



Palisade Bio Announces First Patient Enrolled and Dosed in Pivotal Phase 3 Study Evaluating LB1148 for Postoperative Return of Bowel Function

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CARLSBAD, Calif., Aug. 17, 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 dosed in its Phase 3 study evaluating LB1148 to accelerate the return of bowel function in adult patients undergoing gastrointestinal surgery.

Tom Hallam, Ph.D., Chief Executive Officer of Palisade Bio, commented, "The dosing of our first patient in the LB1148 Phase 3 marks a noteworthy milestone for the company and another important step forward in the execution of our strategy. With what we believe to be a pivotal Phase 3 study now fully underway, we are focused on building momentum and completing enrollment as quickly and efficiently as possible. The design of this Phase 3 study mirrors that of our positive Phase 2 study where LB1148 demonstrated a statistically significant improvement in the time of return of bowel function."

[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.

"LB1148 represents a promising opportunity to establish the standard of care for accelerating the postoperative return of bowel function. In my opinion, the data with LB1148 to date is encouraging and provides a solid foundation as we begin to dose patients in this phase of development," added Dr. Soghomonyan, a (Principal Investigator) at The Ohio State University Wexner Medical Center.

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 minimally invasive 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 late-stage biopharmaceutical company focused on developing therapeutics that protect the integrity of the intestinal barrier. The Company utilizes over three decades of research and established science that links the role of intestinal barrier biology and human disease to develop novel therapeutics that target and improve the integrity of the intestinal barrier.

The Company's lead program, LB1148, is a broad-spectrum serine protease inhibitor which acts to neutralize digestive enzymes, potentially reducing intestinal damage. In multiple clinical studies, LB1148 has demonstrated positive results in accelerating the time to return of postoperative bowel function, and the Company recently presented analysis that LB1148 reduced the incidence and severity of post-surgical abdominal adhesions. LB1148 is currently being evaluated in a Phase 3 clinical study for accelerating the return of postoperative bowel function and in a Phase 2 study for the prevention of post-surgical abdominal adhesions.

The Company believes that addressing the disruption of the intestinal barrier has the potential to fundamentally change the way diseases are treated and to establish new standards of patient care. 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 potential to fundamentally change the way diseases are treated, the completion of enrollment for the Phase 3 study, the potential for the statistically significant Phase 3 data to allow for NDA approval, 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; the company's ability to achieve additional financing to fund clinical development 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 June 30, 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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