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XOMA Reports First Quarter 2014 Operational Highlights and Financial Results

BERKELEY, Calif., May 7, 2014 (GLOBE NEWSWIRE) -- XOMA Corporation (Nasdaq:XOMA), a leader in the discovery and development of therapeutic antibodies, today announced its operational highlights and financial results for the first quarter ended March 31, 2014.

First Quarter 2014 Operational Highlights

- Met with the U.S. Food and Drug Administration (FDA) to determine the requirements for a Phase 3 gevokizumab program in patients with pyoderma gangrenosum (PG), a rare neutrophilic dermatosis of painful expanding necrotic skin ulcers. The Company is completing and will submit the Phase 3 protocols for final comments from the Agency within the next several weeks.
- Announced gevokizumab had been granted Orphan Drug Designation by the FDA for the treatment of PG.
- Reported data from the Company's erosive osteoarthritis of the hand (EOA) proof-of-concept studies. Based upon the results, the Company has elected not to pursue the broad EOA indication for Phase 3 testing.
- XOMA's partner, SERVIER, continued to enroll patients in EYEGUARD™-B, which is studying gevokizumab in patients who have non-infectious uveitis (NIU) with underlying Behçet's disease, a rare indication.
- Continued to enroll patients in EYEGUARD-A and EYEGUARD-C studies investigating gevokizumab in patients with active and controlled NIU involving the intermediate and/or posterior segment of the eye.
- As of April 30, 2014, SERVIER, had opened EYEGUARD-A and -C clinical trial sites in 15 countries representing 52 clinical study centers. SERVIER also obtained approval in an additional 4 countries representing 12 clinical study sites.

"Our first quarter 2014 activities centered on advancing gevokizumab towards a Biologics Licensing Application. We have initiated a program to further increase patient enrollment at the 70 U.S. clinical sites conducting the EYEGUARD-A and C studies, and we are starting to see the first signs that this new outreach program could have the impact we are seeking. We conducted our meeting with the FDA to determine the Agency's requirements for a gevokizumab Phase 3 program in patients with pyoderma gangrenosum. Based upon the oral and written comments, we are submitting our Phase 3 protocol, and while we await any final comments, we are very actively working with clinical sites in the U.S. and in several other countries to ensure they are ready to enroll patients in the PG studies as soon as they are launched," stated John Varian, Chief Executive Officer of XOMA. "SERVIER is nearing their anticipated date for the pre-set final exacerbation in the EYEGUARD-B study, which will give us our first Phase 3 data in patients who have non-infectious uveitis and underlying Behçet's disease. Our clinical team has been working on the protocol for a supplemental Phase 3 study in this indication, which will give us the option to pursue a Behçet's uveitis-only label."

Financial Results

The financial results for the first quarter of 2014 reflect reduced reimbursements from SERVIER associated with gevokizumab development activities, as SERVIER met the initial \$50 million cap of fully reimbursable NIU costs during the third quarter of 2013. XOMA now pays 50% of the cost of gevokizumab development costs in NIU. The comparisons between the first quarters ended March 31, 2014 and 2013, reflect this development.

XOMA recorded total revenues of \$3.4 million for the three months ended March 31, 2014, compared with \$9.5 million during the corresponding period of 2013, which included a \$3.9 million milestone payment from SERVIER related to a product development program that XOMA subsequently transferred to Symplmed.

Annual research and development (R&D) expenses for first quarter ended 2014 were \$21.5 million compared to \$16.6 million in the corresponding 2013 period. The increases reflect the increased external clinical trial costs associated with XOMA's gevokizumab clinical development programs, increased spending on preclinical development activities related to the XMet platform, and an increase in stock-based compensation. Selling, general and administrative expenses (SG&A) were \$5.3 million for the three months ended March 31, 2014, compared to \$4.1 million incurred during the same period of 2013, primarily reflecting an increase in stock-based compensation.

