Complete Data from Connect Biopharma's Phase 1b Study of CBP-201 Demonstrate Rapid, Early and Continuous Improvement in Patient Quality of Life and Atopic Dermatitis (AD)

October 29, 2020

SAN DIEGO, CA and TAICANG, SUZHOU, China – October 29, 2020 – Connect Biopharma, a clinical-stage biopharmaceutical company focused on the discovery and development of next-generation immune modulators for the treatment of serious autoimmune and inflammatory diseases, today presented for the first time at a scientific meeting, the data set from its completed Phase 1b study of CBP-201, a novel antibody against IL-4Rα. These results show a well tolerated and favorable safety profile out to week 11 and rapid, early and continued improvements in multiple efficacy assessments as well as in Dermatology Life Quality Index (DLQI) scores, out to the end of dosing at week 4. The data are being presented today in a poster at the European Academy of Dermatology and Venereology Congress (EADV), which is being held virtually October 29 -31, 2020.

Based on a comparison with published data from studies of competitor therapies in patients with moderate-to-severe AD, Connect Biopharma believes that CBP-201 may have a more rapid onset of action and provide earlier relief of AD symptoms, as well as early and continuous improvements in patient quality of life beginning only one week after dosing. These data support the further evaluation of CBP-201's effects in an ongoing dose-ranging study in patients with moderate-to-severe AD (NCT04444752)

"Despite the availability of corticosteroids and newer biologic therapies, many patients with moderate-to-severe AD continue to have unmet need and could benefit from additional treatment options," said Dr. Zheng Wei, co-founder and CEO of Connect Biopharma. "The safety and efficacy results seen in this Phase 1b study and, in particular, the rapid, early and continuous improvement in AD symptoms and patient quality of life observed, suggest that CBP-201 has the potential to provide superior efficacy in AD with faster onset of action, and less frequent dosing compared with the current standard of care approved for the treatment of moderate-to-severe AD. We believe that CPB-201 has best-in-class potential in this indication."

Key Trial Results

Favorable safety and tolerability profile at 11 weeks

- No life-threatening serious adverse events (SAEs) or treatment-emergent adverse events (TEAEs); TEAEs leading to the discontinuation from the study; adverse events (AEs) of clinically significant injection site reactions or conjunctivitis/keratitis; or deaths were reported.
- The majority (35/51 events in 65.2% patients in the pooled CBP-201 group and 7/11 events in 37.5% of patients in the placebo group) of TEAEs were mild, 18/62 TEAEs reported (15 events in 43.5% of patients on CBP-201 and 3 events in 25.0% of patients on placebo) were moderate; there were two severe TEAEs.
- The number and severity of TEAEs and treatment related TEAEs did not increase with increasing CBP-201 dose level and there were no apparent differences between the CBP-201 dose cohorts and placebo cohort in terms of study treatment-related TEAEs. Of 51 TEAEs reported across the pooled CBP-201 group, 9 events were deemed by the Investigator to be related to CBP-201 and 3/11 TEAEs in the placebo group were deemed related to placebo treatment. There were no treatment-related severe TEAEs reported.
- The most common TEAEs reported in the study by patients were dermatitis atopic (6 events in 6 patients in the pooled CBP-201 group; 4 events in 3 placebo patients), headache (7 events in 4 patients in the pooled CBP-201 group and 0 events in placebo patients), and upper respiratory track infection (3 events in 2 patients in the pooled CBP-201 group and 0 events in placebo patients). The most frequent SOC for TEAEs was Skin and Subcutaneous Tissue Disorders, likely related to the underlying AD of patients.
- There were no changes in vital signs, ECG parameters, or physical examination findings that were clinically significant or related to study treatment.

Early, rapid and continued improvements in multiple efficacy assessments

- CBP-201 treatment at the 150 mg or 300mg dose resulted in rapid improvement in skin lesion compared with placebo as measured by change from baseline in Eczema Area and Severity Index (EASI) scores, beginning at week 1 and increasing through week 4. At week 4, EASI change from baseline was 74.0% and 74.4% for the 150 mg and 300 mg doses, respectively, compared with 32.9% for placebo.
- Reductions from baseline in affected Body Surface Area (BSA) were also observed as early as week 1 for the 150 mg and 300 mg doses, with clear separation from placebo for each dose as early as week 3. Reductions were sustained over the study period, reaching 62.7% and 58.7%, respectively at week 4, compared with 28.7% for placebo.
- Weekly average Pruritus Numeric Rating Scale scores for frequency and intensity each showed improvement compared with placebo by week 1 and these improvements increased over the study period. At week 4, percent change from baseline of PNRS frequency score was 40.3% and 54.4% for the 150 mg and 300 mg dose, respectively, compared with 21.0% for placebo; results for PNRS intensity score change from baseline were 41.0% and 52.8% for CBP-201 and 22.8% for placebo.
- 42.9% and 50.0% of patients receiving 300 mg or 150 mg, respectively, achieved "clear/almost clear" skin, defined as a

score of 0 or 1 in the Investigator's Global Assessment (IGA) scores, the primary efficacy endpoint required for FDA approval, compared with 12.5% in the placebo group.

