9 Meters Biopharma, Inc Announces the Closing of Naia Rare Diseases Acquisition

May 7, 2020

- Previously announced in late 2019 this transaction accelerates the development of novel long-acting GLP-1 receptor agonist as the Company's Co-Lead Program-

- Phase 2 trial for Short Bowel Syndrome planned in 2H 2020 and top-line results in 2021-

RALEIGH, NC / ACCESSWIRE / May 7, 2020 / 9 Meters Biopharma, Inc (NASDAQ:NMTR), today announced that it has closed the merger with Naia Rare Diseases, a company developing a proprietary long-acting glucagon-like peptide-1 (GLP-1) receptor agonist for the treatment of Short Bowel Syndrome (SBS) and other rare gastrointestinal diseases. The deal also includes a proprietary long-acting glucagon-like peptide-2 (GLP-2) being developed for an undisclosed orphan indication. The transaction follows the recent financing, led by Orbimed Advisors, LLC, announced earlier this week after signing $22 million in new funding.

"Our strategy and approach is completely aligned with that of Naia Rare Diseases," said John Temperato President & Chief Executive Officer of 9 Meters, "We aim foremost to improve the lives of patients with incapacitating GI disorders. For some of these disorders, there are currently no FDA-approved treatments, and for others, currently available therapies are sub-optimal. The addition of Naia's pipeline of long-acting GLPs greatly enhances our ability to do exactly that."

Our mission at 9 Meters is straightforward and focused - The Company believes its' long-acting GLP-1 agonist, NM-002, is designed specifically to address the current gaps in the standard of care, by decreasing the rapid gut transit time in patients with SBS. Currently, NM-002 is the only therapy being developed in SBS that directly addresses increased bowel motility. By slowing down gut motility, it acts as a natural brake on stomach contractions and gut transit, causing an increase in nutrient absorption and potentially allowing patients to eliminate the need for parenteral nutrition while improving their quality of life.

NM-002 has demonstrated efficacy and an extended half-life up to 30 days in a 70-patient clinical study[1] and received Orphan Designation by the U.S. Food and Drug Administration. The Company, along with Cedars-Sinai Medical Center, plans to initiate a clinical program in SBS in mid-2020, with the goal of developing a potentially safer, more efficacious and convenient therapy.

Andrew Jablonski of the Short Bowel Syndrome Foundation (SBSF) commented that, "The development of this new therapy is extremely innovative in that it could potentially help the gut absorb more nutrients from patients' daily intake. It is promising to see the development of new therapies in SBS to help those living with this condition. With few options in this rare disease, including total parenteral nutrition (TPN) and tube feedings which are confining for many, new agents such as NM-002 could allow weaning of typical therapies, translating into a major milestone for both the patient and the caregiver."

H. Daniel Perez, M.D., co-founder, chairman and CEO of Naia Rare Diseases, said, "The potential behind the combination of these companies is powerful. We believe the high-caliber, experienced team will advance our exciting pipeline, as they share our commitment of bringing innovative new medicines to patients suffering from SBS and other debilitating gastrointestinal rare diseases with few options."

Based on encouraging and published proof-of-concept data, 9 Meters will initiate a Phase 1b/2a clinical trial in mid-2020. This study will assess the safety and tolerability of three different doses in adult patients with SBS. We expect to have topline data in the first half of 2021.

About Short Bowel Syndrome
According to the National Institute of Diabetes, and Digestive and Kidney Diseases (NIDDK), SBS is a rare syndrome of problems related to poor absorption of nutrients as a result of at least half of the small intestine being removed and sometimes all or part of the large intestine; significant damage to the small intestine; or poor motility, or movement inside of the intestines.[2] The incidence of SBS is poorly known but estimated at about 5 to 10 patients per year per million population. In adults, the incidence of SBS requiring at-home parenteral nutrition is estimated at two adult patients per year per million population.[3] Pharmacologic therapies for SBS include trophic factors, such as short-acting daily injectable GLP-2 analogues, which may not be appropriate for all patient types.

About the Short Bowel Syndrome Foundation

The Short Bowel Syndrome Foundation, Inc. (SBSF) is a 501c3 organization that helps support and educate those who live with and care for Short Bowel Syndrome. In the last nine years, the Foundation has helped grow a community of patients and caregivers supporting each other through social media. SBSF offers support, advocacy and education for patients and caregivers to help give a better understanding of SBS and its treatments. SBSF administers online support groups for adults, international patients, along with a family and caregivers support group. The Foundation has been on several different expert advisory boards for short bowel syndrome, and has served as an expert consultant for NPS Pharma, Naia Rare Diseases, and Shire Pharmaceuticals respectively. The Foundation strives to continue working alongside industry leaders to create better patient and caregiver experiences.

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.

About Naia Rare Diseases

Naia Rare Diseases is a development-stage biopharmaceutical company developing novel drugs for rare gastrointestinal disorders. The company is pursuing three development programs including NB 1001 for Adult SBS, NB 1001 for pediatric SBS and NB 1002, a GLP-2 agonist, for an undisclosed orphan gastrointestinal indication. Naia Rare Diseases has been funded primarily by its parent company, Naia Limited, a company focused on building and funding new biotech companies using de-risked clinical-stage assets. For more information, please visit www.naiapharma.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.

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1. Data presented at the 71st American Diabetes Association conference (2011)
2. NIH Health Information - Short Bowel Syndrome
3. Amiot A, Messing B, Corcos O, Panis Y, Joly F. Determinants of home parenteral nutrition dependence and survival of 268 patients with non-malignant short bowel syndrome. Clin Nutr 2013;32(3):368-74.

SOURCE: 9 Meters Biopharma

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