Press Release

SuppreMol Receives U.S. Orphan Drug Designation for SM101

Martinsried/Munich, Germany, April 19, 2010 -- SuppreMol GmbH, a privately held biopharmaceutical company developing novel therapeutics for the treatment of autoimmune diseases, today announced that the FDA's Office of Orphan Products Development has granted Orphan Drug Designation (ODD) for SuppreMol's lead product SM101, a recombinant human soluble Fcγ receptor IIb, for the treatment of Idiopathic Thrombocytopenic Purpura (ITP). At present, SM101 is in a Phase Ib/IIa clinical study in ITP, with results expected in early 2011. For the same indication, the molecule has already been granted Orphan Medicinal Product Designation in Europe by the EU Commission in 2007.

"We are very pleased that the FDA, too, has granted orphan drug status for SM101 for the treatment of ITP," said Peter Buckel, CEO of SuppreMol. "The decision indicates the FDA's recognition that our drug candidate may address significant unmet medical needs in patients suffering from this autoimmune disease. SM101 has already demonstrated excellent tolerability and safety in Phase I trials and is currently in a clinical study to obtain proof-of-concept."

The US Orphan Drug Act provides incentives to encourage the development of drugs for rare disease conditions affecting fewer than 200,000 persons in the United States. Orphan drug designation offers a number of potential incentives, which may include waiver of FDA user fees, study design assistance, funding for clinical studies, tax credits for clinical research and a seven-year period of U.S. marketing exclusivity if the drug receives US marketing approval. It should be noted that orphan drug designation does not limit a drug to the particular orphan disease. The drug may be developed for more common diseases in parallel or afterwards.

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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 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 Laureate 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.

About SM101

SuppreMol's lead product SM101 is a recombinant, soluble, non-glycosylated version of the Fcγ receptor IIb. The protein binds to immune complexes and thereby blocks the triggering of Fcγ 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) and has entered a Phase Ib/IIa trial in this indication in 2010. SuppreMol has been granted orphan medicinal product designation in the EU as well as orphan drug designation in the US for ITP. The company believes that SM101 may also have therapeutic potential in Systemic Lupus Erythematosus (SLE), Rheumatoid Arthritis (RA) and other autoimmune diseases.

About Idiopathic Thrombocytopenic Purpura (ITP)

Idiopathic Thrombocytopenic Purpura (ITP) is a bleeding condition characterized by defective blood clotting due to a decreased number of platelets. While children developing ITP frequently experience complete spontaneous remission, adults often develop chronic ITP. It is estimated that chronic ITP effects over 70,000 individuals in Europe and the USA. The disease is characterized by persistent moderate to severe thrombocytopenia that puts patients at risk for bleeding with trauma and can also result in spontaneous hemorrhage of variable severity. Standard treatment options include steroids, but about 70% of patients do not adequately respond to steroids and are candidates for splenectomy. However, about half of splenectomized patients continue to have thrombocytopenia. For those refractory patients, treatment options usually include immunosuppression, but clinical experience is limited and no comparative trials are available so far.

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