PRESS RELEASE

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Elcelyx Therapeutics Enrolling Phase 2b Trial of NewMet for Type 2 Diabetes

SAN DIEGO, May 20, 2013 /PRNewswire via COMTEX/ -- Enrollment of patients with Type 2 diabetes is underway in Elcelyx Therapeutics' Phase 2b dose-finding clinical trial of product candidate NewMet(TM), a delayed-release formulation of generic metformin, the foundational treatment for Type 2 diabetes. Elcelyx expects to complete enrollment of 240 patients in the multicenter U.S. program in June. Results of the trial's primary endpoint of change in fasting plasma glucose are expected in late summer, and the read-out for long-term glucose lowering and weight benefits is due in the fourth quarter of 2013.

Elcelyx has not changed the way metformin works but instead, has discovered how and where metformin works and has leveraged that understanding to develop an improved product. Elcelyx believes metformin's primary site of action is the lower bowel rather than the circulation. By targeting the lower bowel, NewMet dramatically reduces the amount of active ingredient in the bloodstream while still maintaining metformin's potent glucose lowering benefit. Phase 2a trial results indicate that a significantly lower once-daily dose of NewMet that maintains efficacy may meaningfully reduce metformin's gastrointestinal side effects and eliminate the need for titration to initiate treatment.

"Elcelyx's approach of reducing bioavailability of metformin is quite ingenious and turns on its head the incorrect belief that greater exposure to metformin is needed for superior therapeutic benefit," said Ralph A. DeFronzo, M.D., Professor of Medicine and Chief of the Diabetes Division at the University of Texas Health Science Center and the Audie L. Murphy Memorial Veterans Administration Hospital in San Antonio, Texas. "Results from previous NewMet trials indicate that by targeting the hormone-producing enteroendocrine cells in the lower gut, NewMet may have better tolerability with the preserved efficacy of metformin at a lower dose. This would make NewMet ideal for the millions of Type 2 diabetes patients who have difficulty tolerating metformin or are unable to take the medication due to contraindications. I am eager to see the results of the additional planned clinical studies of NewMet to further understand this attractive profile."

Dr. DeFronzo is a world-renowned clinician, teacher and investigator who led the trials that supported the U.S. Food and Drug Administration approval of metformin in 1994. He and fellow investigators will be presenting the Elcelyx-sponsored NewMet Phase 2a trial results at the 2013 American Diabetes Association Scientific Sessions in June.

This randomized, double-blind, dose-finding Phase 2b trial is evaluating NewMet once-daily doses of 1,000, 800 and 600 milligrams compared to placebo. There are also two comparator arms with generic extended-release metformin dosed once-daily at 1,000 and 2,000 milligrams. The primary endpoint of the study is fasting plasma glucose at 4 weeks of treatment. Secondary endpoints through 12 weeks include changes in fasting plasma glucose, hemoglobin A1c, weight and measures of safety and tolerability.

"Our research has been eye opening for physicians and endocrinologists who appreciate the clinical benefits of metformin such as glucose control and weight loss but are frustrated by its gastrointestinal side effects, need for titration and exclusion of patients with moderate and severe impaired kidney function. Type 2 diabetes patients who have difficulty tolerating generic metformin either come off of it completely or drop down to a less than maximally effective dose," explained Alain Baron, M.D., President and Chief Executive Officer of Elcelyx Therapeutics. "The goal of this study is to demonstrate that NewMet has long-term glucose lowering benefits with a tolerability and safety profile that is superior to currently marketed metformin, the #1 diabetes product in the world. This would allow many more patients with Type 2 diabetes to enjoy the full benefit of metformin's active ingredient."

In Phase 2a studies in patients with Type 2 diabetes, NewMet reduced fasting plasma glucose to a similar extent as generic metformin but had improved tolerability. Pharmacokinetic/pharmacodynamic studies have shown that glucose lowering and augmented release of the gut hormones peptide YY (PYY) and glucagon-like peptide-1 (GLP-1) were similar to generic metformin despite NewMet's dramatically lower plasma exposure.

By targeting the lower gut and reducing systemic absorption, NewMet may be appropriate for the large population of renally impaired patients with Type 2 diabetes that are contraindicated for metformin use due to the risk of lactic acidosis, a life-threatening result of metformin build-up in the blood. There are few safe and sufficiently effective oral agents to treat Type 2 diabetes patients with renal impairment. Elcelyx plans to initiate a pharmacokinetics/pharmacodynamics study of NewMet in Type 2 diabetes patients with mild, moderate and severe renal impairment. The study is expected to begin this summer.

NewMet is also an ideal candidate for fixed-dosed combinations with other oral antidiabetic agents, such as DPP4is and SGLT2is, because it can deliver a maximally effective dose of metformin in a single once-daily tablet and does not require titration.

About Elcelyx TherapeuticsElcelyx Therapeutics develops pharmaceutical and consumer healthcare products based on its proprietary Gut Sensory Modulation (GSM) platform. Pharmaceutical product candidate NewMet(TM) is being developed for use by Type 2 diabetes patients who have difficulty tolerating generic metformin or are contraindicated for its use. In the consumer health area, Elcelyx is developing Lovidia(TM) as a dietary supplement for weight management. These product candidates are backed by rigorous science and clinical data and present near-term, blockbuster commercial opportunities. Elcelyx is based in San Diego, CA. For more information, visit www.Elcelyx.com.

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