Connect Biopharmaceuticals Reports Positive Phase 1b Result for Novel S1P1 Modulator CBP-307 for Autoimmune Diseases

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Taicang, Suzhou, January 8, 2016 – Suzhou Connect Biopharma announced today that it has successfully completed a Phase 1b study of its lead clinical candidate CBP-307, a novel and selective sphingosine-1-phosphate receptor 1 (S1P1) modulator. The randomized, double-blind, placebo controlled study assessed the tolerability, pharmacokinetics and pharmacodynamics of CBP-307 at 0.15 mg and 0.25 mg once daily doses for 4 weeks in healthy volunteers. The study was conducted in Melbourne, Australia, through Connect's subsidiary Connect Biopharma Australia Pty Ltd.

In this study CBP-307 exhibited potent T cell modulation activity. Mean circulating lymphocyte count, a highly predictive biomarker of immune modulation, was reduced by up to 75% from baseline in the 0.25 mg cohort. Lymphocyte counts returned to baseline level within 7 days after the conclusion of 4 weeks of daily dosing. CBP-307 was found to be safe and well tolerated in this study.

Suzhou Connect completed a single ascending dose study (Phase 1a) in July 2015, in which CBP-307 demonstrated excellent safety features and optimal pharmacokinetics and pharmacodynamics profiles.

"We are extremely pleased that CBP-307 demonstrated such potent T cell modulation activity and excellent safety features after 4 weeks of dosing." said Dr. Zheng Wei, CEO of Suzhou Connect Biopharma "The robust lymphocyte count reduction achieved in this study clearly met the threshold that correlated well with strong clinical efficacy in Phase 2/3 clinical trials. The impressive results from this study continue to support the best in class potential of CBP-307. Planning is currently underway to evaluate the drug in Phase 2 studies in patients with autoimmune diseases."

About S1P1

Sphingosine-1-phosphate receptor subtype 1 (S1P1) is a G-protein coupled receptor (GPCR) found on the surface of T cells and has a central role in regulating T cell movement. Functional inhibition of S1P1 confines certain T cell populations (those that express chemokine receptor CCR7) to the lymph nodes, resulting in blockade of these immune cells into tissues to cause and exacerbate inflammation. S1P1 is a clinically validated drug target, and modulators are effective in treating multiple sclerosis (MS), psoriasis, and inflammatory bowel disease (IBD) and transplant rejection, and are being studied to treat a wide array of autoimmune diseases.

About CBP-307

CBP-307 is a novel, orally active second generation S1P1 modulator discovered by Suzhou Connect Biopharmaceuticals, and is currently under development as a treatment for a variety of autoimmune diseases. It has markedly improved receptor subtype selectivity over fingolimod, a first generation S1P1 modulator approved as a treatment for relapsing remitting multiple sclerosis (RRMS). CBP-307 is extraordinarily potent, with an EC50 of 0.09 nM for S1P1 and has greater than 10,000 fold selectivity against S1P3, a S1P receptor subtype linked to tissue fibrosis safety concerns. CBP-307 does not interfere with the hERG potassium ion channel and therefore has no safety concern of QT prolongation of some other drug candidates of the same class. Extensive preclinical studies have shown that CBP-307 is highly potent in reducing disease severity in autoimmune disease models and has an excellent safety and tolerability profile.

About the Phase 1 Study

The two-part Phase 1 study is a randomized, double-blind, placebo-controlled study in healthy volunteers to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of CBP-307. A total of 44 healthy volunteers were enrolled in the single ascending dose (Phase 1a) and the 4-week repeat dose study (Phase 1b). The trial was conducted in Melbourne, Australia, through Connect's subsidiary Connect Biopharma Australia Pty Ltd.

About Suzhou Connect Biopharmaceuticals

Suzhou Connect Biopharma discovers and develops novel immune modulators for the treatment of autoimmune diseases and inflammation. The company identifies and advances its drug candidates through internal discovery and in-licensing. Its lead program CBP-307 is an orally-active S1P1 agonist with best-in-class potential for the treatment of a wide range of autoimmune disorders including inflammatory bowel disease (IBD), psoriasis, and multiple sclerosis (MS). In addition, the company is advancing CBP-174, an in-licensed drug candidate for allergic inflammation; and CBP-201, an internally discovered monoclonal antibody for the treatment of asthma, eczema and other inflammatory diseases.