Leading BioSciences Reports Positive Interim Results from Phase 2 Trial of LB1148 in Patients Undergoing Major Surgery

Novel Gastroprotective Treatment Demonstrates 3.2 Day Decrease in Hospital Length of Stay Following Surgery Compared to Placebo; LB1148 Triggers Statistically Significant 18-Hour Improvement in Post-Operative Return to Bowel Function Compared to Placebo

CARLSBAD, CA – June 19, 2018 – Leading BioSciences, a drug development company focused on improving human health through therapeutic protection of the Gastrobiome™, today reported positive interim data from the company's ongoing Phase 2 clinical trial of its lead drug candidate, LB1148, in patients undergoing major cardiovascular surgery. Results from the planned interim analysis demonstrated that subjects treated with LB1148 had a decrease in stay in the intensive care unit (ICU) of 1.1 days and an overall decrease in hospital length of stay of 3.2 days, as compared to placebo.

Additional findings demonstrated a statistically significant 18-hour improvement in return to normal bowel function for patients treated with LB1148 as compared to placebo ($p = 0.044$), the study's primary endpoint. As a point of comparison, the only currently approved treatment for improving post-surgery recovery of gastrointestinal (GI) function demonstrated less improvement in return to bowel function following GI surgery. The interim study results also suggest that LB1148 was well tolerated with an adverse event profile that was comparable to placebo.

"The statistically significant 18-hour improvement in return of normal GI function seen with LB1148 is very promising not only as it relates to improving patients' overall surgical experience but also for its potential to reduce length of patient stays in the ICU and hospital, as well as the associated costs," said Tom Hallam, Ph.D., chief executive officer of Leading BioSciences. "Importantly, when compared to the only treatment currently approved in the US to improve post-surgery bowel function recovery, these data for LB1148 show a more rapid recovery of GI function, as well as significant administration and safety benefits. We believe these results support the potential of LB1148 to address a key unmet medical need while providing dramatic cost savings for patients, hospitals and healthcare system."

"As a surgeon, I have firsthand experience with the limited nature of the current therapeutic options for addressing post-operative GI function restoration." said David B. Hoyt, M.D., FACS., former chairman, department of surgery, executive vice dean of the school of medicine, and John E. Connolly professor of surgery at the University of California, Irvine Medical Center, as well as a member of Leading BioSciences' clinical steering committee. "I am encouraged by the interim data reported for LB1148, as it suggests the treatment may ultimately be able to deliver important benefits to patients and hospitals alike. I will monitor the continued development of the treatment with interest and look forward to the reporting of this study's full data set later this year."

The ongoing Phase 2 study is a randomized, double-blind, parallel, placebo-controlled trial in 120 subjects undergoing coronary artery bypass grafting (CABG) and/or heart valve replacement surgery requiring cardiopulmonary bypass (CPB). Patients are being randomized to receive LB1148 or placebo in conjunction with surgery. The trial's primary objective is to evaluate the improvement in subjects' post-operative recovery with LB1148 treatment as compared to placebo. This is being measured through assessment of treatment impact on the time to return of normal GI function, length of stay in the ICU, length of stay in the hospital, and mortality rate.

There are more than 10 million surgeries conducted each year in the US that are at risk for resulting in a breakdown of the natural intestinal mucosal barrier and triggering post-operative interruption of GI function. Importantly, patients undergoing these surgeries generally cannot be discharged from the hospital until their GI function is restored, which can add several days to their hospital stay. It is estimated that each extra day a patient remains in the hospital awaiting return of GI function results in approximately $3,500 in hospital costs. As such, a treatment that can safely and effectively reduce delays in return of GI function following surgery has the potential to provide significant cost savings to hospitals, insurers and the healthcare system.

Leading BioSciences will present these results of the interim trial analysis at a future medical meeting.

About LB1148

LB1148 is a patent-protected formulation of a broad-spectrum serine protease inhibitor designed to neutralize the activity of potent digestive enzymes that can cause a range of serious complications if they escape the intestines through a compromised mucosal barrier. The ability to safely and effectively inhibit the activity of digestive proteases can prevent the damage they cause to GI tissues once they escape the intestines, speed the return of GI function and shorten patients' post-surgery stay in the ICU and hospital. A Phase 2 clinical study of LB1148 in subjects undergoing major cardiovascular surgery is underway and a Phase 2/3 trial in patients undergoing gastrointestinal surgery is preparing to initiate patient enrollment.

About Leading BioSciences

Leading BioSciences is developing novel therapeutics designed to improve human health through therapeutic protection of the Gastrobiome™. Leading BioSciences' initial focus is combatting the interruption of GI function (ileus) following major surgery to reduce recovery times and shorten patients' length of stay in the hospital. Additionally, the company believes that its programs have the potential to prevent the formation of post-operative adhesions (reducing hospital re-admissions and additional surgeries), as well as to address the myriad of health conditions and complications associated with chronic disruption of the intestinal mucosal barrier.

Learn more at: www.leadingbiosciences.com

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