NGM Bio Announces First Participant Dosed in EMERALD Phase 2 Clinical Study of NGM120 for the Treatment of Hyperemesis Gravidarum (HG) in Pregnant Patients

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- HG is a rare, debilitating condition of pregnancy, characterized by intractable nausea and uncontrollable vomiting and frequent, serious complications
- An increase in the hormone GDF15 is believed to be a root cause of nausea and vomiting in HG
- NGM Bio is a pioneer and long-time leader in elucidating GDF15 biology, including discovering GDF15's cognate receptor GFRAL
- NGM120, a monoclonal antibody, is designed to block GDF15 activity by binding to GFRAL

SOUTH SAN FRANCISCO, Calif., Feb. 24, 2025 (GLOBE NEWSWIRE) -- NGM Biopharmaceuticals, Inc. (NGM Bio), a privately held biotechnology company focused on discovering and developing transformative therapeutics for patients, today announced that it has dosed the first participant in its EMERALD Phase 2 clinical study of NGM120, a GFRAL antagonist designed to block GDF15 activity, for the treatment of hyperemesis gravidarum (HG), a rare, debilitating condition of pregnancy.

The leading cause of hospitalization in early pregnancy, HG is characterized by intractable nausea and vomiting, which can be as frequent as 10 to 15 times per day and results in dehydration, debility, weight loss and malnutrition. HG has a significant physical and psychosocial impact on patients and leads to overall higher rates of fetal loss and termination, preeclampsia, preterm birth, low birth weight, fetal malnutrition, maternal depression, and in some cases, suicidal thoughts. HG typically recurs in subsequent pregnancies. There are no approved therapies that target the underlying cause of HG.

"We are proud to advance NGM120 into the clinic to evaluate its potential to address hyperemesis gravidarum, or HG, by targeting a major underlying cause of this debilitating condition," said Wendy Yeh, M.D., Chief Medical Officer at NGM Bio. "Unfortunately, the severity and impact of HG are often underappreciated. At NGM, we understand how devastating this condition is, and we hear the pleas of women who experience the physical and mental toll of HG for an effective therapeutic solution. By inhibiting the activity of GDF15, NGM120 may potentially help reduce symptoms associated with HG, and, thereby, mitigate the impact and significant risks this condition can present during pregnancy."

Although GDF15 is a hormone that everyone produces, levels of GDF15 are higher in pregnant women and can be even higher in women with HG. The extremely high levels of GDF15 are believed to cause the nausea and vomiting that are hallmarks of HG. NGM120 is an antibody designed to bind to the receptor (known as GFRAL) for GDF15. This binding blocks the interaction of GDF15 with GFRAL, which, in turn, inhibits the activity of GDF15, potentially alleviating HG symptoms.

NGM120 has been generally well-tolerated in over 140 non-pregnant participants treated in clinical trials to date. To learn more about NGM120 as a potential treatment for HG, link here.

About the Randomized, Placebo-Controlled EMERALD Phase 2 Study

The randomized, placebo-controlled EMERALD study is designed to assess the safety and tolerability of NGM120 in addition to standard of care and supportive care. Eligible pregnant participants diagnosed with HG who are enrolled in the study will receive a single subcutaneous dose of NGM120 or placebo on the first day of the assigned study period, which lasts seven days. Participants assigned to the NGM120 arm and participants assigned to the placebo arm will also receive the following: intravenous (IV) fluids with multivitamins on several days prior to and throughout the seven-day study period as supportive care; IV multivitamins according to the standard of care at each study center; and 4 mg ondansetron (a prescription medicine that counteracts nausea and vomiting) three times daily, per standard of care.

The EMERALD study is enrolling participants in the United Kingdom (ISRCTN76681798) and Australia (ACTRN12624001421527). To learn more, please visit the following clinical trial listings:

United Kingdom (Link here)
Australia (Link here)

About NGM Bio

NGM Biopharmaceuticals, Inc. (NGM Bio), a wholly owned subsidiary of NGM Bio Holdings, Inc., a privately held biotechnology company, is focused on discovering and developing novel, life-changing medicines for people whose health and lives have been disrupted by disease. NGM Bio's biology-centric drug discovery approach aims to seamlessly integrate interrogation of complex disease-associated biology and protein engineering expertise to unlock proprietary insights that are leveraged to generate

promising product candidates, enable their rapid advancement into proof-of-concept studies and address high unmet patient need.

NGM Bio has three clinical-stage programs: NGM120, a GFRAL antagonist designed to block the activity of GDF15, in development for hyperemesis gravidarum and for cancer cachexia, and aldafermin, an engineered analog of the human hormone FGF19, in development for primary sclerosing cholangitis.

Visit us at http://www.ngmbio.com for more information.

Abbreviations

FGF19 = fibroblast growth factor 19; GDF15 = growth differentiation factor 15; GFRAL = glial cell-derived neurotrophic factor receptor alpha-like

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