Press Release

SuppreMol releases positive interim Phase Ib/IIa results on SM101 in Primary Immune Thrombocytopenia (ITP) trials

Data confirm excellent safety profile and therapeutic activity

Munich, Germany, 14th February, 2012. SuppreMol GmbH, an autoimmune diseases specialist, today announced interim results of the Phase Ib/IIa clinical trial of SM101 to treat Primary Immune Thrombocytopenia (ITP). SM101 was safe and very well tolerated with encouraging efficacy data.

The Phase Ib section of this randomized, double-blind, placebo-controlled, dose escalating, multi-centric trial enrolled 36 patients that received up to 12 mg/kg intravenous doses of SM101 as weekly administrations for 4 weeks. SM101 was safe and well tolerated. These data also verify findings from the earlier Phase Ia trial in 48 healthy volunteers that did not report any dose limiting toxicity of SM101. The study showed a dose dependent platelet increase confirming the first therapeutic activity of SM101 in humans. In the highest dosage group the increase of platelet level continued throughout the three month follow up period. No ITP rescue treatment was necessary in these patients.

“These exciting results provide convincing evidence and reason for SuppreMol to continue with the further development of SM101 in ITP and other B cell driven autoimmune diseases”, said Prof. Peter Buckel, CEO of SuppreMol GmbH. “We are very encouraged by these data that indicate the efficacy of SM101 in humans, especially the long lasting effect on platelet increase that confirms its fascinating therapeutic potential. SM101 continues to work after only one treatment cycle, unlike current treatments for ITP, possibly due to its new mode of action. In particular, SM101 may require a lower dosage frequency than thrombopoietin receptor agonists.”

SuppreMol intends to report full Phase Ib data at a scientific conference later in 2012.

About SuppreMol

SuppreMol is a privately held biopharmaceutical company developing novel therapeutics for the treatment of autoimmune and allergic diseases. The company is pioneering the development of soluble Fc gamma receptors (FcγRs), which are recombinant autologous therapeutic proteins with a specific immunoregulatory potential. The company plans to develop FcγRs for the treatment of Primary Immune Thrombocytopenia (ITP), Systemic Lupus Erythematosus (SLE), Rheumatoid Arthritis (RA) and other autoimmune conditions. SuppreMol’s pipeline comprises two early antibody development programs utilizing the inhibitory effect of FcγRIIb suitable for alternative treatment strategies and indications as well as an anti-IL-3 antibody to treat RA. SuppreMol was founded in 2002 as a spin-off from the laboratory of Prof. Dr. Robert Huber, Nobel Prize for Chemistry in 1988, at the Max Planck Institute for Biochemistry in Martinsried, Germany. Investors in the company include MIG Fonds, BioMedPartners AG, Santo Holding GmbH and FCP Biotech Holding GmbH along with KfW Mittelstandsbank, Bayern Kapital GmbH, Max Planck Society, and Z-Cube. The study has been in part supported by a grant from the Federal German Ministry of Education and Research (BMBF).

About SM101
SuppreMol's lead candidate SM101 is a recombinant, soluble, non-glycosylated version of the Fcγ receptor IIb. The protein binds to autoantibody/autoantigen complexes and blocks the activation of Fc receptors on the surface of immune cells. As a result, the immune response is down regulated and triggering of the inflammation cascade, typically seen in autoimmune diseases, is prevented. SM101 has been validated in relevant animal models and has shown strong efficacy by decreasing inflammation and immune reactions. At present, SM101 is being developed in Primary Immune Thrombocytopenia (ITP). For this indication, SM101 has received orphan drug designation in the US and Europe. In November 2011 SM101 started a Phase IIa, double-blind clinical trial in patients suffering from Systemic Lupus Erythematosus (SLE). The company believes SM101 may also have potential in Rheumatoid Arthritis (RA) and other B cell driven autoimmune diseases.

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