Loxo Oncology Announces Acquisition of Highly Selective, Reversible BTK Inhibitor Program

July 31, 2017

STAMFORD, Conn., July 31, 2017 (GLOBE NEWSWIRE) -- Loxo Oncology, Inc. (Nasdaq:LOXO), a biopharmaceutical company innovating the development of highly selective medicines for patients with genetically defined cancers, today announced that the company has entered into a definitive agreement to purchase the Bruton's tyrosine kinase (BTK) inhibitor program from Redx Pharma Plc. The lead candidate from this program is expected to enter clinical development in 2018.

"We are excited to add another program to our pipeline that so nicely aligns with our larger strategic vision and capabilities," said Jacob Van Naarden, chief business officer of Loxo Oncology. "The Redx team has created novel chemical matter that selectively and reversibly inhibits BTK, a validated molecular target across numerous B-cell leukemias and lymphomas. It is our belief that the widespread use of covalent BTK inhibitors, such as ibrutinib, will increasingly drive acquired resistance through a mutational event in BTK called C481S, leading to a group of relapsing patients in need of new therapies. Our work suggests that a highly selective, reversible BTK inhibitor can address this emerging unmet need in patients whose disease has progressed on a covalent BTK inhibitor. The development of a highly selective compound in a genetically-defined population is a Loxo Oncology core competency."

Under the terms of the agreement, Loxo Oncology has made a $40M payment to Redx Pharma Plc for the full acquisition of the BTK discovery program, including lead candidate LOXO-305 (formerly RXC005). Loxo Oncology is not subject to milestone or royalty obligations.

LOXO-305 was designed to reversibly bind BTK and preserve activity in the presence of the C481S acquired resistance mutation. Additionally, it was designed to avoid off-target kinases that have complicated the development of both covalent and reversible BTK inhibitors, such as EGFR, BMX, TEC, ITK, BLK, LCK and SRC. LOXO-305 will be entering studies in the coming months to enable submission of an Investigational New Drug (IND) application in 2018.

About Loxo Oncology

Loxo Oncology is a biopharmaceutical company innovating the development of highly selective medicines for patients with genetically defined cancers. Our pipeline focuses on cancers that are uniquely dependent on single gene abnormalities, such that a single drug has the potential to treat the cancer with dramatic effect. We believe that the most selective, purpose-built medicines have the highest probability of maximally inhibiting the intended target, thereby delivering best-in-class disease control and safety. Our management team seeks out experienced industry partners, world-class scientific advisors and innovative clinical-regulatory approaches to deliver new cancer therapies to patients as quickly and efficiently as possible. For more information, please visit the company's website at 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, the availability of funding, timing and success of our clinical trials, success in our collaborations and the potential therapeutic benefits of our lead product candidate or other product candidates. 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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