Palisade Bio and Newsoara Receive NMPA Clearance to Commence Phase 3 Clinical Trial in China Evaluating LB1148 to Accelerate the Return of Bowel Function Following Abdominal Surgery

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NMPA clearance expands global Phase 3 clinical development program; Company recently announced clearance from U.S. Food and Drug Administration to commence Phase 3 study

Newsoara to fully fund Phase 3 program in China

Under the Co-Development Agreement, commencement of Phase 3 program in China will trigger milestone payment to Palisade Bio

CARLSBAD, Calif. and SHANGHAI, China, May 05, 2022 (GLOBE NEWSWIRE) -- Palisade Bio (Nasdaq: PALI), a clinical stage biopharmaceutical company advancing therapies for acute and chronic gastrointestinal (GI) complications and co-development partner Newsoara Biopharma Co. Ltd, today announced they have received clearance from the National Medical Products Administration (NMPA) in China to proceed with their Phase 3 clinical trial to evaluate LB1148 for accelerated return of bowel function in adult patients undergoing bowel/abdominal surgery. This comes shortly after the announcement of the Phase 3 protocol clearance by the U.S. Food and Drug Administration (FDA).

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. In a previously conducted Phase 2 trial in gastrointestinal (GI) surgery, Palisade Bio and Newsoara demonstrated LB1148 had a statistically significant (p=0.0008) effect in accelerating the return of bowel function in patients undergoing elective bowel resection surgery. Based on the strong efficacy profile in acceleration of the time to recover bowel function combined with a favorable safety and tolerability profile observed, Palisade Bio and Newsoara are advancing LB1148 to Phase 3 clinical trials in the United States and China for accelerating the return of bowel function for major surgical indications.

The Phase 3 trial is designed as a multi-centered, randomized, double-blinded, parallel-group, placebo-controlled clinical trial, 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 clearance from NMPA for the expansion of the LB1148 Phase 3 program in China represents an important milestone for our global development and commercial strategies for LB1148. As demonstrated in the successful Phase 2 study, Newsoara has the ability to quickly enroll patients and contribute critical data to this program. Further, the Phase 3 trial is nearly identical to the successful Phase 2 study, which we believe increases the probability of success for the Phase 3 program. The primary difference in trial design is the elimination of any adhesion assessments. This should allow us to read out the top-line data much faster as we will only need three months of follow-up instead of seven months,” commented Tom Hallam, Ph.D., Chief Executive Officer of Palisade Bio.

“We continue to be encouraged by the potential of LB1148 to protect gastrointestinal integrity and accelerate the return of postoperative GI function. Based on the positive data to-date, we believe LB1148 has the potential to truly establish the standard of care and provide hospitals with a potentially safe solution to accelerate patient discharge. Along with our co-development partner Newsoara, we are pleased with the positive response from NMPA and are excited to further LB1148’s development in a Phase 3 study in China,” added Michael Dawson MD, Chief Medical Officer of Palisade Bio.

“Delayed return of bowel function continues to impact millions of patients across the globe every year. Despite the persisting need for a safe solution, there has been relatively few advancements for this global population. We believe LB1148 has demonstrated the potential to address this need and, we are pleased to advance toward initiating the Phase 3 study and, if approved, bring a much-needed option to patients to accelerate postoperative return of GI function,” said Dr. Benny Li, Newsoara’s Chief Executive Officer.

As previously announced, LB1148 is being developed in China for return of postoperative bowel function and reduction of post-surgical adhesions. Under the terms of the existing agreement with the Company, Newsoara is responsible for fully funding the Phase 3 development in China and will be required to make milestone payments to Palisade Bio upon achievement of certain regulatory and, if approved, commercial milestones and tiered royalty payments on any future annual net sales of LB1148 in greater China.

About LB1148
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.

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.

About Newsoara Biopharma

Newsoara Biopharma is a biotech company based in Shanghai, China with research laboratories in the Suzhou BioBAY focusing on novel drug research and development to address unmet medical needs in patients with various diseases.

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 and, the potential for LB1148 to transform the current 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 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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