Palisade Bio Announces First Patient Screened in Phase 3 Study Evaluating LB1148 for Postoperative Return of Bowel Function

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CARLSBAD, Calif., July 27, 2022 (GLOBE NEWSWIRE) -- Palisade Bio, Inc. (Nasdaq: PALI), a clinical stage biopharmaceutical company advancing therapies for acute and chronic gastrointestinal (GI) complications, today announced the first patient has been screened in its Phase 3 study evaluating LB1148 to accelerate the return of bowel function in adult patients undergoing gastrointestinal surgery.

"The operational execution of our Phase 3 clinical development program for LB1148 remains our number one priority. With the first U.S. clinical site open, our team is working to enroll patients as quickly as possible and expects to complete enrollment within the next 18-24 months. We believe that LB1148 has the opportunity to potentially establish the standard of care for millions of patients undergoing abdominal surgeries each year. We are pleased with the progress made and believe we are another critical step closer to bringing LB1148 to patients in need," commented Tom Hallam, Ph.D., Chief Executive Officer of Palisade Bio.

LB1148, the company's lead asset in development, is a novel oral liquid formulation of the well-characterized digestive enzyme inhibitor tranexamic acid, with the potential to both reduce abdominal adhesions and help restore bowel function following surgery. LB1148 is currently being developed for administration prior to surgeries that are at risk of disrupting the intestinal epithelial barrier.

The Phase 3 study is designed as a multi-center, randomized, double-blind, parallel-group, placebo-controlled clinical trial set to enroll approximately 600 patients, which will assess the safety and efficacy of LB1148. The primary endpoint is time to recovery of the upper and lower gastrointestinal tract following surgery, defined as the time from the end of surgery to the toleration of food and first bowel movement. All patients enrolled in the study will undergo a scheduled bowel resection surgery that will include either laparotomy or laparoscopic surgical approaches. The clinical study will utilize the same dosing of LB1148 used in the company's completed Phase 2 study in which LB1148 demonstrated a 1.1-day improvement in return of bowel function.

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

About Palisade Bio
Palisade Bio is a clinical stage biopharmaceutical company advancing therapies that aim to aid patients suffering with acute and chronic gastrointestinal complications stemming from post-operative digestive enzyme damage. Palisade Bio's innovative Phase 3 lead asset LB1148, is a protease inhibitor with the potential to both reduce abdominal adhesions and help restore bowel function following surgery. Positive data from Phase 2 studies 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 for purposes of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include statements regarding Palisade's intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things: the expected completion of enrollment for the Phase 3 study, and the potential for LB1148 to establish the standard of care, if approved. 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, the uncertain and time-consuming regulatory approval process, including due to the company's clinical trials in China; the company's ability to achieve additional financing to fund future operations and the company's ability to comply with the continued listing requirements for Nasdaq. Additional risks and uncertainties can be found in Palisade Bio's Quarterly Report on Form 10-Q for the quarter ended March 31, 2022. 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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