For the first quarter ended March 31, 2014, XOMA had a net loss of \$4.7 million, or \$0.04 per share, compared with a net loss of \$24.9 million, or \$0.30 per share, in the quarter ended March 31, 2013. The net losses in the three months ended March 31, 2014 and 2013, included a \$20.0 million gain and \$12.8 million loss, respectively, in non-cash revaluations of contingent warrant liabilities, resulting primarily from fluctuations in XOMA's stock price. Excluding those revaluations, the net loss for the three months ended March 31, 2014, was \$24.7 million, or \$0.23 per share, compared with the net loss for the same reporting period in 2013 of \$12.0 million, or \$0.15 per share.

On March 31, 2014, XOMA had cash, cash equivalents, and short-term investments of \$93.7 million compared with \$121.6 million at December 31, 2013.

"Our first quarter spend is well aligned with our expectations of the cash requirements for XOMA's operations in 2014," commented Fred Kurland, Vice President, Finance, Chief Financial Officer and Secretary of XOMA. "Today we reaffirm our anticipated cash used in ongoing operating activities of approximately \$55.0 million to \$60.0 million during 2014. This guidance reflects the costs associated with conducting two separate Phase 3 programs for the gevokizumab, the EYEGUARD program and the pyoderma gangrenosum program, and it includes the expectation we will receive license and contract-related revenue during the year, which is consistent with our history of entering into such agreements."

Investor Conference Call and Webcast

XOMA will host a conference call and webcast today, May 7, 2014, at 4:30 p.m. ET / 1:30 PT. The 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 until close of business on August 7, 2014. Telephone numbers for the live audiocast are 877-369-6589 (U.S./Canada) and 408-337-0122 (international).

About Gevokizumab

Gevokizumab is a potent monoclonal antibody with unique allosteric modulating properties and has the potential to treat patients with a wide variety of inflammatory and other diseases. Gevokizumab binds strongly to interleukin-1 beta (IL-1 beta), a pro-inflammatory cytokine, and modulates the cellular signaling events that produce inflammation. IL-1 beta has been shown to be involved in diverse array of disease states, including non-infectious uveitis (including Behçet's uveitis), cardiovascular disease, and other auto-inflammatory diseases.

Gevokizumab currently is being studied in a global Phase 3 clinical program, termed EYEGUARD™, which is being conducted by SERVIER and XOMA. This program is designed to determine gevokizumab's ability to treat acute non-infectious uveitis (NIU) involving the intermediate and/or posterior segment of the eye in EYEGUARD-A, to prevent disease flares in patients with Behçet's uveitis in EYEGUARD-B, and to prevent disease flares in NIU patients who are controlled with steroids in EYEGUARD-C.

XOMA has a Proof-of-Concept (POC) program underway in which the Company is exploring the efficacy and safety of gevokizumab in multiple indications. Separately, SERVIER initiated a Phase 2 study to determine gevokizumab's ability to reduce arterial wall inflammation in patients with marked atherosclerotic plaque inflammation and who have experienced an acute coronary syndrome event in the previous twelve months, as well as POC studies in polymyositis/dermatomyositis, giant cell arteritis, and Schnitzler syndrome. Information about gevokizumab clinical studies can be found at www.clinicaltrials.gov and www.clinicaltrialsregister.eu.

About XOMA

XOMA has built a portfolio of innovative therapeutic antibodies, both in late-stage clinical development and in preclinical research. XOMA focuses its antibody research and development on allosteric modulation, which offers opportunities for new classes of therapeutic antibodies to treat a wide range of human diseases. XOMA's lead product candidate, gevokizumab (IL-1 beta modulating antibody), is in a global Phase 3 program in non-infectious uveitis with its partner SERVIER and multiple proof-of-concept studies in other IL-1-mediated diseases. XOMA's scientific research also produced the XMet program, which consists of three classes of preclinical antibodies, including Selective Insulin Receptor Modulators (SIRMs) that could have a significant effect on the treatment of diabetes.

More detailed information can be found at www.xoma.com.

