Loxo Oncology Announces FDA Orphan Drug Designation Granted to LOXO-101 for Treatment of Soft Tissue Sarcoma

September 2, 2015

STAMFORD, Conn., Sept. 2, 2015 (GLOBE NEWSWIRE) -- Loxo Oncology, Inc. (Nasdaq:LOXO), a biopharmaceutical company focused on the discovery, development, and commercialization of targeted cancer therapies, today announced that the United States Food and Drug Administration (FDA) has granted the company orphan drug designation for LOXO-101 for treatment of patients with soft tissue sarcoma. Soft tissue sarcomas are cancers of the body's connective or supportive tissues, such as cartilage, fat, muscle, fibrous tissue, and blood vessels. The FDA's Office of Orphan Drug Products grants orphan drug designation to support the development of medicines for underserved patient populations, or rare disorders, that affect fewer than 200,000 people in the United States. Orphan drug designation provides to Loxo certain benefits, including market exclusivity upon regulatory approval if received, exemption of FDA application fees and tax credits for qualified clinical trials.

About LOXO-101

LOXO-101 is a potent, oral, selective inhibitor of tropomyosin receptor kinase (TRK) signaling molecules. The TRK family (TRKA, TRKB, and TRKC) has been implicated in diverse tumor types such as lung cancer, head and neck cancer, melanoma, colorectal cancer, sarcoma, and breast cancer. LOXO-101 was built specifically to inhibit TRK and is currently the only selective TRK inhibitor in clinical development. LOXO-101 is currently being evaluated in a Phase 1 dose escalation trial for patients with advanced solid tumors.

About Loxo Oncology

Loxo Oncology is committed to the discovery, development, and commercialization of targeted cancer therapies with best-in-class potential. Our diverse pipeline reflects the convergence of proven therapeutic technologies with emerging insights into the underlying susceptibilities of cancer and drug resistance. We leverage the expertise of our partners in academia and industry and our management team's deep clinical-regulatory experience to deploy focused clinical development strategies in well-defined patient populations. Our goal is to create important new cancer therapies as efficiently as possible to substantially benefit patients. www.loxooncology.com.

Forward Looking Statements

This press release contains "forward-looking" statements within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words such as: "anticipate," "intend," "plan," "goal," "seek," "believe," "project," "estimate," "expect," "strategy," "future," "likely," "may," "should," "will" and similar references to future periods. These statements are subject to numerous risks and uncertainties that could cause actual results to differ materially from what we expect. Examples of forward-looking statements include, among others, statements we make regarding our future financial performance, business plans and objectives, partnerships, timing and success of our clinical trials, our ability to obtain regulatory approval, the potential therapeutic benefits and economic value of our lead product candidate or pipeline candidates, potential growth opportunities, financing plans, competitive position, industry environment and potential market opportunities. Further information on potential risk factors that could affect our business and its financial results are detailed in our most recent Quarterly Report on Form 10-Q, and other reports as filed from time to time with the Securities and Exchange Commission. We undertake no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as
a result of new information, future developments or otherwise.

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