



## **Leap Therapeutics Announces an Investigator-Initiated Study of DKN-01 in Patients with DKK1+ Advanced Prostate Cancer**

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CAMBRIDGE, Mass., Jan. 14, 2019 /PRNewswire/ -- Leap Therapeutics, Inc. (Nasdaq: LPTX), a biotechnology company developing targeted and immuno-oncology therapeutics, today announced an investigator-initiated study led by David R. Wise, M.D., Ph.D. of the Perlmutter Cancer Center at NYU Langone Health to study DKN-01, as a monotherapy and in combination with docetaxel in patients with advanced prostate cancer. This clinical trial is specifically targeting a biomarker-selected patient population in metastatic castration-resistant prostate cancer (mCRPC) with elevated Dickkopf-1 (DKK1) levels.

"DKK1 can promote prostate cancer growth through suppressing the anti-tumor immune response. We have discovered that DKK1 is upregulated in the substantial portion of advanced prostate cancers that lack expression of androgen receptor," commented Dr. Wise. "Patients with this type of prostate cancer have a very poor prognosis and may benefit from this new immunotherapy strategy targeting DKK1 therapy with DKN-01."

"An important part of our DKN-01 development strategy is to target biomarker-selected patient populations," said Cynthia Sirard, M.D., Vice President, Clinical Development of Leap Therapeutics. "In our esophagogastric cancer study, we have identified DKK1 levels measured by RNAScope as a potential predictor of response to DKN-01-based therapy. We are looking forward to treating mCRPC patients with elevated DKK1 levels in this study, building on our and Dr. Wise's work."

The study is expected to begin enrolling patients in the first quarter of 2019. mCRPC patients who have progressed on one or more androgen receptor (AR) therapies (Xtandi or Zytiga) will be screened for DKK1 elevation in their plasma or in a tumor sample. Up to 97 patients will be enrolled in a dose-escalation and then dose expansion cohorts. DKK1+ mCRPC patients who have not received prior taxane chemotherapies will be treated with DKN-01 and docetaxel. DKN-01 will be given as a monotherapy to DKK1+ mCRPC patients who have progressed on or refused docetaxel treatment.

### **About Prostate Cancer**

Prostate cancer is the leading type of non-skin cancer in the US, and the second leading cause of cancer worldwide. Approximately 1 in 9 men will be diagnosed with prostate cancer at some point in their lives. Androgen receptor (AR)-targeted therapy can be highly effective for the treatment of prostate cancer. Unfortunately, most patients will eventually develop resistance and progress to castration-resistant prostate cancer (CRPC), an incurable form of the disease.

### **Disclosure**

Dr. Wise is compensated to serve as a consultant to Leap Therapeutics. Also, Dr. Wise's involvement in this upcoming study does not constitute an institutional endorsement from NYU Langone Health or its Perlmutter Cancer Center of the drug DKN-01 being studied.

### **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's second clinical candidate, TRX518, is a humanized G1TR agonist monoclonal antibody designed to enhance the immune system's anti-tumor response that is in advanced solid tumor studies. For more information about Leap Therapeutics, visit <http://www.leaptx.com> or our public filings with the SEC that are available via EDGAR at <http://www.sec.gov> or via <https://www.leaptx.com/investors>.

### **FORWARD-LOOKING STATEMENTS**

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995, which involve risks and uncertainties. These statements include statements regarding Leap's expectations with respect to the development and advancement of DKN-01 and TRX518, including the initiation, timing, design and results of future studies, enrollment in future studies, business development, 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: 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; our plans to research, develop, and commercialize our drug product candidates; our ability to achieve market acceptance of our drug product candidates; unanticipated costs or delays in research, development, and commercialization efforts; the applicability of clinical study results to actual outcomes; 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 Securities and Exchange Commission (the "SEC"), including Leap Therapeutics' Form 10-K that Leap filed with the SEC on February 23, 2018. Any forward-looking statements contained in this release speak only as of its date. We undertake 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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