NAIARAREDISEASES

Naia Rare Diseases Announces Investigational New Drug Application Submission to Initiate Clinical Trials of NB 1001 for Short Bowel Syndrome

-- Mark Pimentel, MD, of Cedars-Sinai to be Principal Investigator--

RICHMOND, Calif., November 29, 2016 –Naia Rare Diseases, a biopharmaceutical company developing drugs for Short Bowel Syndrome (SBS) and other rare gastrointestinal diseases today announced that it has submitted an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) to initiate a Phase 1b clinical trial for its long-acting GLP-1 agonist, NB 1001, in adult patients with SBS.

Mark Pimentel, MD, FRCPC, chairman of Naia's board of scientific and clinical advisors and professor of medicine and director of the gastrointestinal motility program and laboratory at Cedars-Sinai Medical Center, will be the principal investigator (PI) of the study.

"We are pleased to have this IND under review by the FDA," said H. Daniel Perez, MD, President and CEO of Naia Rare Diseases. "We very much appreciate that Dr. Pimentel has agreed to lead the clinical trial as PI. We look forward to providing further details on the progress of the trial in the near future."

"I am excited to participate in this study," said Dr. Pimentel. "I believe NB 1001 has the potential to make a significant impact on the lives of patients with SBS, and look forward to working with the team at Naia as they develop NB 1001 further. NB1001 is the only drug in development that I am aware of that directly addresses bowel motility. As a result it should allow many patients to eliminate the need for parenteral nutrition, thus considerably improving their quality of life."

NB1001 will be administered as a replacement therapy (replacing endogenous GLP-1 lost by bowel resection), in contrast to GLP-1 agonists used to treat Type 2 diabetes, which are administered at pharmacologic levels in order to lower blood sugar. Lower doses of NB1001 combined with a longer half-life will provide a differentiated, safe, effective and convenient therapeutic approach for these patients.

About NB 1001

NB1001 (XTEN™-GLP-1) is a long-acting glucagon-like peptide-1 (GLP-1) receptor agonist that combines exenatide with a proprietary extended half-life technology. Licensed from Amunix Operating Inc., NB 1001 uses Amunix's proprietary "XTEN" technology to extend the half-life of the GLP-1 peptide and allows for up to once-per-month dosing, thus considerably increasing convenience for patients and caregivers. Because of lower overall exposure and dose required (as a replacement therapy) NB 1001 will have an increased safety window compared to other GLP-1 agonists, important as SBS patients are a very fragile population. NB 1001 was previously developed to treat type 2 diabetes and in a 70 patient clinical study demonstrated efficacy and an extended half-life up to 30 days.

NB1001 has received orphan drug designation by the FDA.

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, 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.

Contact:
Mark Bagnall, Naia Pharmaceuticals
510-926-8237
mbagnall@naiapharma.com