Flagship Biosciences and Leap Therapeutics Announce Partnership and Approach Using RNAscope and Image Analysis for Patient Enrollment

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Laboratory Developed Test for Manual and Image Analysis-assisted Pathologist Interpretation

WESTMINSTER, Colo. and CAMBRIDGE, Mass., April 12, 2021 /PRNewswire/ -- Flagship Biosciences, the leader in data-centric pathology and tissue analysis, and Leap Therapeutics (Nasdaq: LPTX), a biotechnology company focused on developing targeted and immuno-oncology therapeutics, today announced a partnership to use a clinically validated tumor expression assay utilizing RNAscope® and tissue image analysis. In a poster shared this week at the American Association for Cancer Research (AACR) Annual Meeting 2021, the companies presented data on the validation of a Dickkopf-1 (DKK1) RNAscope chromogenic in situ hybridization (CISH) assay and digital image analysis solution.

DKK1 is a secreted modulator of Wnt signaling that is frequently overexpressed in tumors and associated with a poor prognosis for patients. DKN-01 is a humanized monoclonal therapeutic antibody that binds to and blocks the activity of DKK1 and has demonstrated clinical activity in gastric/gastroesophageal junction (G/GEJ) adenocarcinoma patients with elevated tumoral expression of DKK1 RNA. The companies have demonstrated that the DKK1 RNAscope assay and accompanying digital image analysis solution is specific, sensitive, accurate and reproducible according to Clinical Laboratory Improvement Amendments (CLIA) guidelines. The assay is currently being applied to prospectively identify G/GEJ patients with elevated tumoral expression of DKK1 for treatment with a DKN-01 plus tislelizumab combination (Leap Therapeutics; NCT04363801).

"CISH assays can be used for the interrogation of clinical samples when protein targets are not sufficient," said Flagship Biosciences CEO, Trevor Johnson. "However, reading these assays can be challenging for pathologists. At Flagship, our pathologist-driven image analysis generates unique cellular data profiles that allow for the kind of robust quantitative solution that Leap was looking for. Using our proprietary image analysis technology and patented, cell-based tissue analysis, we deliver the data-rich tissue interpretations to support therapeutic development."

"This is a robust laboratory developed test (LDT) that is superior to traditional DKK1 immunohistochemistry (IHC) by demonstrating improved specificity and sensitivity," said Michael Kagey, Ph.D., Senior Director of Translational Medicine. "Furthermore, the use of the digital image analysis algorithm to quantify DKK1 signal and support pathologist interpretation is a novel approach that reduces the risk of scoring bias."

To select patients for their clinical study, Leap Therapeutics sends samples from the United States and the Republic of Korea to Flagship's centralized laboratory. Flagship conducts the RNAscope assay, image analysis, data analysis, and in-house pathologist review, providing the information needed to make clinical trial enrollment decisions.

"The DKK1 RNAscope LDT is an integral component of our clinical development strategy," said Douglas E. Onsi, President and CEO of Leap Therapeutics. "The rapid sample turnaround time from Flagship has allowed for the prospective screening of patients to support enrollment. We look forward to our continued partnership with Flagship."

About Flagship Biosciences
Founded in 2009 and headquartered in Westminster, Colorado, Flagship Biosciences, Inc. is a technology-driven tissue analysis services company delivering the most accurate and informative data available. We are revolutionizing tissue analysis to improve drug development and diagnostics using the power of AI with a consultative approach. Our services and technology dramatically improve on the data and interpretation from traditional pathology methods, eliminating variability associated with typical tissue assessments, and bringing new insights to tissue analysis results. We provide expert scientific consultation for every client. Our team interprets results, contextualizes tissue biology, and identifies the best course for success. https://flagshipbio.com/

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 https://www.leaptx.com or view our public filings with the SEC that are available via EDGAR at https://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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