About SERVIER

Founded in 1954, SERVIER is an independent French pharmaceutical research company. Its development is based

on the continuous pursuit of innovation in the therapeutic areas of cardiovascular, metabolic, neurologic, psychiatric, bone and joint diseases, as well as cancer. In 2013, the company recorded a turnover of 4.2 billion euros. 91% of SERVIER drugs are consumed internationally. 27% of turnover from SERVIER drugs were reinvested in Research and Development in 2013. With a strong international presence in 140 countries, SERVIER employs more than 21,000 people worldwide. The SERVIER Group contributed 35% to the 2013 French trade surplus in the pharmaceuticals sector.

Forward-Looking Statements

Certain statements contained in this press release including, but not limited to, statements related to anticipated timing of initiation and completion of clinical trials, Proof-of-Concept trials, anticipated size of clinical trials, regulatory approval of unapproved product candidates, sufficiency of our cash resources and anticipated levels of cash utilization, 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.

XOMA CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(unaudited)
(in thousands, except per share amounts)

	<u>March 31</u>	
	<u>2014</u>	<u>2013</u>
Revenues:		
License and collaborative fees	\$ 964	\$ 399
Contract and other	<u>2,446</u>	<u>9,054</u>
Total revenues	<u>3,410</u>	<u>9,453</u>
Operating expenses:		
Research and development	21,546	16,636
Selling, general and administrative	5,254	4,124
Restructuring	<u>84</u>	<u>17</u>
Total operating expenses	<u>26,884</u>	<u>20,777</u>
Loss from operations	(23,474)	(11,324)
Other income (expense):		
Interest expense	(1,125)	(1,172)
Other (expense) income	(90)	449
Revaluation of contingent warrant liabilities	<u>20,002</u>	<u>(12,840)</u>
Net loss	<u>\$ (4,687)</u>	<u>\$ (24,887)</u>
Basic and diluted net loss per share of common stock	<u>\$ (0.04)</u>	<u>\$ (0.30)</u>
Shares used in computing basic and diluted net loss per share of common stock	<u>106,158</u>	<u>82,595</u>
Other comprehensive loss:		
Net loss	\$ (4,687)	\$ (24,887)
Net unrealized gains on available-for-sale securities	<u>7</u>	<u>3</u>
Comprehensive loss	<u>\$ (4,680)</u>	<u>\$ (24,884)</u>

XOMA CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share amounts)

	March 31,	December
	2014	2013
	(unaudited)	(audited)
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 73,706	\$ 101,659
Short-term investments	19,996	19,990
Trade and other receivables, net	4,312	3,781
Prepaid expenses and other current assets	<u>2,558</u>	<u>1,630</u>
Total current assets	100,572	127,060
Property and equipment, net	6,028	6,456
Other assets	<u>1,029</u>	<u>1,266</u>
Total assets	<u><u>\$ 107,629</u></u>	<u><u>\$ 134,782</u></u>
LIABILITIES AND STOCKHOLDER'S EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	\$ 8,851	\$ 9,616
Accrued and other liabilities	4,895	9,934
Deferred revenue	2,158	2,218
Interest bearing obligation - current	4,085	5,835
Accrued interest on bearing obligations – current	<u>264</u>	<u>2,042</u>
Total current liabilities	20,253	29,645
Deferred revenue – long-term	3,636	4,105
Interest bearing obligations – long-term	34,658	35,150
Contingent warrant liabilities	<u>47,342</u>	<u>69,869</u>
Total liabilities	<u>105,889</u>	<u>138,769</u>
Stockholders' equity (deficit):		
Common stock, \$0.0075 par value, 138,666,666 shares authorized, 106,885,926 and 105,386,216 shares outstanding at March 31, 2014 and December 31, 2013, respectively	799	787
Additional paid-in capital	1,086,798	1,076,403
Accumulated comprehensive income	6	(1)
Accumulated deficit	<u>(1,085,863)</u>	<u>(1,081,176)</u>
Total stockholders' equity (deficit)	<u>1,740</u>	<u>(3,987)</u>
Total liabilities and stockholders' equity (deficit)	<u><u>\$ 107,629</u></u>	<u><u>\$ 134,782</u></u>

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