Press Release

SuppreMol Completes Successful Pre-IND Meeting with FDA

Martinsried/Munich, Germany, January 24, 2011 -- SuppreMol GmbH, a privately held biopharmaceutical company developing innovative therapeutics for the treatment of autoimmune diseases, today announced that it has successfully completed a pre-Investigational New Drug Application (pre-IND) meeting with the U.S. Food and Drug Administration (FDA) for its lead compound SM101, which is being developed for the treatment of Primary Immune Thrombocytopenia (ITP) and Systemic Lupus Erythematosus (SLE).

Already, SM101 has successfully completed a Phase Ia trial in 48 healthy volunteers without observation of any SM101-associated adverse reactions. In April 2010, SM101 entered a multi-centric, randomized, double-blind, placebo-controlled, Phase Ib/IIa dose escalating study. In the Phase Ib, up to 36 patients will receive repeated intravenous doses of SM101 or matching placebo once weekly over a period of four weeks. 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 and doubling of platelet count). 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.

„We now have discussed the subsequent development plan for SM101 in ITP, including the design of a Phase III study," said Sascha Tillmanns, Medical Director of SuppreMol. "During the meeting, the FDA has provided very helpful comments on our study protocols. We will now incorporate the FDA's recommendations and are very confident that we can meet our planned development schedule."

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Notes to Editors

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 Fc gamma receptors (sFc©Rs), which are recombinant autologous therapeutic proteins with a proven, strong immunosuppressive potential. The company plans to develop sFc©Rs for the treatment of Primary Immune Thrombocytopenia (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 35.2 million in three financing rounds since May 2006 and received over EUR 2 million from BMBF research grants since 2007.

About SM101
SuppreMol's lead candidate SM101 is a recombinant, soluble, non-glycosylated version of the Fc© receptor IIb. 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 Primary Immune Thrombocytopenia (ITP). SuppreMol has been granted orphan medicinal product designation in the EU as well as orphan drug designation in the US for this indication. The company believes SM101 may also have potential in Systemic Lupus Erythematosus (SLE), Rheumatoid Arthritis (RA) and other autoimmune diseases.

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