the complexities of the disease. This is one element that can help to lower the burden of daily diabetes management."[4]

Sources:
1 Fang, M. J Gen Intern Med 35, 1427–1434 (2020) | 2 Sims, EK et al., Nat Med. 2021 Jul;27(7):1154-1164. | 3 Roche Data on file; data presented at Roche-sponsored symposium at the 17th ATTD International Conference, March 6, 2024, Florence, Italy (symposium recording to be available here) | 4 Ehrmann, D. et al, European association for the study of diabetes, 2023, Short-oral: "Anticipated reduction in hypoglycaemia fear and diabetes distress from increasing the glucose prediction of current CGM algorithms", publication submitted JDST.

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