9 Meters Biopharma, Inc Receives Thorough QT Study Waiver by FDA for Larazotide Being Studied for Celiac Disease

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US FDA grants request for a Thorough QT (TQT) waiver request based on larazotide's robust pre-clinical and clinical data

Highlights larazotide's safety profile as a first-in-class gut-restricted, minimally absorbed peptide being studied in Phase 3 for celiac disease

RALEIGH, NC / ACCESSWIRE / May 11, 2020 / 9 Meters Biopharma, Inc (NASDAQ:NMTR), today announced that it has received a thorough QT (TQT) study waiver as requested by the Company from the US Food and Drug Administration's Center for Drug Evaluation and Research, pursuant to the Company's development of its co-lead Phase 3 larazotide acetate program in celiac disease. The waiver supports the candidate's strong precedent of safety and will potentially streamline the program's timeline and cost-effectiveness.

The FDA requires most new chemical entities to be subjected to a randomized dedicated electrocardiogram trial involving normal volunteers, termed a thorough QT (TQT) study.1 "QT" refers to a specific time interval in the series of electric signals governing the heartbeat, in which the heart's electrical system repolarizes , or 'recharges', after each beat.2

The purpose of TQT studies is to determine if novel agents under investigation demonstrate an abnormal effect on cardiac function with respect to the QT interval, which would warrant further safety analyses during the already rigorous path towards commercializing novel products in the United States.

Larazotide acetate was assessed in multiple pre-clinical, Phase 1 and Phase 2 studies in healthy subjects and celiac patients that include higher doses than the proposed highest dose currently in clinical development. In those studies, neither larazotide acetate nor its metabolites were detected in human serum using highly sensitive assays, resulting in the decision by the FDA to grant a waiver of a TQT study.

Patrick H. Griffin, M.D., chief medical officer at 9 Meters, commented, "This is a significant achievement in the clinical development for larazotide as it progresses through late-stage development for adults with non-responsive celiac disease. The waiver permits larazotide to bypass a milestone along the regulatory and development path toward treatment for patients who currently lack a pharmaceutical treatment option ."

9 Meters is currently conducting a Phase 3 trial evaluating larazotide acetate in patients with non-responsive celiac disease, a severe variant of celiac disease in which patients experience gastrointestinal symptoms despite adherence to a gluten-free diet. Larazotide represents the only Phase 3-stage therapeutic in development for celiac disease, with the trial's interim analysis expected in the second half of 2021.

About Celiac Disease

Celiac disease affects approximately 3 million people in the United States and approximately 15 million individuals worldwide. Celiac disease is an autoimmune disorder that is triggered by the ingestion of gluten, which is primarily found in bread, pasta and other foods containing wheat, barley or rye. People with celiac disease who are exposed to gluten experience an immune reaction in their small intestines, causing damage to the inner surface (villi) of the intestine, and an inability to absorb certain nutrients. Signs and symptoms of celiac disease include intestinal pain, bloating, diarrhea and failure to thrive (infants and small children). These symptoms can be reduced, and sometimes eliminated, by avoiding food that contains gluten. However, many patients remain symptomatic despite a gluten-free diet, and these patients may have non-responsive celiac disease and could benefit from the addition of pharmacotherapy. Currently, there are no pharmacological therapies available to treat celiac disease.

About Larazotide Acetate

In celiac disease, larazotide is the only drug which has successfully met its primary endpoint with statistical significance in a Phase 2b efficacy clinical trial (342 patients). Nearly 600 subjects have been exposed to larazotide in clinical trials, and a safety profile comparable to placebo has been demonstrated. Larazotide has received Fast Track designation from the FDA and is currently enrolling patients in late-stage clinical development for celiac disease.

About 9 Meters Biopharma

9 Meters Biopharma, Inc. is a rare, orphan and unmet needs-focused GI company. The Company is advancing NM-002, a proprietary long-acting GLP-1 agonist into Phase 2 trial for Short Bowel Syndrome (SBS), a rare, orphan disease, as well as larazotide, a Phase 3 tight junction regulator being evaluated for patient-reported symptom improvement in non-responsive celiac disease.

For more information, please visit www.9meters.com.

Forward-looking Statements

This press release includes forward-looking statements based upon the Company's current expectations. Forward-looking statements involve risks and uncertainties, and include, but are not limited to, the potential effects of the ongoing coronavirus outbreak and related mitigation efforts on the Company's clinical, financial and operational activities; the Company's continued listing on Nasdaq; expectations regarding future financings; the future operations of the Company; the nature, strategy and focus of the Company; the development and commercial potential and potential benefits of any product candidates of the Company; anticipated preclinical and clinical drug development activities and related timelines, including the expected timing for data and other clinical and preclinical results; the Company having sufficient resources to advance its pipeline; and any other statements that are not historical fact. 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: (i) uncertainties associated with the clinical development and regulatory approval of product candidates; (ii) risks related to the inability of the Company to obtain sufficient additional capital to continue to advance these product candidates and its preclinical programs; (iii) uncertainties in obtaining successful clinical results for product candidates and unexpected costs that may result therefrom; (iv) 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; (v) the impact of COVID-19 on our operations, clinical trials or proposed merger and future financings and (vi) risks associated with the possible failure to realize certain anticipated benefits of the proposed Merger and the Naia acquisition, including with respect to future financial and operating results. 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. 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 Innovate Biopharmaceuticals, Inc. Annual Report on Form 10-K for the year ended December 31, 2019 and in other filings that Innovate has made and future filings the Company 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. The company 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.

References:

1. Overview of the ICH E14 Guideline & Its Implementation Within FDA: https://www.fda.gov/media/104642/download
2. Heart Rhythm Society Patient Resources Page: https://www.upbeat.org/the-normal-heart/electrical-system

Corporate contacts:

Edward J. Sitar
Chief Financial Officer
9 Meters BioPharma, Inc.
investor-relations@9meters.com
www.9meters.com

Media contact:

Amy Jobe, Ph.D.
LifeSci Communications, LLC
ajobe@lifescicomms.com
315-879-8192

Investor contact:

Corey Davis, Ph.D.
LifeSci Advisors, LLC
cdavis@lifesciadvisors.com
212-915-2577

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