Suzhou Connect Biopharma Reports Positive Phase 1a Results for CBP-307, a novel, orally active S1P1 modulator for autoimmune diseases

Taicang, Suzhou, July 30, 2015 – Suzhou Connect Biopharma announced today that it has successfully completed the single ascending dose study of its lead clinical candidate CBP-307 in healthy volunteers. This first-in-man study assessed the tolerability, pharmacokinetics and pharmadynamics of CBP-307 at doses ranging from 0.1 mg to 2.5 mg. The study was conducted in Melbourne, Australia, through Connect's subsidiary Connect Biopharma Australia Pty Ltd.

In this study CBP-307 exhibited highly potent immune modulation activity at each of the studied doses in a dose-dependent manner. Circulating lymphocyte count, a well-established biomarker, was reduced by roughly 75% at the 2.5 mg dose, indicating that the maximal on-target effect has been achieved. Full recovery of lymphocyte counts to the pre-dose levels occurred within 7 days after dosing.

CBP-307 also exhibited excellent pharmacokinetic properties. Blood concentrations of the study drug showed good dose proportionality across the entire dose range. Maximal drug concentrations were reached approximately 6 hours after dosing, and the mean elimination half-life was approximately 25 hours.

Based on these and the good safety results, a multiple ascending dose study has been initiated to further evaluate CBP-307 with 4 weeks of daily dosing. Completion of the study is expected later this year.

"We are very pleased that CBP-307 demonstrated such potent T-cell modulation activity and ideal pharmacokinetic properties," said Dr. Zheng Wei, CEO of Suzhou Connect Biopharma "A half-life of 25 hours will adequately support once daily dosing while allowing rapid recovery of lymphocyte functions after conclusion of dosing. The preclinical and clinical data accumulated so far continue to be very encouraging, and we look forward to the completion of the ongoing repeat dose study."

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 such immune cells into tissues to exacerbate inflammation. S1P1 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 Biopharma and is under development as a treatment for 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). 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. Up to 64 healthy volunteers will be enrolled in the single ascending dose (Phase 1a) and the 4-week repeat dose study (Phase 1b). The trial is conducted in Melbourne, Australia, through Connect's subsidiary Connect Biopharma Australia Pty Ltd.

About Suzhou Connect Biopharmaceuticals

Founded in 2012, 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 range of autoimmune disorders including multiple sclerosis (MS), inflammatory bowel disease (IBD), and psoriasis. 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 and eczema.

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