April 27, 2016

XOMA Initiates XOMA 358 Proof-of-Concept Study in Patients with Hypoglycemia Post Gastric Bypass Surgery

Novel first-in-class antibody enters clinic for second rare hypoglycemic indication

BERKELEY, Calif., April 27, 2016 (GLOBE NEWSWIRE) -- XOMA Corporation (Nasdaq:XOMA), a leader in the discovery and development of therapeutic antibodies, announced today it has initiated its proof-of-concept study to evaluate the safety and clinical pharmacology of a single dose of XOMA 358 in patients who experience dangerously low blood glucose levels (hypoglycemia) after undergoing gastric bypass surgery. XOMA 358 is a fully human allosteric monoclonal antibody that reduces both the binding of insulin to its receptor and downstream insulin signaling.

“Significant numbers of morbidly obese patients have turned to gastric bypass surgery as a critical healthcare intervention,” said Paul Rubin, M.D., Senior Vice President, Research and Development, and Chief Medical Officer at XOMA. “Unfortunately, some of these bypass surgery patients can develop a condition where they experience severe hypoglycemia after eating a meal. In some cases, this severe hypoglycemia cannot be managed by diet modification or resolved by existing pharmacologic agents, requiring patients to be treated with either a reversal of the bypass procedure or even a partial pancreatectomy. This clinical study will determine if XOMA 358 could be developed further as a first-in-class medical alternative for the treatment of severe hyperinsulinemic hypoglycemia in post gastric bypass patients.”

Proof-of-Concept Study Design
The open-label, single-dose, multi-center study, in which patients serve as their own control, is designed to evaluate ascending dose levels of XOMA 358 in patients with documented hypoglycemia after gastric bypass surgery. This is a cohort study, with the first cohort receiving a dose of XOMA 358 chosen based on the safety and pharmacodynamics results from XOMA’s Phase 1 study in healthy subjects. Subsequent cohorts may receive a higher or lower dose dependent on the results seen in the first cohort. The study will document consistent hypoglycemic events prior to treatment with XOMA 358 and the ability of XOMA 358 to prevent these events after dosing.

Safety will be monitored throughout the study. In addition, serial blood samples will be collected for pharmacokinetic and pharmacodynamic assessments. Various markers of drug

activity will be assessed, including changes in glucose, ketones, insulin, C-peptide and free fatty acid levels. Additional measurements of biological effect will include protein challenges and continuous glucose monitoring.

About XOMA 358
Insulin is the major physiologic hormone for controlling blood glucose levels. Abnormal increases in insulin secretion can lead to profound hypoglycemia (low blood sugar), a state that can result in significant morbidities, including brain damage, seizures and epilepsy. XOMA, leveraging its scientific expertise in allosteric monoclonal antibodies, developed the XMet platform, consisting of separate classes of selective insulin receptor modulators (SIRMs) that could have a major effect on treating patients with abnormal metabolic states. XOMA 358 binds selectively to insulin receptors and attenuates insulin action.

XOMA presented positive Phase 1 data on XOMA 358 at ENDO 2015, the Endocrine Society's annual meeting, in March 2015. Results of the study, in which 14 healthy volunteers received XOMA 358 and 5 received placebo, showed XOMA 358 reduced insulin sensitivity and decreased glucose lowering after exogenous insulin injection. In the study, XOMA 358 appeared to be well tolerated, with no serious adverse events observed.

XOMA 358 is being investigated as a novel treatment for non-drug-induced, endogenous hyperinsulinemic hypoglycemia, as well as hypoglycemia post-bariatric surgery and other related disorders. A therapy that safely and effectively mitigates insulin-induced hypoglycemia has the potential to address a significant unmet therapeutic need for certain rare medical conditions associated with hyperinsulinism. More information on the XOMA 358 clinical trials may be found at www.clinicaltrials.gov.

About Hypoglycemia Post Gastric Bypass Surgery [i,ii,iii,iv]
As the number of gastric bypass surgeries to treat severe obesity has increased, so too has the awareness that this population may experience postprandial hypoglycemia (low blood glucose following a meal) with symptoms developing months or years following the gastric bypass surgery. Postprandial hypoglycemia occurs with a range of severity in post-gastric bypass patients. The mild end of the spectrum may be managed largely through diet modification. The most severe forms are more prevalent in patients who underwent a Roux-en-Y procedure, and result in severe refractory postprandial hyperinsulinemic hypoglycemia with neuroglycopenic symptoms (altered mental status, loss of consciousness, seizures) that cannot be managed through diet modification. If currently available pharmacologic agents do not resolve the condition, these patients are treated with either a partial pancreatectomy or reversal of the gastric bypass.

About XOMA Corporation
XOMA Corporation is a leader in the discovery and development of therapeutic antibodies. The Company's innovative product candidates result from its expertise in developing ground-breaking monoclonal antibodies, including allosteric antibodies, which have created new opportunities to potentially treat a wide range of human diseases. XOMA's scientific research has produced a portfolio of five endocrine assets, each of which has the opportunity to address multiple indications. The Company's lead product candidate, XOMA 358, is an allosteric monoclonal antibody that reduces insulin receptor activity, which could have a major impact on hyperinsulinism. The Company recently initiated Phase 2 development activities for XOMA 358 in patients with congenital hyperinsulinism and in patients who

experience hypoglycemia following gastric bypass surgery. For more information, visit www.xoma.com.

Forward-Looking Statements

Certain statements contained in this press release including, but not limited to, statements related to anticipated timing of clinical trials, anticipated timing of the release of clinical data, regulatory approval of unapproved product candidates, the anticipated process of clinical data analysis, the anticipated success of any clinical trial, cash usage, or statements that otherwise relate to future periods are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements are based on assumptions that may not prove accurate, and actual results could differ materially from those anticipated due to certain risks inherent in the biotechnology industry and for companies engaged in the development of new products in a regulated market. Potential risks to XOMA meeting these expectations are described in more detail in XOMA's most recent filing on Form 10-K and in other SEC filings. Consider such risks carefully when considering XOMA's prospects. Any forward-looking statement in this press release represents XOMA's views only as of the date of this press release and should not be relied upon as representing its views as of any subsequent date. XOMA disclaims any obligation to update any forward-looking statement, except as required by applicable law.

[i] Foster-Schubert KE. Hypoglycemia complicating bariatric surgery: incidence and mechanisms. Curr Opin Endocrinol Diabetes Obes 2011;18(2):129-33.

[ii] Patti ME and Goldfine AB. Hypoglycaemia following gastric bypass surgery--diabetes remission in the extreme? Diabetologia 2010;53(11):2276-9.

[iii] Service GJ, Thompson GB, Service FJ, Andrews JC, Collazo-Clavell ML and Lloyd RV. Hyperinsulinemic hypoglycemia with nesidioblastosis after gastric-bypass surgery. N Engl J Med 2005;353(3):249-54.

[iv] Vella A and Service FJ. Incretin hypersecretion in post-gastric bypass hypoglycemia--primary problem or red herring? J Clin Endocrinol Metab 2007;92(12):4563-5.

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Source: XOMA Corporation