



Leap Therapeutics Announces First Patient Enrolled in DeFianCe Study of DKN-01 for the Treatment of Colorectal Cancer Patients

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CAMBRIDGE, Mass., Oct. 17, 2022 /PRNewswire/ -- Leap Therapeutics, Inc. (NASDAQ: LPTX), a biotechnology company focused on developing targeted and immuno-oncology therapeutics, today announced that the first patient has been enrolled in the Phase 2 DeFianCe study evaluating DKN-01, Leap's anti-Dickkopf-1 antibody (DKK1), in combination with standard of care bevacizumab and chemotherapy as a second-line treatment for patients with advanced colorectal cancer (CRC).

"We believe that DKN-01 has broad clinical potential. Based on the role of DKK1 in suppressing the immune system in the tumor microenvironment and enabling resistance to chemotherapy in CRC, we are excited to explore this new indication, one of the most frequent and dangerous types of GI cancers where patients continue to look for new treatment options," said Cynthia Sirard, M.D., Chief Medical Officer of Leap Therapeutics. "Enrolling the first CRC patient is an important milestone for the DKN-01 clinical program, and we look forward to reporting initial data from this study in mid-2023."

The DeFianCe study ([NCT05480306](https://clinicaltrials.gov/ct2/show/study/NCT05480306)) is a Phase 2, randomized, open-label, multicenter study of DKN-01 in combination with standard of care bevacizumab and chemotherapy in patients with advanced CRC who have received one prior systemic therapy. The study is designed with an initial 20 patient cohort and to then expand into a 130-patient randomized controlled trial against bevacizumab and standard of care chemotherapy. The primary objective is progression free survival. Secondary objectives include overall response rate, duration of response, and overall survival.

About DKN-01

DKN-01 is a humanized monoclonal antibody that binds to and blocks the activity of the Dickkopf-1 (DKK1) protein. DKK1 modulates the Wnt/Beta-catenin and PI3kinase/AKT signaling pathways and has an important role in promoting tumor proliferation, metastasis, angiogenesis, and in mediating an immune suppressive tumor microenvironment through enhancing the activity of myeloid-derived suppressor cells and downregulating NK cell ligands on tumor cells.

About Colorectal Cancer

Colorectal cancer is the third most frequent cancer globally and the second leading cause of death. According to the WHO, there were nearly 2 million new cases of colorectal cancer in 2020, with nearly 1 million deaths. Colorectal cancer includes colon cancer (57.5%), rectal cancers (35%), and anal cancer (2.5%). When the symptoms of CRC appear, such as rectal bleeding, anemia, or abdominal pain, most patients are already in the advanced stage where cancers are aggressive, malignant, and metastatic.

About Leap Therapeutics

Leap Therapeutics (Nasdaq: LPTX) is focused on developing targeted and immuno-oncology therapeutics. Leap's most advanced clinical candidate, DKN-01, is a humanized monoclonal antibody targeting the Dickkopf-1 (DKK1) protein. DKN-01 is being developed in patients with esophagogastric, gynecologic, and colorectal cancers. Leap has entered into a strategic collaboration with BeiGene, Ltd. for the rights to develop DKN-01 in Asia (excluding Japan), Australia, and New Zealand. For more information about Leap Therapeutics, visit <http://www.leaptx.com> or view our public filings with the SEC that are available via EDGAR at <http://www.sec.gov> or via <https://investors.leaptx.com/>.

FORWARD-LOOKING STATEMENTS

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995, which involve risks and uncertainties. These statements include Leap's expectations with respect to the development and advancement of DKN-01, including the initiation, timing and design of future studies, enrollment in clinical studies, potential for the receipt of future option exercise, milestone, or royalty payments from BeiGene, and other future expectations, plans and prospects. Although Leap believes that the expectations reflected in such forward-looking statements are reasonable as of the date made, forward-looking statements are subject to known and unknown risks, uncertainties and other factors that could cause actual results to differ materially from our expectations. Such risks and uncertainties include, but are not limited to: that the initiation, conduct, and completion of clinical trials, laboratory operations, manufacturing campaigns, and other studies may be delayed, adversely affected, or impacted by COVID-19, global conflict or supply chain related issues; unstable global market and economic conditions; the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for financing; the outcome, cost, and timing of our product development activities and clinical trials; the uncertain clinical development process, including the risk that clinical trials may not have an effective design or generate positive results; our ability to obtain and maintain regulatory approval of our drug product candidates; the size and growth potential of the markets for our drug product candidates; our ability to continue obtaining and maintaining intellectual property protection for our drug product candidates; and other risks. Detailed information regarding factors that may cause actual results to differ materially is included in Leap Therapeutics' periodic filings with the SEC, including Leap's Annual Report on Form 10-K for the fiscal year ended December 31, 2021, as filed with the SEC on March 11, 2022 and as may be updated by Leap's Quarterly Reports on Form 10-Q and the other reports Leap files from time to time with the SEC. Any forward-looking statement contained in this release speaks only as of its date. Leap undertakes no obligation to update any forward-looking statement contained in this release to reflect events or circumstances occurring after its date or to reflect the occurrence of unanticipated events.


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