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XOMA Announces Significant Step Toward Initiating Pediatric Phase 2 Clinical Study for XOMA 358 in Children with Congenital Hyperinsulinism

Company Reached Agreement with MHRA on General Trial Design for Multi-dose Testing in Children 2 Years and Older in the United Kingdom

BERKELEY, Calif., Oct. 19, 2016 (GLOBE NEWSWIRE) -- XOMA Corporation (Nasdaq:XOMA), a leader in the discovery and development of therapeutic antibodies, announced today the United Kingdom's Medicines and Healthcare Products Regulatory Agency (MHRA) has accepted in principle the Company's proposal to initiate a multi-dose Phase 2 clinical study of XOMA 358 in children two years and older diagnosed with Congenital Hyperinsulinism (CHI).

"MHRA officials clearly recognize the importance and complexity of conducting a clinical program in CHI, an orphan disease that affects children and infants for whom few effective treatment options are available. The comments resulting from our national advice meeting with the MHRA officials, regarding its requirements to support expedited clinical development for XOMA 358, were clear and thorough," commented Paul Rubin, MD, Senior Vice President Research and Development and Chief Medical Officer of XOMA. "Upon their formal review and acceptance of our protocol, XOMA will be able to launch its first multi-dose extended treatment clinical study for XOMA 358 in CHI patients over the age of two."

"Today's announcement reflects the priority we have placed on our regulatory efforts. Opening our clinical program to younger patients and offering multi-dose studies is a critical step to accelerate XOMA 358 development and reach the patients we believe are most likely to benefit from this first-in-class monoclonal antibody. Additionally, the regulatory body in Germany recently approved our plan to conduct a repeat-dose clinical study in CHI patients over the age of 12. Our first German site has begun enrolling patients and has already contributed to a substantial acceleration in enrollment in our XOMA 358 studies," stated John Varian, Chief Executive Officer of XOMA. "We look forward to continuing our conversations with the MHRA, the European Medicines Agency (EMA), and the US Food & Drug Administration (FDA) to advance the development of XOMA 358, enabling us to get this important treatment to children in need as expeditiously as possible."

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 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 and other related disorders. XOMA is conducting Phase 2 development activities for XOMA 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 XOMA 358 clinical trial may be found at www.clinicaltrials.gov and www.clinicaltrialsregister.eu.

About Congenital Hyperinsulinism[i, ii, iii, iv]

Congenital Hyperinsulinism (CHI) is a genetic disorder in which the insulin 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 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 the treatment of hyperinsulinism. The Company is conducting Phase 2 development activities for XOMA 358 in patients with congenital hyperinsulinism and in patients with hypoglycemia after bariatric surgery. 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 XOMA 358 clinical program, the medical need and market demand for XOMA 358, anticipated future study sites and enrollments, the possible expansion of clinical testing to younger patients, the overall promise of XOMA 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] ghr.nlm.nih.gov/condition/congenital-hyperinsulinism.
[ii] www.chop.edu/conditions-diseases/congenital-hyperinsulinism/about#.VXncFU3bKHt.
[iii] www.chop.edu/conditions-diseases/congenital-hyperinsulinism/about#.VXneYE3bKHu.
[iv] www.ojrd.com/content/pdf/1750-1172-6-63.pdf.

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