

## **9 Meters Biopharma Announces Interim Analysis of Phase 3 Study of Larazotide for Celiac Disease Does Not Support Trial Continuation**

- *Additional analyses to determine if a subgroup of patients and/or symptoms may have been responsive to treatment*
- *Company remains on track to deliver vurolenatide Phase 2 short bowel syndrome results by end of month*

**RALEIGH, NC / ACCESSWIRE / June 21, 2022 /** 9 Meters Biopharma, Inc. (NASDAQ:NMTR), a clinical-stage company pioneering novel treatments for people with rare or debilitating digestive diseases, today announced completion of a pre-specified interim analysis for the Phase 3 study of larazotide, referred to as CedLara® (**C**eliac **d**isease **L**arazotide), for patients with celiac disease who continue to experience gastrointestinal symptoms while adhering to a gluten-free diet. The interim analysis was conducted by an independent statistician, with the sole purpose of re-estimating the treatment group size required to detect a statistically significant clinical effect of larazotide, utilizing patient data from the study.

Based on consultation with the independent statistician, 9 Meters has determined that the additional number of patients needed to determine a significant clinical outcome between placebo and larazotide is too large to support trial continuation. The interim analysis included the first approximately 50% of the initial target enrollment and followed the completion of the 12-week double-blind efficacy portion of study.

“We were hopeful that this study of larazotide would lead to a treatment option for those with celiac disease but also fully recognize the challenges and complexities of the disease and the ability to effectively measure outcomes,” said Dr. Patrick Griffin, M.D., FACP, Chief Medical Officer of 9 Meters. “We plan to continue to analyze the data over the coming weeks to determine if other individual or groups of celiac symptoms might benefit from treatment with larazotide. Completion of the analyses and engagement with FDA will determine further plans for larazotide for the treatment of celiac disease. We are grateful to all the patients with celiac disease, their families, and the investigators who participated in the trial and contributed greatly to our understanding of larazotide.”

John Temperato, President and Chief Executive Officer of 9 Meters added, “Despite this outcome, 9 Meters will continue its mission of developing novel therapeutics for rare or debilitating GI disorders, and we remain enthusiastic about the prospects for vurolenatide for short bowel syndrome and our early-stage pipeline. Pending the final analysis, financial and human resources previously dedicated to this study will be re-deployed to advance our development program for vurolenatide and our early-stage product candidates.”

The Phase 3 CedLara® trial is a randomized, double-blind, placebo-controlled study to evaluate the safety and efficacy of larazotide in patients with celiac disease who continue to experience gastrointestinal symptoms while adhering to a gluten-free diet. The 24-week study consists of a 5-week screening and eligibility period followed by a 12-week double-blind treatment phase and an additional 12-week continued safety phase. The study design includes 525 patients distributed among three dosing arms: larazotide 0.25 mg (n=175), larazotide 0.5 mg (n=175) and placebo (n=175). The primary efficacy endpoint of the study is mean change from baseline for celiac symptom severity based on the CeD PRO (celiac disease patient-reported outcomes) abdominal domain score over 12 weeks. This study follows a Phase 2 clinical trial in 342 adult patients with celiac disease who had been on a gluten-free diet for at least 12 months, which concluded that larazotide 0.5 mg significantly reduced symptoms of celiac disease.

### **About 9 Meters Biopharma**

9 Meters Biopharma, Inc., is a clinical-stage company pioneering novel treatments for people with rare digestive diseases, GI conditions with unmet needs, and debilitating disorders in which the biology of the gut is a contributing factor. 9 Meters is developing vurolenatide, a proprietary Phase 2 long-acting GLP-1 agonist, for short bowel syndrome (SBS); larazotide, a tight junction regulator; and several near clinical-stage assets.

For more information please visit [www.9meters.com](http://www.9meters.com) or follow 9 Meters on [Twitter](#) and [LinkedIn](#).

### **Forward-Looking Statements**

This press release includes forward-looking statements based upon 9 Meters' current expectations. Forward-looking statements include, but are not limited to, statements that express our intentions, beliefs, expectations, strategies, predictions, anticipated milestones, and any other statements relating to our future activities or other future events or conditions. These statements are based on current expectations, estimates and projections about our business based, in part, on assumptions made by management. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation: risks related to our ability to successfully implement our strategic plans; uncertainties associated with the clinical development and regulatory approval of product candidates; uncertainties in obtaining successful clinical results for product candidates and unexpected costs that may result therefrom; risks related to the failure to realize any value from product candidates and preclinical programs being developed and anticipated to be developed in light of inherent risks and difficulties involved in successfully bringing product candidates to market; intellectual property risks; the impact of COVID-19 on our operations, enrollment in and timing of clinical trials; risks related to the inability of 9 Meters to obtain sufficient additional capital to continue to advance these product candidates and its preclinical programs, including in light of current stock market conditions; risk of delisting from Nasdaq; reliance on collaborators; reliance on research and development partners; risks related to cybersecurity and data privacy; and risks associated with

acquiring and developing additional compounds. These and other risks and uncertainties are more fully described in periodic filings with the SEC, including the factors described in the section entitled "Risk Factors" in 9 Meters' Annual Report on Form 10-K for the year ended December 31, 2021, and in other filings that 9 Meters has made and future filings 9 Meters will make with the SEC. You should not place undue reliance on these forward-looking statements, which are made only as of the date hereof or as of the dates indicated in the forward-looking statements. 9 Meters 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 its expectations with regard thereto or any change in events, conditions, or circumstances on which any such statements are based.

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