Making Sense of Metabolic Disorders

Elcelyx Therapeutics Announces Positive Results in Phase 2b Study of NewMet in Type 2 Diabetes

SAN DIEGO, October 21, 2013 – Elcelyx Therapeutics announced today the completion of a 12-week Phase 2b study of NewMet™, a delayed-release formulation of metformin for the treatment of patients with Type 2 diabetes. Elcelyx previously reported that the study met its primary endpoint of statistically significant reduction in fasting plasma glucose at four weeks of treatment with NewMet compared to placebo. The 12-week data confirm the durability of the effect observed at four weeks.

The randomized, 240-patient, multicenter, double-blind, dose-finding trial evaluated NewMet once-daily doses of 1000, 800 and 600 milligrams compared to placebo. There were also two unblinded reference arms with Glucophage® XR dosed once-daily at 1000 and 2000 milligrams.

All NewMet arms showed efficacy comparable to or greater than 1000 milligrams of Glucophage XR. The NewMet 1000 milligram dose was approximately 50% more effective than 1000 milligrams of Glucophage XR and approximately 70% as effective as 2000 milligrams of Glucophage XR. A dose response trend was observed across the three NewMet doses, indicating higher doses of NewMet may provide greater efficacy. All doses of NewMet and Glucophage XR prevented the rise in HbA1c seen with placebo due to washout of previous anti-diabetic medications. All doses of NewMet and Glucophage XR were well tolerated and there were no meaningful weight changes observed.

In previous studies, NewMet, which is targeted to the lower bowel, reduced systemic exposure by as much as 65% compared to metformin immediate release (IR) and metformin XR. The ability of NewMet to significantly reduce fasting plasma glucose over 12 weeks further confirms the durable efficacy of bowel-directed metformin. The dramatic reduction in plasma metformin exposure indicates that NewMet may be an appropriate treatment for Type 2 diabetes patients who have renal impairment and are contraindicated for metformin IR and metformin XR use due to the risk of lactic acidosis, a life-threatening condition that can result from metformin build-up in the blood.

"The American Diabetes Association treatment guidelines state that '*metformin, if not contraindicated and if tolerated, is the preferred initial pharmacological agent for type 2 diabetes',"* said Alain Baron, M.D., President and CEO, Elcelyx Therapeutics. "The positive results from this important longer-term study should be very encouraging for physicians."

The NewMet Phase 2b study results support the further development of NewMet for the more than 3 million U.S. patients with renal impairment currently contraindicated for use of metformin IR and metformin XR. Moreover, lower doses of NewMet make feasible once-daily, fixed-dose combinations with other oral anti-diabetic agents, such as a DPP4i and/or a SGLT2i. Additionally, given the lower doses and the delayed release profile of NewMet, the anticipated improved gastrointestinal tolerability

profile compared to metformin IR and metformin XR could address the unmet need of millions of Type 2 diabetes patients in the U.S. who are unable to take metformin due to intolerance.

About Elcelyx Therapeutics, Inc.

Elcelyx Therapeutics is developing pharmaceutical product candidate NewMet™ for use by Type 2 diabetes patients who have difficulty tolerating generic metformin or are contraindicated for its use. NewMet presents a near-term, blockbuster commercial opportunity. Elcelyx is based in San Diego, CA. For more information, visit www.Elcelyx.com.

Glucophage is a registered trademark of Bristol-Myers Squibb Company

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