

Press release

SuppreMol starts SM101 dosing in the context of SMILE study

Australian study center treats first systemic lupus erythematosus (SLE) patients

Martinsried/Munich, Germany, November 28, 2011 -- SuppreMol GmbH, a privately held biopharmaceutical company developing novel therapeutics for the treatment of autoimmune diseases and allergies, today announced the start of dosing in the context of the international SMILE study (SM101 In Lupus Erythematosus). The phase IIa, double-blind clinical trial of SM101, the lead compound of the company, involves patients suffering from Systemic Lupus Erythematosus (SLE).

The first patient was treated last month in Australia. Additional study centers in Belgium, Germany, France, Great Britain, Italy, the Netherlands, Poland, Spain, and the Czech Republic will commence patient treatment in the coming weeks. Over the course of one month, the study participants will receive placebo or two different doses of SM101 weekly.

“Enrolling the first patient into the SMILE study is another important milestone for SuppreMol,” says Peter Buckel, the company’s CEO. “SLE, along with other conditions such as Rheumatoid Arthritis and Multiple Sclerosis, is an autoimmune disease for which no effective treatment options are available. The current standard therapies either just treat symptoms or are associated with a considerable risk of complications. Our approach focuses on the initial phase of the autoimmune reaction and offers the potential of sustained therapeutic benefit without severe side effects.”

SM101 is a soluble version of the Fc gamma receptor IIb, which binds to autoantibody/autoantigen complexes and thereby blocks the triggering of Fc receptors on the surface of immune cells. SM101 has been studied in the context of a clinical phase Ib/IIa trial for the indication of Primary Immune Thrombocytopenia (ITP) since 2010. For this indication, the product is designated as a drug for rare medical conditions (“orphan drug”) in the European Union and in the United States.

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Explanations

About SuppreMol

SuppreMol is a privately held biopharmaceutical company developing novel therapeutics for the treatment of autoimmune diseases and allergies. The company is pioneering the development of soluble Fc γ -receptors (sFc γ Rs), which are recombinant versions of autologous proteins that can very effectively suppress certain reactions of the immune system. SuppreMol plans to develop sFc γ Rs for the treatment of Primary Immune Thrombocytopenia (ITP), Systemic Lupus Erythematosus (SLE), Rheumatoid Arthritis (RA), and other autoimmune conditions. In addition, the SuppreMol portfolio contains a number of development projects in early stages, including antibodies to Fc γ receptor IIb (Fc γ RIIb), which are being developed for alternative treatment strategies of autoimmune diseases or additional indications such as allergic asthma. SuppreMol is also developing an antibody to IL-3 for the treatment of RA, for which it has recently acquired an exclusive license option.

SuppreMol was established in 2002 as a spin-off from the laboratory of Prof. Dr. Robert Huber, the 1988 Nobel Prize Laureate in Chemistry, at the Max Planck Institute for Biochemistry in Martinsried, Germany. Since May 2006, the company has raised €35.2 million in three financing rounds. Investors include the 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. SuppreMol also has been the recipient of a €2 million grant from the Federal German Ministry of Education and Research (BMBF) since 2007.

About the SMILE study

The multi-center, randomized, double-blind and placebo-controlled phase IIa parallel study involves some 50 patients with Systemic Lupus Erythematosus. These have a SELENA-SLEDAI score of 6 points or more and active serology patient status and may have been treated for Lupus Nephritis in the past. Two groups of twenty patients each will receive weekly intravenous doses of 6 or 12 mg of SM101 per kilogram of body weight over a period of four weeks, while another ten patients will receive a placebo. The study involves thirty clinical centers in Australia, Belgium, Germany, France, Great Britain, Italy, the Netherlands, Poland, Spain, and the Czech Republic.

The primary end point of this feasibility study is the safety of the drug, as measured by the frequency of side effects on the basis of CTCAE criteria (Common Terminology Criteria for Adverse Events). Further safety end points include vital parameters, body temperature and weight, electrocardiogram, certain laboratory parameters, and the occurrence of anti-drug antibodies (ADA). The efficacy of the drug will be documented with a status assessment of the disease, possible renal complications (lupus nephritis) and the detection of proteinuria, urine sediment, and a number of biomarkers as compared to placebo. The use of emergency medications will also be a factor of the efficacy assessment of SM101 vs. placebo. The study results are expected for the year 2013.

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