Roche and Biogen Idec Announce Their Decision to Discontinue the ocrelizumab Clinical Development Programme in Patients with Rheumatoid Arthritis

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BASEL, Switzerland & CAMBRIDGE, Mass.--(BUSINESS WIRE)--Roche (SIX: RO, ROG; OTCQX: RHHBY) and Biogen Idec (NASDAQ: BIIB) today announced their decision to discontinue the ocrelizumab clinical development programme in patients with rheumatoid arthritis (RA).

Following a detailed analysis of the efficacy and safety results from the RA programme, the companies concluded that the overall benefit to risk profile of ocrelizumab was not favourable in RA taking into account the currently available treatment options.

The ocrelizumab RA program included four Phase III studies (SCRIPT, FILM, FEATURE, and STAGE). Most recent analysis included available safety and efficacy data from the SCRIPT Phase III study in patients with previous inadequate response (IR) to TNF-inhibitors and safety data from the Phase III FILM study in patients who were methotrexate (MTX) naïve.

Steps are being taken to inform physicians involved in RA clinical trials to continue patient monitoring as defined in the study termination protocols.

Results from the Phase III ocrelizumab RA programme will be made available to the medical community at an appropriate medical forum.

Ocrelizumab is also being evaluated for relapsing remitting multiple sclerosis (RRMS). Treatment in the ocrelizumab RRMS Phase II study is ongoing and data from this study will be submitted for presentation at the upcoming ECTRIMS conference.

“We thank the investigators and patients who participated in the RA clinical studies. Although this outcome is disappointing for patients, Roche remains committed to the development of treatments for RA,” said Hal Barron M.D., executive vice president, Global Development and chief medical officer, Roche.

In March, Roche and Biogen Idec announced the suspension of treatment in the ocrelizumab RA program. This decision followed a recommendation from the independent ocrelizumab RA & Lupus Data and Safety Monitoring Board (DSMB). The DSMB concluded that the safety risk outweighed the benefits observed in these specific patient populations at that time based on an infection related safety signal which included serious infections, some of which were fatal, and opportunistic infections. Subsequently, the U.S. Food and Drug Administration (FDA) placed the RA studies on clinical hold.

About ocrelizumab

Ocrelizumab is a humanised molecule which selectively targets CD20 positive B cells and has been developed specifically for use in autoimmune diseases such as RA. Ocrelizumab interferes with the inflammatory cascade in RA, inhibiting the series of reactions which lead to the symptoms and irreversible joint damage experienced by people with RA.

About the ocrelizumab RA programme

Two ocrelizumab dose levels have been studied in the phase III RA programme across the various patient populations.

STAGE (DMARD-IR population), and SCRIPT (TNF-IR population) studies are Phase III, international, randomised, double-blind placebo controlled, parallel group studies, consisting of a 48-week double-blind treatment period followed by an open label study extension period. During the double-blind treatment periods, patients received 2 courses at 6 month intervals of either ocrelizumab (at a dose of 2 infusions of 200mg or 2 infusions of 500mg) or placebo by intravenous infusion on days 1 and 15 as well as week 24 and 26, with traditional DMARD(s) as a background therapy. Eligible patients in the study extension period could receive open label treatment with ocrelizumab 500mgx2 at the investigators discretion.

FILM is a Phase III, double-blind placebo controlled, parallel group study with a 2 year double-blind treatment period, followed by an open label study extension period. Patients at baseline received either MTX or MTX and ocrelizumab 200mg (2 infusions) or 500mg (2 infusions). Retreatment was given every 6 months. After week 104, patients could receive open label ocrelizumab at 500mg (2 infusions) every 6 months in the extension period.

FEATURE is a Phase IIIb international randomised, double blind, parallel group study, consisting of a 24-week double-blind placebo-controlled treatment period, followed by a further 24 week double-blind period (not placebo controlled) and a study extension. FEATURE involved patients with active RA who had previously had an inadequate response to treatment with DMARDs and or in previous biologics. During the double-blind placebo-controlled, 24 week treatment period, all patients continued to receive MTX as background therapy and were randomized to one of the following:

- Single infusion of 400mg ocrelizumab on day one and placebo on day 15
- 200mg ocrelizumab infusions on days one and 15
- Placebo infusions on days one and 15

About RA

Rheumatoid arthritis (RA) is an autoimmune disease characterized by inflammation that leads to stiff, swollen and painful joints. This can lead to irreversible joint damage and disability. More than 20 million people worldwide and twice as many women as men suffer from RA.[1] In addition to inflammation of the joints, such as the hands, feet and wrists, RA can cause fatigue, heart disease and increase the likelihood of developing other complications such as osteoporosis, anaemia, and problems with the lungs and eyes.[2] It can shorten life expectancy by around 6-10 years.[3]

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 2008, Roche had over 80,000 employees worldwide and invested almost 9 billion Swiss francs in R&D. The Group posted sales of 45.6 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.

About Biogen Idec

Biogen Idec creates new standards of care in therapeutic areas with high unmet medical needs. Founded in 1978, Biogen Idec is a global leader in the discovery, development, manufacturing and commercialization of innovative therapies. Patients worldwide benefit from Biogen Idec's significant products that address diseases such as lymphoma, multiple sclerosis and rheumatoid arthritis. For product labeling, press releases and additional information about the company, please visit www.biogenidec.com.

[1] WHO report: The global burden of rheumatoid arthritis in the year 2000 http://www.who.int/healthinfo/statistics/bod_rheumatoidarthritis.pdf [Last accessed 6 May 2010]

[2] National Rheumatoid Arthritis Society Website: What is RA? http://www.nras.org.uk/about_rheumatoid_arthritis/what_is_ra/what_is_ra.aspx [Last accessed 6 May 2010]

[3] Firestein GS. Evolving concepts of rheumatoid arthritis. Nature 2003;423:356-361

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