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XOMA Establishes Proof-of-Concept for 358 in Congenital Hyperinsulinism and Hypoglycemia Post-Bariatric Surgery

Congenital Hyperinsulinism Phase 2 study completed and multi-dose study protocol approved in the United Kingdom; Company initiates multi-dose study in hypoglycemic Post-Bariatric Surgery patients

BERKELEY, Calif., Jan. 31, 2017 (GLOBE NEWSWIRE) -- XOMA Corporation (Nasdaq:XOMA), a leader in the discovery and development of therapeutic antibodies, announced today that it has established proof-of-concept for its product candidate 358 in congenital hyperinsulinism (CHI) and hypoglycemia post-bariatric surgery (PBS). The Company will host a webcast and conference call today, January 31, 2017, at 2:00 p.m. PST (5:00 p.m. EST) to share data from these studies. The CHI acute studies have met their objectives of establishing initial safety and 358 proof-of-concept in CHI patients aged 12 and up across several dosing levels. The Company is nearing the launch of a multi-dose study in children with CHI aged 2 and up that will be conducted in the United Kingdom. The PBS study has completed dosing in the single-dose cohorts and has also met its objectives; a multi-dose study has been initiated.

"With the large unmet clinical need in patients with CHI and PBS, 358 provides a first-in-class antibody with the potential to help pediatric and adult patients properly regulate their blood glucose concentrations and prevent hypoglycemic episodes," said Eric P. Brass, M.D., Ph.D., Professor Emeritus of Medicine, David Geffen School of Medicine, University of California, Los Angeles. "These data clearly demonstrate that a single-dose of 358 results in predictable and reproducible pharmacokinetics and meaningful improvements in glucose concentrations. The Company can now assess, in follow-on studies, the consistency and magnitude of 358's effect through multi-dose protocols to yield sustained steady-state drug exposure in the target populations."

CHI is a rare disease that results in the sustained over production of insulin and usually presents early in life. Parents and children living with CHI are required to be hyper vigilant to ensure the child's blood glucose level does not fall below a critical threshold as they face the risk of seizures and long-term cognitive impairment. 358 has been designated an orphan drug intended for the treatment of CHI in the United States (U.S.) and European Union. Post-bariatric surgery patients are also at risk for debilitating episodes of hypoglycemia. Of the nearly 67,000 patients each year that undergo the Roux-en-Y method of bariatric surgery, approximately five percent will develop severe hypoglycemia. Severe hypoglycemia can have a significant impact on a patient's health and ability to participate in the normal activities of daily life.

"There are thousands of children and adults worldwide who are living with hyperinsulinemic hypoglycemia," said Jim R. Neal, Chief Executive Officer of XOMA. "When we consider the totality of preclinical and clinical evidence, we are confident proof-of-concept has been established for 358. It inhibits insulin signaling by binding to the insulin receptor in an allosteric manner and the antibody appears to be safe and well tolerated. It is clear that 358 is ready to move into multi-dose studies."

Conference Call Details

The presentation slides and webcast can be accessed via the Investors and Media section of XOMA's website at <http://investors.xoma.com/events.cfm> and will be available for replay. Telephone numbers for the live audiocast are 1-408-337-0122 and 1-877-369-6589 (Toll-Free) with the passcode 61229012.

About 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.

358 is a fully human negative allosteric modulating insulin receptor antibody derived from the XMet platform. It is being investigated as a novel treatment for non-drug-induced, endogenous hyperinsulinemic hypoglycemia (low blood glucose caused by excessive insulin production), as well as hypoglycemia after bariatric surgery. XOMA is conducting Phase 2 development activities for 358 in patients with congenital hyperinsulinism (CHI) and in patients with hypoglycemia post-bariatric surgery (PBS). 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 358 clinical trials may be found at www.clinicaltrials.gov and www.clinicaltrialsregister.eu.

Open-label, Phase 2 studies evaluated 358 in 14 patients with congenital hyperinsulinism (CHI) and 13 patients with hypoglycemia post-bariatric surgery (PBS). The studies were performed with expert disease centers in Philadelphia, Magdeburg, Germany, and London for CHI, and top U.S. centers in Denver, Baltimore, Boston, and Rochester, Minnesota for PBS.

The Phase 2 studies were monitored for safety, and serial blood samples were collected for pharmacokinetic and pharmacodynamic assessments. Various markers of drug activity were assessed, including changes in glucose, ketones, insulin, C-peptide and free fatty acid levels. Controlled tests included monitored fasts, protein challenges, and oral glucose tolerance.

About Congenital Hyperinsulinism^{i,ii,iii}

Congenital Hyperinsulinism (CHI) is a genetic disorder in which the insulin-secreting cells of the pancreas (beta cells) secrete inappropriate and excessive insulin. Ordinarily, beta cells secrete just enough insulin to keep blood sugar in the normal range. In people with CHI, the secretion of insulin is not properly regulated, causing excess insulin secretion and frequent episodes of low blood sugar (hypoglycemia). In infants and young children, these episodes are characterized by a lack of energy (lethargy), irritability or difficulty feeding. Repeated episodes of low blood sugar increase the risk for serious complications, such as breathing difficulties, seizures, intellectual disability, vision loss, brain damage, coma, and possibly death. About 60 percent of infants with CHI experience a hypoglycemic episode within the first month of life. Other affected children develop hypoglycemia by early childhood. Current treatments for CHI are limited to medical therapy and surgical removal of part or all of the pancreas (pancreatectomy).

About Hypoglycemia Post-Bariatric Surgery^{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-bariatric surgery 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 possible 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 attempted reversal of the gastric bypass.

About XOMA Corporation

XOMA Corporation is a leader in the 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 endocrine assets, each of which has the opportunity to address multiple indications. The Company's lead product candidate, 358, is an allosteric monoclonal antibody that reduces insulin receptor activity, which could have a major impact on the treatment of hyperinsulinism. For more information, visit www.xoma.com.

Forward-Looking Statements

Certain statements contained in this press release 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, including statements regarding: the future progress of the 358 clinical program, the medical need and market demand for 358, anticipated future study sites and enrollments, the initiation of international multi-dose studies, the overall promise of 358, and statements that otherwise relate to future periods. 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 Congenital hyperinsulinism. National Institutes of Health website. ghr.nlm.nih.gov/condition/congenital-hyperinsulinism. January 24, 2017. Accessed January 31, 2017.

ⁱⁱ Congenital Hyperinsulinism. Children's Hospital of Philadelphia website. www.chop.edu/conditions-diseases/congenital-hyperinsulinism/about#.VXncFU3bKHt. Accessed January 31, 2017.

iii Arnoux et al.: Congenital hyperinsulinism: current trends in diagnosis and therapy. Orphanet Journal of Rare Diseases 2011. 6:63.

iv Singh et al.: Hypoglycemia After Gastric Bypass Surgery. Diabetes Spectrum 2012 Nov; 25(4): 217-221.

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