Basel, 10 July 2013

Roche halts investigation of aleglitazar following regular safety review of phase III trial

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that following the results of a regular safety review of the aleglitazar AleCardio phase III trial, the independent Data and Safety Monitoring Board (DSMB) has recommended to halt the trial due to safety signals and lack of efficacy. Based on this recommendation, Roche has decided to terminate the AleCardio trial and all other trials involving aleglitazar.

“The safety of patients is our first priority. Roche is working with investigators to support the management of patients and their transition from aleglitazar treatment to other blood sugar control therapies,” said Hal Barron M.D., Chief Medical Officer and Head, Global Product Development. “We are disappointed by this outcome as we hoped that aleglitazar would provide significant benefit for patients with type 2 diabetes who are at risk of cardiovascular disease.”

The AleCardio trial evaluated the efficacy and safety of aleglitazar in patients with a recent acute coronary syndrome event and type 2 diabetes. The data from the trial will be further analysed to fully understand the findings and will be made available at a future medical meeting.

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, infectious diseases, inflammation, metabolism and neuroscience. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management. Roche’s personalised healthcare strategy aims at providing medicines and diagnostic tools that enable tangible improvements in the health, quality of life and survival of patients. In 2012 Roche had over 82,000 employees worldwide and invested over 8 billion Swiss francs in R&D. The Group posted sales of 45.5 billion Swiss francs. 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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**Roche Group Media Relations**

Phone: +41 61 688 8888 / e-mail: basel.mediaoffice@roche.com
- Alexander Klauser (Head)
- Silvia Dobry
- Daniel Grotzky
- Štěpán Kráčala