Palisade Bio Provides Business Outlook and Highlights Expected Near-Term Pipeline Advancements

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Phase 3 study of LB1148 in lead indication for postoperative return of bowel function on track to commence Q2 2022

CARLSBAD, Calif., May 02, 2022 (GLOBE NEWSWIRE) -- Palisade Bio (Nasdaq: PALI), a clinical stage biopharmaceutical company advancing therapies for acute and chronic gastrointestinal (GI) complications, today provided a business outlook and outlined its expected near-term pipeline advancements.

"The positive data we have amassed continues to support our development strategy and provides us with confidence as we advance our lead program into a Phase 3 study this quarter. Each day that a patient remains in the hospital can cost upwards of approximately $2,400, representing a significant burden on the cost of healthcare. We believe, if approved, LB1148 will protect gastrointestinal integrity and accelerate the return of postoperative GI function, providing hospitals with a potentially safe solution to accelerate patient discharge. Additionally, LB1148 has the potential to reduce abdominal adhesions – a problem that can cause an alarming number of post-surgery complications. With our data in hand, we have aligned on a strategy for LB1148 to transform the current standard of care which will allow us to unlock significant value for our shareholders," commented Tom Hallam, Ph.D., Chief Executive Officer of Palisade Bio.

Clinical Program Update

LB1148: oral formulation of a broad-spectrum serine protease inhibitor designed to neutralize the activity of potent digestive proteases released from the gut during surgery

LB1148 is a novel oral liquid formulation of the well-characterized digestive enzyme inhibitor, tranexamic acid ("TXA"), with potential to both reduce abdominal adhesions and help restore bowel function following surgery. The therapy is being developed for administration prior to major surgeries that are at risk of disrupting the intestinal epithelial barrier. Evidence suggests that the release of digestive proteases contributes to the temporary loss of normal gastrointestinal function and the formation of postoperative adhesions. By inhibiting the activity of these digestive proteases, LB1148 has the potential to prevent damage to GI tissues, accelerate the time to the return of normal GI function, and shorten the duration of costly post-surgery hospital stays.

Postoperative Return of Bowel Function: GI Surgery

In March 2022, the Company received a "Study May Proceed" letter from the U.S. Food and Drug Administration (FDA) to initiate its Phase 3 clinical trial evaluating LB1148 to accelerate the return of bowel function in adult patients undergoing bowel/abdominal surgery. The trial is designed as a multi-centered, randomized, double-blinded, parallel-group, placebo-controlled clinical trial set to enroll approximately 600 patients, and will assess the safety and efficacy of LB1148. All patients enrolled in the trial will undergo a scheduled bowel resection surgery that will include either laparotomy or laparoscopic surgical approaches.

The expected timelines are management's current forecasts and will be updated as enrollment progresses.

Expected Upcoming Milestones

- Q2 2022: Phase 3 study initiation
- 2H 2022: Phase 3 study first patient enrolled

Prevention of Post-Surgical Abdominal Adhesions: GI Surgery

Digestive enzymes can escape the intestine during major surgery and cause damage to the intestines and surrounding organs resulting in the formation of scar tissue known as adhesions. Adhesion prevalence has historically reported to be >90% in patients who undergo abdominal surgery and represents a potentially significant contribution to serious complications. Adhesions can be the cause of chronic pain and may prevent normal organ function, including bowel obstructions of the intestine. Adhesions can increase the difficulty of subsequent surgeries causing complications and are the leading cause of secondary infertility in women. In some cases, adhesions require a second corrective surgical procedure. There are currently no approved medications to prevent or treat adhesions.

Previously the Company had just three patients who had been assessed for adhesions following GI surgery. In the Company's recent data presentation at the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) 2022 Annual Meeting, a pooled-study analysis of 17 patients demonstrated LB1148 reduced incidence of adhesions by 72% and reduced the extent and severity of adhesions by 93% in patients undergoing bowel resection.

The Company is conducting an ongoing randomized, double-blind, placebo-controlled, parallel-group, multicenter Phase 2 clinical trial of LB1148 in up to 200 patients undergoing elective bowel resection surgery in the United States. This trial is designed to evaluate whether patients treated with LB1148 experience fewer postoperative intra-abdominal adhesions. The trial will also assess LB1148's impact on recovery of GI function, as compared to placebo.

Expected Upcoming Milestones

- Q4 2022: Phase 2 enrollment completion
- 1H 2023: Phase 2 study completion
- 2H 2023: Report Phase 2 topline results

Postoperative Return of Bowel Function: Cardiovascular Surgery

The Company previously announced positive topline data from its Phase 2 study demonstrating LB1148 achieved its primary endpoint with statistically significant improvement in bowel function following cardiovascular surgery. The Phase 2 clinical trial was 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) with patients randomized to receive LB1148 or placebo in conjunction with surgery. LB1148 provided a 30% improvement in the time to normal bowel function following cardiovascular surgery ($p<0.001$) compared to placebo. This improvement resulted in a 1.1-day reduction in average length of stay in the ICU and a 1.0-day reduction in average hospital length of stay. LB1148 was also shown to be safe and well-tolerated in the study.

The Company plans to initiate additional CV surgery studies with LB1148 after the completion of the studies to accelerate the return of bowel function in patients undergoing bowel/abdominal surgery.

The U.S. FDA has previously granted Fast Track designation to LB1148 for two clinical indications: reduction of adhesions following abdominal or pelvic surgery and treatment of postoperative GI dysfunction in pediatric patients undergoing cardiac surgery.

About Palisade Bio
Palisade Bio is a clinical stage biopharmaceutical company advancing therapies that aid patients suffering with acute and chronic gastrointestinal complications stemming from post-operative digestive enzyme damage. Palisade Bio's innovative lead asset LB1148, advancing toward Phase 3, is a protease inhibitor with the potential to both reduce abdominal adhesions and help restore bowel function following surgery. Positive data from Phase 2 trials of LB1148 demonstrated safety and tolerability as well as a statistically significant improvement in the return of bowel function and a decrease in the length of stay in ICU and hospital compared to placebo. Palisade Bio believes that its investigational therapies have the potential to address the myriad health conditions and complications associated with the chronic disruption to the gastrointestinal epithelial barrier. For more information, please go to www.palisadebio.com.

Forward Looking Statements
This communication contains "forward-looking" statements, including, without limitation, statements related to its expected near-term pipeline advancements and milestones, expectations regarding regulatory submissions, the potential for LB1148 to transform the current standard of care, if approved and the ability for the Company to unlock significant value for our shareholders. Any statements contained in this communication that are not statements of historical fact may be deemed to be forward-looking statements. These forward-looking statements are based upon Palisade's current expectations. Forward-looking statements involve risks and uncertainties. Palisade's actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, the Company's ability to advance its clinical programs and the uncertain and time-consuming regulatory approval process. Additional risks and uncertainties can be found in Palisade Bio's Annual Report on Form 10-K for the year ended December 31, 2021. Palisade expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in Palisade's expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.

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