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Leap Therapeutics Announces Completion of Enrollment for First-Line Patient Cohort in Study of DKN-01 in Combination with Tislelizumab for the Treatment of Gastric or Gastroesophageal Junction Cancer

April 1, 2021

CAMBRIDGE, Mass., April 1, 2021 /PRNewswire/ -- Leap Therapeutics, Inc. (Nasdaq:LPTX), a biotechnology company focused on developing targeted and immuno-oncology therapeutics, today announced the completion of enrollment for the first-line patient cohort in the DisTinGuish study, a clinical trial evaluating Leap's anti-Dickkopf-1 (DKK1) antibody, DKN-01, in combination with tislelizumab, BeiGene Ltd.'s anti-PD-1 antibody, with or without chemotherapy, in patients with gastric or gastroesophageal junction cancer (G/GEJ).

"The completion of enrollment for the first-line patients in the DisTinGuish study is an important milestone for the DKN-01 and tislelizumab combination development program," said Cynthia Sirard, M.D., Chief Medical Officer of Leap Therapeutics. "In collaboration with our partner, BeiGene, we are committed to realizing the potential of DKN-01 as part of a new combination therapy with tislelizumab aimed at treating gastric and gastroesophageal junction cancer patients, where a high global unmet medical need remains."

The DisTinGuish trial (NCT04363801) is a Phase 2a, nonrandomized, open-label, multicenter study of DKN-01 in combination with tislelizumab with or without chemotherapy as first-line or second-line therapy in adult patients with inoperable, locally advanced G/GEJ adenocarcinoma. The study, which will be conducted in two parts in the United States and the Republic of Korea, includes up to 24 patients with first-line G/GEJ cancer and up to 48 patients with second-line G/GEJ cancer whose tumors express high levels of DKK1. Initial data is expected in the second half of 2021. Leap is conducting this combination study as part of an exclusive option and license agreement with BeiGene for the development of DKN-01 in Asia (excluding Japan), Australia, and New Zealand. Leap retains exclusive rights for the development, manufacturing, and commercialization of DKN-01 for the rest of the world.

About gastric / gastroesophageal junction cancer

Gastric adenocarcinoma (gastric cancer) remains one of the most common and deadly cancers worldwide, especially among older males[i]. 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 2018[i]. Ninety-five percent of cancers of the stomach are adenocarcinomas[i]. Gastric cancer incidence and mortality are highly variable by region and highly dependent on diet and Helicobacter pylori infection[i]. 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 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, which have 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 cell ligands on tumor cells. The U.S. Food and Drug Administration has granted DKN-01 Orphan Drug Designation for the treatment of gastric and gastroesophageal junction cancer and Fast Track Designation in combination with tislelizumab for the treatment of patients with gastric and gastroesophageal junction adenocarcinoma whose tumors express high DKK1 protein, following disease progression on or after prior fluoropyrimidine- and platinum-containing chemotherapy and if appropriate, human epidermal receptor growth factor (HER2)/neu-targeted therapy.

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 in clinical trials in patients with esophagogastric, hepatobiliary, gynecologic, and prostate cancers. Leap has entered into a strategic partnership 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 FOR LEAP THERAPEUTICS

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, 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 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, 2020, as filed with the SEC on March 12, 2021 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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[i] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6444111/

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