FDA clears Accu-Chek Combo system - Roche’s new interactive insulin pump system for people with diabetes

The system will be available in the United States in the second half of 2012

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that it has received clearance from the U.S. Food and Drug Administration (FDA) for the Accu-Chek Combo system for insulin pump therapy. The Accu-Chek Combo system seamlessly combines a blood glucose meter with an insulin pump, which are able to exchange data in both directions via Bluetooth wireless technology. The meter not only enables the user to quickly test blood glucose levels: It allows for operating the insulin pump remotely and by means of an easy-to-handle bolus advisor it provides support in defining the right amount of insulin. With this the Accu-Chek Combo system not only supports a more targeted therapy management, but it also allows for a discrete insulin administration without the need to touch the pump.

“We are very pleased to announce that our new insulin pump system will soon be available for people with diabetes in the U.S.,” said Daniel O’ Day, COO Roche Diagnostics. “With this clearance we are now looking forward to launch the second device in the U.S. this year, after the successful clearance of the Accu-Chek Nano SmartView system in the first quarter. Both launches represent a significant milestone for our Diabetes Care business.”

According to the 2011 National Diabetes Fact Sheet published by the Centers for Disease Control and Prevention, more than 25 million people in the U.S. live with diabetes. It is also estimated that 79 million people live with pre-diabetes in the U.S.

“The Accu-Chek Combo system clearly demonstrates Roche’s dedication to integrated diabetes management solutions, combining the technical components for blood glucose monitoring, data management and insulin delivery. This new system is designed to support insulin pump patients in managing diabetes easily and discretely in their everyday life,” said Luc Vierstraete, Head of Roche Diabetes Care.
The Accu-Chek Combo system has been launched successfully in several European and APAC (Asia-Pacific) countries already - including France, Germany, UK, and Australia.

**About the Accu-Chek Combo system:**
In addition to being discrete and easy-to-use, the Accu-Chek Combo system also features:
- Bluetooth technology for two-way wireless communication between the smart meter and the insulin pump;
- A full-color display that brings to life blood glucose data, insulin dose information and pump settings;
- A bolus advice function on the meter to allow users to easily calculate and deliver a bolus without touching the pump;
- Flexibility to adjust the basal rate to as low as 0.05 units per hour – in increments as precise as 0.01 units; and
- An insulin cartridge that holds up to 315 units of insulin, the largest capacity among pumps sold in the U.S.

**About Roche Diabetes Care**
Roche Diabetes Care is a pioneer in the development of blood glucose monitoring systems and a global leader for diabetes management systems and services. For more than 35 years, the Accu-Chek brand has been dedicated to enable people with diabetes to live life as normal and active as possible as well as to empower healthcare professionals manage their patients’ condition in an optimal way. Today, the Accu-Chek portfolio offers people with diabetes and healthcare professionals innovative products and impactful solutions for convenient, efficient and effective diabetes management spanning from blood glucose monitoring through information management to insulin delivery. The Accu-Chek brand encompasses blood glucose meters, insulin delivery systems, lancing devices, data management systems and education programs – leading to an improved medical outcome.
For more information, please visit [www.accu-chek.com](http://www.accu-chek.com).

**About Roche**
Headquartered in Basel, Switzerland, Roche is a leader in research-focused healthcare with combined strengths in pharmaceuticals and diagnostics. Roche is the world’s largest biotech company with truly differentiated medicines in oncology, virology, inflammation, metabolism and CNS. Roche is also the world leader in in-vitro diagnostics, tissue-based cancer diagnostics and a pioneer in diabetes management. Roche’s personalized healthcare strategy aims at providing...
medicines and diagnostic tools that enable tangible improvements in the health, quality of life and survival of patients. In 2011, Roche had over 80,000 employees worldwide and invested over 8 billion Swiss francs in R&D. The Group posted sales of 42.5 billion Swiss francs. Genentech, United States, is a wholly owned member of the Roche Group. Roche has a majority stake in Chugai Pharmaceutical, Japan. For more information: www.roche.com.

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