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XOMA Receives Orphan Drug Designation in the European Union for XOMA 358 for Treatment of Congenital Hyperinsulinism

- XOMA 358 previously secured Orphan Drug Designation from the FDA for the treatment of Congenital Hyperinsulinism (CHI)
- Phase 2 clinical studies currently enrolling patients with CHI in the United States and European Union

BERKLEY, Calif., July 20, 2016 (GLOBE NEWSWIRE) -- XOMA Corporation (NASDAQ:XOMA), a leader in the discovery and development of therapeutic antibodies, today announced the European Medicines Agency (EMA) has granted Orphan Drug Designation to XOMA 358 for the treatment of congenital hyperinsulinism (CHI), a rare genetic disorder in which the insulin cells of the pancreas (beta cells) secrete inappropriate and excessive insulin. XOMA 358 is a negative allosteric antibody that binds to the insulin receptor and down-regulates insulin action. It is in Phase 2 development for CHI with clinical sites in the United States and European Union (EU) actively enrolling patients.

“Congenital hyperinsulinism is a devastating disease that presents in infancy and leads to profound hypoglycemia, which can cause significant morbidities, including brain damage, seizures and epilepsy. Both the disease and current treatments have potentially life-long physical and psychological impacts on patients and their families. The EMA Orphan Drug Designation for CHI recognizes the significant unmet medical need for CHI patients, and is an important step in the development pathway for XOMA 358,” said Paul Rubin, M.D., Senior Vice President, Research and Development, and Chief Medical Officer at XOMA. "The CHI community has been very supportive of our efforts to advance the XOMA 358 clinical program. With Orphan Drug Designation now secured in both the US and EU, we will continue to work closely with agencies in both regions to design a regulatory pathway that will expedite the clinical development for XOMA 358.”

To qualify for orphan designation in the EU, a therapeutic agent must be intended to treat a life-threatening or chronically debilitating disease that affects no more than five people in 10,000, and for which there is no treatment option or the current treatment options are unsatisfactory. Orphan Drug Designation in the EU brings numerous benefits to the company developing the therapeutic agent, including assistance with clinical protocols, scientific advice, and up to 10 years of marketing exclusivity upon approval.

About Congenital Hyperinsulinism
CHI is a genetic disorder in which the insulin cells of the pancreas (beta cells) secrete inappropriate and excessive insulin. In healthy individuals, 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 with 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 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 down-regulates insulin action.

XOMA 358, which has received Orphan Drug Designation from the U.S. Food and Drug Administration and from the European Medicines Agency, is being investigated as a novel treatment for non-drug-induced, endogenous hyperinsulinemic hypoglycemia, as well as hypoglycemia after bariatric surgery. XOMA recently initiated Phase 2 studies in patients with CHI, and in patients with hypoglycemia post bariatric surgery. 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 can be found at www.clinicaltrials.gov and www.clinicaltrialsregister.eu.

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.

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