



Leap Therapeutics Announces FDA Fast Track Designation Granted to DKN-01 for the Treatment of Gastric and Gastroesophageal Junction Cancer

September 24, 2020

CAMBRIDGE, Mass., Sept. 24, 2020 /PRNewswire/ -- Leap Therapeutics, Inc. (Nasdaq:LPTX), a biotechnology company focused on developing targeted and immuno-oncology therapeutics, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to DKN-01 for the treatment of patients with gastric and gastroesophageal junction (G/GEJ) adenocarcinoma whose tumors express high Dickkopf-1 protein (DKK1), following disease progression on or after prior fluoropyrimidine- and platinum- containing chemotherapy and if appropriate, human epidermal receptor growth factor (HER2)/neu-targeted therapy. DKN-01 is a humanized monoclonal antibody that binds to and blocks the activity of DKK1 protein, a modulator of Wnt/Beta-catenin signaling.

The Fast Track program is intended to facilitate the development and expedite the review of drug candidates and vaccines that treat serious conditions and fill an unmet medical need. The purpose of Fast Track is to get important new drugs to the patient earlier. Programs with Fast Track designation may benefit from early and frequent communication with the FDA, in addition to a rolling submission of the marketing application. DKN-01 has also received Orphan Drug Designation for the treatment of gastric and gastroesophageal junction cancer from the FDA.

"We are pleased with the FDA's decision to grant Fast Track designation for the development of DKN-01 to treat patients with gastric and gastroesophageal junction cancer whose tumors express high levels of DKK1," said Douglas E. Onsi, President and Chief Executive Officer of Leap. "The designation highlights the existing unmet medical need for new and effective treatments for this patient population. We believe that DKN-01 shows promise as a novel treatment option for biomarker-selected patients with these cancers, and this designation provides us with earlier and more frequent opportunities to interact with the FDA during the development of DKN-01."

DKN-01 is currently being evaluated in clinical trials for gastroesophageal, gynecologic, hepatobiliary, and prostate cancers. In September 2020, the first patient was dosed in the Company's combination study of DKN-01 plus tislelizumab, BeiGene, Ltd.'s anti-PD-1 antibody, in patients with gastric or gastroesophageal junction cancer.

About DKN-01

DKN-01 is a humanized monoclonal antibody that binds to and blocks the activity of the Dickkopf-1 (DKK1) protein, a modulator of Wnt/Beta-catenin signaling, a signaling pathway frequently implicated in tumorigenesis and suppressing the immune system. DKK1 has an important role in tumor cell signaling and in mediating an immuno-suppressive tumor microenvironment through enhancing the activity of myeloid-derived suppressor cells and downregulating NK ligands on tumor cells.

About gastric / gastroesophageal junction cancer

Gastric adenocarcinoma (gastric cancer) remains one of the most common and deadly cancers worldwide, especially among older males¹. Based on GLOBOCAN 2018 data, stomach cancer is the 5th most common neoplasm and the 3rd most deadly cancer, with an estimated 783,000 deaths globally in 2018¹. Ninety-five percent of cancers of the stomach are adenocarcinomas¹. Gastric cancer incidence and mortality are highly variable by region and highly dependent on diet and Helicobacter pylori infection¹. The gastroesophageal junction (GEJ) is the area where the esophagus and stomach join together. Given its anatomic location, GEJ adenocarcinomas have often been grouped together with either esophageal or gastric cancers in clinical trials.

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, a Wnt pathway modulator. DKN-01 is in clinical trials in patients with esophagogastric, hepatobiliary, gynecologic, and prostate cancers. Leap has entered into a 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 future studies, potential for the receipt of future option exercise, milestones 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 related issues; 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 will be 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, 2019, as filed with the SEC on March 16, 2020 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 statements contained in this release speak only as of its date. Leap undertakes no obligation to update any forward-looking statements 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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ⁱ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6444111/>



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