Krystal Biotech Reports Second Quarter 2020 Financial Results and Provides Update on Operational Progress

August 10, 2020

Initiated the pivotal GEM-3 clinical study evaluating B-VEC in DEB patients

Today announced enrollment of 1st patient in Phase 2 clinical study evaluating KB105 in ARCI patients

On track to initiate Phase 1 trial of KB301 for an aesthetic indication in 2H 2020

Strong balance sheet with June 30, 2020 cash, cash equivalents and marketable securities of $297 million

PITTSBURGH, Aug. 10, 2020 (GLOBE NEWSWIRE) -- Krystal Biotech, Inc. (Nasdaq: KRYS), a fully integrated gene therapy company driven by its proprietary, engineered herpes simplex virus type 1 vector (HSV-1) platform, today reported financial results and key operational progress updates for the second quarter ending June 30, 2020.

"The future of Krystal shines brighter than ever. We enter the second half of the year with a Phase 3 trial in DEB, a Phase 2 trial in ARCI and expect to initiate a Phase 1 trial in aesthetic skin conditions in the near term, leading to multiple data readouts in the next 6 to 12 months," said Krish Krishnan, chairman and chief executive officer of Krystal Biotech, Inc. He added, "With the completion of our recent stock offering, we have the financial strength to support our clinical programs, expand our pipeline to pulmonary indications and complete our second GMP facility to support growth in our pipeline demand. I look forward to updating you as the year progresses."

Program Highlights & Upcoming Events

Beremagene Geperpavec (B-VEC) for DEB

- In July 2020, Krystal announced the initiation of the pivotal GEM-3 study. The trial is a randomized, double-blind, intra-patient, placebo controlled multicenter study designed to evaluate the efficacy and safety of B-VEC for patients suffering from both recessive and dominant dystrophic forms of Epidermolysis Bullosa. Details of the pivotal study can be found at www.clinicaltrials.gov under NCT identifier NCT04491604.
- Top line data and Biologics License Application (BLA) filing are anticipated in 2021. Data from this trial will also form the basis of an Marketing Authorisation Application (MAA) filing in the EU which is anticipated to occur shortly after the BLA filing.
- In May 2020, at the Society for Investigative Dermatology (SID) annual meeting, Dr. Peter Marinkovich, M.D. (associate professor of dermatology and director of the Blistering Disease Clinic at Stanford University) presented an overview of data from the GEM-1 and GEM-2 studies.

KB105 for ARCI-Icthyosis

- Today Krystal announced the enrollment and dosing of the first patient in the Phase 2 clinical study of KB105 in patients with TGM1 deficient autosomal recessive congenital ichthyosis (ARCI). Treatment of a larger area is being evaluated. Details of the Phase 2 study can be found at www.clinicaltrials.gov under NCT identifier NCT04047732.
- Positive safety and efficacy data from the first 3 adult patients enrolled in the study were reported in May 2020 and were presented at the SID meeting by Dr. Amy S. Paller, M.D. (chair, Department of Dermatology, Northwestern University).

KB407 for Cystic Fibrosis

- In May 2020, at the American Society of Gene & Cell Therapy (ASGCT) meeting, Krystal presented initial in vitro pharmacology data for KB407. The data showed that our vector was able to efficiently infect Small Airway Epithelial Cells (SAEC) derived from CF patients and generate full-length, properly localized, and functional CFTR protein.
- Pre-clinical validation work is ongoing, and an IND filing is anticipated in 2021.

KB301 for Aesthetic Indications

- The Company is on track to initiate a Phase 1 clinical safety and efficacy study of KB301 for the treatment of wrinkles and acne scars in 2H 2020.

KB104 for Netherton Syndrome

- The Company continues to work towards an IND filing.

Financial results for the quarter ended June 30, 2020

- Cash, cash equivalents and short-term investments totaled $297.2 million on June 30, 2020. The cash balance as of June 30, 2020 reflects the receipt of net proceeds of $117.2 million from the Company's May 2020 follow-on stock offering.
- Research and development expenses for the second quarter ended June 30, 2020 were $3.6 million, compared to $4.2 million for second quarter 2019.
- General and administrative expenses for the second quarter ended June 30, 2020 were $3.3 million, compared to $1.7 million for second quarter 2019.
- Net losses for the quarters ended June 30, 2020 and 2019 were $6.8 million and $5.3 million or ($0.37) and ($0.37) per common share (basic and diluted), respectively.
- For additional information on the Company's financial results for the second quarter ended June 30, 2020, refer to form 10-Q filed with the SEC.

About Krystal Biotech

Krystal Biotech, Inc. (NASDAQ:KRYS) is a gene therapy company dedicated to developing transformative medicines to treat diseases caused by protein or gene dysfunction.. For more information, please visit http://www.krystalbio.com.

Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for Krystal Biotech, Inc., including but not limited to statements about the development of Krystal's product candidates, such as plans for the design, conduct and timelines of ongoing clinical trials of beremagene geperpavec ("B-VEC"), KB105, KB104, KB301 and KB407; the clinical utility of B-VEC, KB105, KB104, KB301 and KB407, and Krystal's plans for filing of regulatory approvals and efforts to bring B-VEC, KB105, KB104, KB301 and KB407 to market; the market opportunity for and the potential market acceptance of B-VEC, KB105, KB104, KB301 and KB407; plans to pursue research and development of other product candidates; the sufficiency of Krystal's existing cash resources; the unanticipated impact of COVID-19 on Krystal's business operations, pre-clinical activities and clinical trials; and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "likely," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the uncertainties inherent in the initiation and conduct of clinical trials, availability and timing of data from clinical trials, whether results of early clinical trials or trials will be indicative of the results of ongoing or future trials, uncertainties associated with regulatory review of clinical trials and applications for marketing approvals, the availability or commercial potential of product candidates including B-VEC, KB105, KB104, KB301 and KB407, the sufficiency of cash resources and need for additional financing and such other important factors as are set forth under the caption "Risk Factors" in Krystal's annual and quarterly reports on file with the U.S. Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent Krystal's views as of the date of this release. Krystal anticipates that subsequent events and developments will cause its views to change. However, while Krystal may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing Krystal's views as of any date subsequent to the date of this release.

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