Early, rapid and continued improvement in DLQI

- At week 1, mean percent decrease from baseline DLQI score was 30.6% and 38.5% for the CBP-201 150 mg and 300 mg doses, respectively, compared with 3.9% for placebo. DLQI changes increased over the study period, reaching 65.7% and 69.9% for the CBP-201 150 mg and 300 mg doses, respectively, at week 4 compared with 6.5% for placebo.

About the Phase 1b Trial of CBP-201 in Patients with Moderate-to-Severe AD

The randomized, double-blind, placebo-controlled, multiple dose escalation study conducted in ten sites in Australia and New Zealand, evaluated the efficacy and safety of CBP-201 in 31 patients with moderate-to-severe AD who have had inadequate response to topical corticosteroids and immunosuppressants. Ten patients per cohort were randomized 4:1 to CBP-201 (75 mg, 150 mg or 300 mg) or matching placebo, and received study treatment once weekly by subcutaneous injection for four consecutive weeks, with follow-up for an additional seven weeks. The primary objective of the study was to assess safety and tolerability of CBP-201 over the 11-week duration of the study, with secondary objectives to evaluate efficacy as determined by multiple assessments (EASI, IGA, affected BSA and PNRS) at week 4.

About AD

AD, a common condition that can have multiple negative effects on the lives of affected individuals, is a chronic inflammatory disorder characterized by eczematous skin lesions, itch, localized pain, and sleep disturbances. It is also a common condition, occurring in 10-15% of children and 2-4% of adults. Approximately 30% of individuals with AD have moderate-to-severe disease. Patients with moderate-to-severe AD who are not helped by topical corticosteroids continue to have significant unmet needs.

About CBP-201

CBP-201 is a potent monoclonal antibody against IL-4Rα, a cell surface protein required for the signaling of both IL-4 and IL-13, which have significant overlapping biological activities and play key roles in inflammatory diseases mediated by type 2 helper T cells (Th2). CBP-201 was discovered internally using Connect Biopharma's proprietary Immune Modulation Technology Platform and is under clinical development to treat atopic dermatitis (AD). Additional clinical studies examining the potential of CBP-201 in other Th2 inflammatory diseases that have high unmet medical needs such as Asthma and Chronic Rhinosinusitis with Nasal Polyps, will be initiated shortly.

Results with CBP-201 from a Phase 1b clinical study in adult patients with moderate-to-severe atopic dermatitis, showed a favorable safety profile and exploratory efficacy data found that 42.9% and 50.0% of patients receiving CBP-201 300 mg or 150 mg, respectively, achieved clear/almost clear skin (IGA 0,1) at four weeks. Additionally, skin lesion improvements were rapid, as evidenced as early as one week after dosing and were correlated with a rapid reduction in pruritus intensity and frequency. This suggests the potential for a differentiated efficacy profile, with faster onset of action for CBP-201 compared with data from clinical trials of the current biologic standard of care therapy. Phase 2 dose ranging studies with CBP-201 are now underway to explore the efficacy and safety profile, as well as the potential for dosing every four weeks (NCT04444752).

About Connect Biopharma

Connect Biopharma is a U.S.- and China-based clinical-stage biopharmaceutical company, focused on the discovery and development of next-generation immune modulators to be used in the treatment of serious autoimmune and inflammatory diseases. Leveraging our expertise in the biology of T cell modulation and our proprietary Immune Modulation Technology Platform, a high-throughput screening platform that rapidly and efficiently identifies molecules that target clinically validated disease pathways, we are a company passionate about developing innovative medicines and improving the lives of those suffering from these chronic and debilitating diseases worldwide.

In addition to our lead drug candidates, CBP-201 and CBP-307, we are also advancing three preclinical programs, comprising two small molecule candidates (CBP-174 and CBP-312) and one antibody targeting IL-33 (CBP-233) as treatments for various serious inflammatory conditions. We hold all global rights to our proprietary pipeline and discovery technologies. For additional information about Connect Biopharma, please visit our website at www.connectbiopharm.com