Press Release

SuppreMol initiates Phase Ib/IIa clinical trial with its lead candidate SM101

Martinsried/Munich, Germany, April 12, 2010 -- SuppreMol GmbH, a privately held biopharmaceutical company developing novel therapeutics for the treatment of autoimmune diseases, today announced the initiation of a Phase Ib/IIa clinical trial with its lead product SM101 in Idiopathic Thrombocytopenic Purpura (ITP).

The first patient in the multi-centric, randomized, double-blind, placebo-controlled, dose escalating study has been enrolled in Poland. In the Phase Ib, up to 36 patients will receive repeated doses of SM101 weekly for four weeks, or matching placebo intravenously. Subsequently, SuppreMol plans to enroll an additional 15 patients to expand the study to a Phase IIa parallel-group clinical trial, which will be conducted in Germany, Belgium, Poland, and Russia.

The primary endpoint is safety based on the incidence of adverse events according to the Common Terminology Criteria for Adverse Events (CTCAE). The main efficacy endpoint is the proportion of subjects with a substantial platelet response (i.e. more than 30,000 platelets/µl blood). Secondary endpoints comprise number of bleeding events, time to reach platelet response, duration of platelet response, proportion of subjects with rescue medication, and dose reduction of concomitant ITP medication.

In a Phase Ia trial in 48 healthy volunteers started in April 2009 no SM101-associated adverse reactions have been observed. Detailed results of this study will be published soon.

"Following the successful completion of the Phase Ia trial in March this year, we are very pleased to expand our clinical studies with our lead molecule SM101," said Peter Buckel, CEO of SuppreMol. "We are looking forward to completing the Phase Ib/IIa trial by December, 2011, and to generate some initial data on the efficacy of SM101 by February, 2011 from phase Ib then."

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Notes to Editors

About SM101

SuppreMol's lead product SM101 is a recombinant, soluble, non-glycosylated version of the Fc-receptor FcγRIIb. The protein binds to autoantibody/autoantigen complexes and blocks the triggering of Fc-receptors on the surface of immune cells. As a result, the immune response is downregulated and the activation of the inflammation cascade typically seen in autoimmune diseases is prevented.

SM101 has been validated in relevant animal models and has shown strong efficacy in terms of decrease in inflammation and immune reaction.

At present, SM101 is being developed in Idiopathic Thrombocytopenic Purpura (ITP). SuppreMol has been granted orphan medicinal product designation in the EU for this indication. The Company believes SM101 may also have potential in Systemic Lupus Erythematosus (SLE), Rheumatoid Arthritis (RA) and other autoimmune diseases.

About SuppreMol

SuppreMol is a privately held biopharmaceutical company developing novel therapeutics for the treatment of autoimmune diseases. The company is pioneering the development of soluble Fcγ-Receptors (sFcγRs), which are recombinant autologous therapeutic proteins with a proven strong immunosuppressive potential. The company plans to develop sFcγRs for the treatment of Idiopathic Thrombocytopenic Purpura (ITP), Systemic Lupus Erythematosus (SLE), Rheumatoid Arthritis (RA) and other autoimmune conditions.

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. The Company has raised EUR 19.7 million in two financing rounds since May 2006 and received a EUR 1.75 million “Innovative Therapeutics” grant from the BMBF in March 2007 as well as additional funding by BMBF's “BioChance” program in 2009.

Contact

Dr. Peter Buckel, CEO
SuppreMol GmbH
Am Klopferspitz 19
82152 Martinsried/München
Germany
tel +49 (0)89 30 90 50 680
fax +49 (0)89 30 90 50 68 68
info@suppremol.com
www.suppremol.com