LIB Therapeutics Announces Positive Results from the Phase 3 Long-term efficacy and safety of Lerodalcibep in heterozygous familial hypercholesterolemia (LIBerate-HeFH) trial.

August 28, 2023

-- Monthly Lerodalcibep achieved both co-Primary Endpoints, with Statistically Significant (p<0.0001) placebo adjusted reductions in mean LDL-Cholesterol in the intent-to-treat population of 58.6% at Week 24 and 65.0% at the mean of Weeks 22 and 24.

-- 68% of subjects on lerodalcibep achieved both a reduction in LDL-C ≥50% and the recommended ESC LDL-C targets during the study.

-- Favorable tolerability and safety were observed with treatment-emergent adverse events were generally similar between lerodalcibep and placebo

Heterozygous FH affects nearly 1 in 300, or over 30 million, people worldwide, causing very high LDL-Cholesterol levels from birth, and if untreated or under-treated, is associated with early morbidity and mortality from cardiovascular disease (“CVD”) requiring additional reductions in LDL-cholesterol (‘LDL-C’ or “LDL”), in patients on maximally tolerated statins and other oral lipid lowering agents, announced the results of the LIBerate-HeFH Trial. The results from the large global Phase 3 randomized, placebo-controlled trial, of lerodalcibep, the company’s monthly small binding protein PCSK9 inhibitor, in patients with heterozygous familial hypercholesterolemia (HeFH) were presented today at the European Society of Cardiology and simultaneously published in the European Heart Journal.

Results from the Phase 3 LIBerate-HeFH Trial

Commenting on the trial Prof Raal continued “In this, the largest on active drug, and one of the longest, controlled trials in HeFH with an inhibitor of circulating PCSK9, lerodalcibep, demonstrated very effective and sustained reductions of LDL-C with just a monthly small 1.2 mL dose. The mean reductions of 81 mg/dL, at the 4 week trough and over 100 mg/dL at 2 week post dose peak, provides patients with HeFH who had mean baseline LDL-C of about 150 mg/dL on existing statins and ezetimibe, a highly effective, well tolerated alternative to current PCSK9 inhibitors to achieve the most recent, lower ESC and ACC suggested LDL-C goals.”

"After presenting results demonstrating equivalent LDL-C response, and safety, to evolocumab in the rare and most difficult to treat homozygous FH population in the large, global, diverse cross-over Phase 3 trial, LIBerate-HoFH, at the recent European Atherosclerosis Society (“EAS”) Scientific Sessions in May, we are pleased to now also report further robust results from the Phase 3 trial in HeFH patients with the same small monthly dose of lerodalcibep” said Evan Stein, M.D.PhD, Chief Executive and Chief Scientific Officer of LIB Therapeutics. “We now await the completion in early November of our final two Phase 3 trials, LIBerate-CVD and LIBerate-HR, in more than 1800 patients with CVD or at very high and high risk for CVD, and more moderate LDL-C elevations despite maximal tolerated statins and other oral therapy. However, the results in patients with FH with the highest LDL-C and most difficult to achieve current treatment targets, are the most pleasing for me personally as patients with both HoFH and HeFH began my interest in lipid metabolism, where no effective drugs existed 50 years ago. As always we are most grateful to the over 500 FH patients, including the children and adolescents who participated in the HoFH trial, for their time and interest in contributing to these results. We also thank the dedicated investigators and their clinic staff who kept the trials going through the covid epidemic.”

The Phase 3 LIBerate-HeFH Trial

The Phase 3 trial, LIBerate-HeFH, was a placebo-controlled, double-blind, randomized, trial to evaluate the efficacy, safety and tolerability of lerodalcibep 300 mg in 1.2 mL monthly SC injection in patients with HeFH on stable, maximally tolerated statin therapy with or without additional oral lipid lowering therapy. The trial enrolled 478 adult participants, who were randomized 2:1 to receive lerodalcibep or placebo for a 24-week treatment period.

Based on intent-to-treat (ITT) patients treated with lerodalcibep, achieved a mean reduction in LDL-C of 58.6% at Week 24 and 65% at the coprimary end point of Weeks 22 and 24 respectively, as compared to patients treated with placebo. In a per-protocol analysis patients treated with lerodalcibep achieved a placebo adjusted mean (SE) reduction in LDL-C of 63.6 (3.3)% at week 24 and at the week 22/24 mean (SE) of 70.2 (2.8)% (p value...
The mean reduction in Apolipoprotein B of 45.6% and median reduction in Lp(a) of 24% compared to patients treated with placebo were statistically significant (p<0.0001). Lerodalcibep was well-tolerated, with a safety profile generally comparable to placebo with only mild injection site adverse events being observed more frequently than placebo.

**About Lerodalcibep**

Lerodalcibep is a next-generation, small binding protein alternative to a monoclonal antibody, PCSK9 inhibitor being developed by LIB Therapeutics to potentially overcome the limitations of current LDL-lowering treatments. The Company believes that with the 1.2 mL small volume, monthly dosing and long ambient stability combined with excellent and sustained LDL-C efficacy, lerodalcibep, if approved, will increase the treatment options for patients to achieve the recent more aggressive LDL-C goals in national and international guidelines. The Company is conducting two additional randomized placebo-controlled Phase 3 pivotal trials with lerodalcibep in over 1800 patients, LIBerate-CVD and LIBerate-HR, added to maximally tolerated oral lipid-lowering therapies to assess LDL-lowering in CVD, very high and high-risk for CVD patients. These 52 week trials are anticipated to complete in early November.

**About LIB Therapeutics Inc.**

LIB Therapeutics is a clinical-stage biopharmaceutical company dedicated to bringing a novel, effective, safe and convenient injectable and oral PCSK9 inhibitors to the millions of patients with CVD or at very high or high risk of CVD who require additional large reductions in LDL-C despite maximally tolerated statins and other oral lipid lowering agents.

Based in Cincinnati, LIB Therapeutics is a privately funded company. For more information, please visit: [www.libtherapeutics.com](http://www.libtherapeutics.com).

**Company Contact**

Kate Caldwell at [kcaldwell@libtherapeutics.com](mailto:kcaldwell@libtherapeutics.com)