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Leap Therapeutics Presents Updated Positive Data from the DisTinGuish Study of DKN-01 Plus Tislelizumab at the ESMO Congress

September 16, 2021

- DKN-01 plus tislelizumab and chemotherapy demonstrated compelling activity in first-line patients with gastric or gastroesophageal junction cancer

- Additional data presented today showed responses to treatment are independent of PD-L1 expression, with 79% ORR in patients with PD-L1 low (CPS < 5) tumors

- Company to host conference call on Friday, September 17, 2021 at 8:00 a.m. ET

CAMBRIDGE, Mass., Sept. 16, 2021 /PRNewswire/ -- Leap Therapeutics, Inc. (Nasdaq:LPTX), a biotechnology company focused on developing targeted and immuno-oncology therapeutics, today announced the presentation of updated positive data from the first-line cohort of the DisTinGuish study, a Phase 2a clinical trial evaluating Leap's anti-Dickkopf-1 (DKK1) antibody, DKN-01, in combination with tislelizumab, BeiGene Ltd.'s anti-PD-1 antibody, and chemotherapy, in patients with gastric or gastroesophageal junction cancer (G/GEJ), at the European Society for Medical Oncology (ESMO) Congress. The Company will host a conference call on Friday, September 17, 2021 to discuss preliminary results from the study.

The Company announced positive initial data from the DisTinGuish study on Monday, September 13, 2021 based on 25 G/GEJ patients enrolled in the trial that showed DKN-01 in combination with tislelizumab and chemotherapy as first-line therapy was well tolerated with compelling activity. The results presented at the ESMO Congress today included additional patient data stratified by tumoral PD-L1 expression levels based on visually-estimated combined positive score (vCPS), showing that robust objective clinical responses can be achieved from this combination regimen independently of PD-L1 expression.

"Initial data from this trial have shown that patients with high levels of DKK1 expression, a group with a poor prognosis, had encouraging responses to treatment. The additional data presented today show evidence that not only is DKK1 a critical biomarker in predicting response to DKN-01 and tislelizumab therapy, but also that the combination can induce deep responses regardless of the patient's PD-L1 status, including particularly poor prognosis patients with both low PD-L1 and high DKK1," said Samuel Klempner, MD, Member of the Faculty at Massachusetts General Hospital Cancer Center and Harvard Medical School. "Taken together, these are promising results for the combination therapy of DKN-01 with tislelizumab and chemotherapy in first line patients with gastric or gastroesophageal junction cancers."

About the DisTinGuish Study

The DisTinGuish study (NCT04363801) is a Phase 2a study of DKN-01 in combination with tislelizumab, an anti-PD-1 antibody, with or without chemotherapy as first-line or second-line therapy in patients with inoperable, locally advanced, G/GEJ adenocarcinoma. The study is being conducted in two parts in the United States and the Republic of Korea. Enrollment of Part A has been completed with 25 first-line HER2- G/GEJ cancer patients whose tumors express either high levels of DKK1 (DKK1-high) or low levels of DKK1 (DKK1-low). Part B of the study will enroll up to 48 patients with second-line, DKK1-high G/GEJ cancer. 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.

Key Findings

- Among patients who received a full cycle of DKN-01 therapy, the ORR was 68.2%, with 90% ORR in DKK1-high patients and 56% in DKK1-low patients
- Response was independent of PD-L1 expression, and particularly strong in the less favorable to checkpoint inhibitor therapy, PD-L1 low (vCPS < 5), population
    - Among those patients with PD-L1-low expression (vCPS < 5), the ORR was 79%, with 100% in DKK1-high patients and 57% in DKK1-low patients
    - Among those patients with PD-L1-high expression (vCPS ≥ 5), the ORR was 67%, with 75% ORR in DKK1-high patients and 50% in DKK1-low patients
    - DKK1 levels could not be determined in one patient who had PD-L1 expression data; however, the patient's PD-L1 expression level was determined to be low (vCPS score 0) and the patient achieved a partial response
- DKK1 expression and PD-L1 expression are not correlated
- Median duration of response and progression-free survival data are not yet mature, and patient follow-up continues

Twenty-five first-line patients were enrolled, and as of the cut-off date of the presentation, 15 patients had experienced a partial response (PR), six patients had a best response of stable disease (SD), one patient was non-evaluable for response (NE), and three patients were unable to complete a full cycle of DKN-01 therapy (non-modified ITT (mITT)).

Among the 21 patients that had RNAscope® DKK1 expression available, 12 were DKK1-high [9 PR, 1 NE, 2 non-mITT] and 9 were DKK1-low [5 PR, 4 SD].

Among the 20 patients that had PD-L1 expression available, 14 were PD-L1 low vCPS < 5 [11 PR, 3 SD] and 6 were PD-L1 high vCPS ≥ 5 [4 PR, 1 SD, 1 NE].

A copy of the poster presentation is available on the Company's website at https://www.leaptx.com/our-pipeline.

Conference Call

Leap will host a conference call on Friday, September 17, 2021 at 8:00 a.m. Eastern Time to further discuss the data. In addition to Leap's executive management team, Dr. Jaffer Ajani of M.D. Anderson Cancer Center and Dr. Samuel Klempner of Massachusetts General Hospital will be on the call. The call can be accessed by dialing (866) 589-0108 (U.S. and Canada) or (409) 231-2048 (international). The passcode for the conference call is 1729397. The presentation will be webcast live and may be accessed on the Investors page of the Company's website at https://investors.leaptx.com/, where a replay of the event will also be available for a limited time.

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/.

RNAscope® is a registered trademark of Advanced Cell Diagnostics, Inc., Newark, CA, USA.

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, 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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