

Basel, 18 June 2010

Roche announces amendment of the trial protocols for the taspoglutide Phase III programme

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced the implementation of a risk mitigation plan in the taspoglutide Phase III programme.

In the Phase III studies, the incidence of hypersensitivity reactions reported as related to taspoglutide is higher than expected for the study population, although it remains uncommon (i.e. incidence < 1%). The most frequently reported symptoms in patients who developed hypersensitivity reactions were skin reactions and gastrointestinal symptoms, while cardiovascular and respiratory symptoms were less frequent. All patients recovered without complications.

Roche has identified a potential association between hypersensitivity reactions and anti-drug antibodies (ADAs). In consultation with the FDA, Roche has decided to implement a risk mitigation plan which has been communicated to Health Authorities globally. The plan is designed to identify patients at potential risk of these reactions. As such, ADA levels will be routinely monitored and patients that develop pre-specified ADA levels will discontinue treatment and continue to be monitored in the trials.

The continued safety of patients in our clinical development programmes remains the highest priority for Roche and we are committed to working with Health Authorities globally to continue the development of taspoglutide to meet the needs of patients with type 2 diabetes. Roche is investigating the cause of the hypersensitivity reactions and testing specific means to resolve this issue.

The impact of this plan on the project and in particular on the timelines for regulatory filing are currently being assessed, however, a minimum of 12 to 18 months delay is anticipated.

Roche looks forward to sharing with the medical community, at the forthcoming American Diabetes Association, data from five Phase III trials demonstrating that taspoglutide delivered combined benefits of consistent, robust glycemic control across a wide spectrum of patients versus exenatide, sitagliptin and even the highest dose of insulin glargine used in a development program. In addition, taspoglutide was associated with a low risk of hypoglycaemia and clinically important weight loss. Over the next few weeks, Roche also expects to get the headline data on the 52-weeks extended trials.

Roche exercised its licensing option for taspoglutide from Ipsen in 2006 and acquired exclusive worldwide rights to develop and market taspoglutide, except in Japan where these rights are shared with Teijin and in France where Ipsen has elected to retain co-marketing rights.

About the T-emerge Programme

The T-emerge Phase III clinical trial programme is designed as multicenter, multi-country, randomized, controlled (active or placebo), double-blind and open studies. Over 6,000 patients have been enrolled in the eight studies that comprise the T-emerge programme. Studies include two parallel taspoglutide arms including 10 mg once weekly and 10 mg once weekly titrated up to 20 mg once weekly after four weeks. Four of the eight studies have active comparators, including exenatide, sitagliptin, insulin glargine and pioglitazone.

About Taspoglutide

Taspoglutide is the first once-weekly human glucagon-like peptide-1 (GLP-1) analogue being developed to address the important unmet needs of patients with type 2 diabetes. Taspoglutide is similar to the naturally occurring human hormone GLP-1 which plays a key role in blood glucose

modulation while slowing down food absorption and suppressing appetite resulting in glycemic control, weight loss and no incremental risk of hypoglycemia. Taspoglutide is currently in Phase III clinical trials. The most common side effects observed in patients taking taspoglutide in the clinical development programme were gastrointestinal and injection site reactions.

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 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 2009, Roche had over 80,000 employees worldwide and invested almost 10 billion Swiss francs in R&D. The Group posted sales of 49.1 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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Roche IR Contacts:

Dr. Karl Mahler

Phone: +41 (0)61 687 85 03

e-mail: karl.mahler@roche.com

Dianne Young

Phone: +41 (0)61 688 93 56

e-mail: dianne.young@roche.com

Dr. Sabine Borngräber

Phone: +41 (0)61 688 80 27

e-mail: sabine.borngraeber@roche.com

Dr. Nicolas Dunant

Phone: +41 (0)61 687 05 17

e-mail: nicolas.dunant@roche.com

Dr. Nina Mojas

Phone: +41 (0) 61 687 13 00

e-mail: nina.mojas@roche.com

Thomas Kudsk Larsen

Phone: +1 973 235 3655

Mobile phone: +1 973 393 5315

e-mail: thomas_kudsk.larsen@roche.com

Nina Sachdev

Phone: +1 973 562 2793

Mobile phone: +1 973 362 5098

e-mail: nina.sachdev@roche.com

Science Support:

Susan Morris, Diane Schrick, Nadine O'Campo

Phone: +1 650 225 4150

e-mail: morris.sue@gene.com; schrick.diane@gene.com; ocampo.nadine@gene.com