Krystal Biotech Reports Third Quarter 2018 Financial Results and Provides Corporate Update

November 5, 2018

Announced positive interim results from randomized placebo-controlled Phase 1/2 clinical study of KB103, a first-in-class topical gene therapy for the treatment of dystrophic epidermolysis bullosa

PITTSBURGH, Nov. 05, 2018 (GLOBE NEWSWIRE) -- Krystal Biotech (Nasdaq: KRYS), a gene therapy company advancing “off-the-shelf” topical and intra-dermal treatments for skin diseases, today reported financial results for the third quarter ended September 30, 2018, and provided an update on the Company’s corporate progress.

Commenting on third quarter, Krish S. Krishnan, chairman and chief executive officer of Krystal Biotech, said, “Although the data we announced from the Phase 1/2 clinical trial with KB103 are early and in two patients to date, the results, when confirmed in additional patients, will represent an unprecedented advancement in bringing a treatment for dystrophic epidermolysis bullosa to market." Mr. Krishnan continued, “We are focused on getting the KB103 pivotal study started in the second half of 2019 and are working presently to complete our GMP manufacturing facility to produce clinical materials for the pivotal study and future commercial requirements.”

Recent Corporate Highlights

- In October 2018, announced positive interim results from the placebo-controlled Phase 1/2 study of KB103, a first-in-class topical gene therapy for the treatment of dystrophic epidermolysis bullosa (DEB). Results to date from the two-patient study met all primary efficacy and safety endpoints in topically administered KB103 wounds. Final results are expected in H1 2019.

- In October 2018, completed a successful underwritten public offering of 3,450,000 shares of common stock, gross proceeds of $69.0 million.

- The U.S. Food and Drug Administration (FDA) granted Orphan Drug Designation for KB105 for the treatment of patients with transglutaminase 1 (TGM-1) deficient autosomal recessive congenital ichthyosis (ARCI). There are currently no treatments for this disease and Krystal Biotech plans to file an investigational new drug application (IND) for KB105 before the end of 2018.

- Entered into a securities purchase agreement with Frazier Healthcare Partners in August 2018 for the private placement of 625,000 shares of common stock, raising $10 million in gross proceeds.

Financial Results for the Quarter Ended September 30, 2018

- Cash, cash equivalents and short-term investments totaled $52.3 million at September 30, 2018, compared with $45.5 million at June 30, 2018;

- Research and development expenses for the third quarter were $1.9 million;

- General and administrative expenses for the third quarter were $1.1 million; and

- Net losses for the quarters ended September 30, 2018 and 2017 were $2.8 million and $5.3 million, or ($0.26) and ($1.26) per common share (basic and diluted) respectively.

Subsequent Event

Following the end of the quarter, as mentioned above, Krystal Biotech completed a $69.0 million public offering of common stock the proceeds of which, after underwriting commissions and estimated offering expenses, were approximately $64.5 million. Cash, cash equivalents and short-term investments totaled approximately $115 million at October 31, 2018.

For further details on the company’s financials, please refer to its quarterly report on Form 10-Q for the quarterly period ended September 30, 2018, as filed with the Securities and Exchange Commission.

About KB103

KB103 is Krystal Biotech’s lead product candidate, currently in Phase 1/2 clinical development and seeks to use gene therapy to treat DEB, an incurable skin blistering condition caused by a lack of collagen in the skin. KB103 is a replication-defective, non-integrating viral vector that has been engineered using the HSV-1 virus employing Krystal Biotech’s STAR-D platform to deliver functional human COL7A1 genes directly to the patients’ dividing and non-dividing skin cells. Krystal Biotech’s vector can penetrate skin cells more efficiently than other viral vectors. Its high payload capacity allows it to accommodate large or multiple genes and its low immunogenicity makes it a suitable choice for direct and repeat delivery to the skin.

About Dystrophic Epidermolysis Bullosa

Dystrophic epidermolysis bullosa is an incurable, often fatal skin blistering condition caused by a lack of collagen protein in the skin. It is caused by mutations in the gene coding for type VII collagen, or COL7, a major component of the anchoring fibrils, which anchor the epidermis to the underlying dermis, and provide structural adhesion in a normal individual. The lack of COL7 in DEB patients causes blisters to occur in the dermis as a result of separation from the epidermis. This makes the skin incredibly fragile, leading to blistering or skin loss at the slightest friction or contact. It is progressive and incredibly painful.

The most severe form of DEB is recessive DEB, or RDEB, which is caused by null mutations in the COL7A1 gene. DEB also occurs in the form of dominant DEB, or DDEB, which is considered to be a milder form of DEB. There are no known treatments, which affect the outcome of either form of the disease, and the current standard of care for DEB patients is limited to palliative treatments. Krystal Biotech is developing KB-103 for the treatment of the broad DEB population, including both recessive and dominant forms of the disease.

About KB105
KB105 is Krystal Biotech's second product candidate, currently in preclinical development and seeks to treat patients with TGM-1 deficient ARCI. There are currently no treatments for this disease which affects approximately 20,000 patients worldwide. KB105 is a replication-defective, non-integrating viral vector that has been engineered employing Krystal Biotech's STAR-D platform to deliver functional TGM-1 gene directly to the patients' dividing and non-dividing skin cells.

About ARCI
TGM-1 is an essential epidermal enzyme that facilitates the formation of the epidermal barrier, which prevents dehydration, and protects the skin from unwanted toxins and surface microorganisms. The loss of TGM-1-activity results in the severe genetic skin disease ARCI. Most patients with a TGM-1-deficiency exhibit life-long pronounced scaling with increased transepidermal water loss. The scales are plate-like, often of a dark color, and cover the whole-body surface area. TGM-1-deficient ARCI is associated with increased mortality in the neonatal period and has a dramatic impact on quality of life.

About the STAR-D Gene Therapy Platform
Krystal has developed a proprietary gene therapy platform, the Skin TARgeted Delivery platform, or STAR-D platform, that consists of an engineered viral vector and skin-optimized gene transfer technology, to develop off-the-shelf treatments for dermatological diseases. The company believes that the STAR-D platform provides an optimal approach for treating dermatological conditions due to the nature of the HSV-1 viral vector it has created. Certain inherent features of the HSV-1 virus, combined with the ability to strategically modify the virus in the form employed as a gene delivery backbone, provide the STAR-D platform with several advantages over other viral vector platforms for use in dermatological applications.

About Krystal Biotech
Krystal Biotech, Inc. (Nasdaq: KRYS) is a gene therapy company dedicated to developing and commercializing novel treatments for patients suffering from dermatological diseases. For more information, please visit http://www.krystalbio.com.

Forward-Looking Statements
This press release contains forward-looking statements and information, including, without limitation, statements regarding the development of the company's product candidates, including KB103 and KB105, the company's plans to file an IND for KB105 in 2018 and the company's plans to develop a GMP manufacturing facility in 2018. The use of words such as "will," "believe," "plan," "future," and "expect," and other similar expressions are intended to identify forward-looking statements and information. Forward-looking statements and information are based on Krystal Biotech's current expectations and assumptions. Because forward-looking statements relate to the future, investors are cautioned that the forward-looking information and statements are subject to inherent uncertainties, risks and changes in circumstances, many of which are difficult to predict and generally beyond the control of the Krystal Biotech, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. Important factors that could cause actual results to differ materially from those in the forward-looking information and statements are set forth under the caption "Risk Factors" and elsewhere in Krystal Biotech's annual report on Form 10-K for the year ended December 31, 2017 and prospectus supplement, dated October 18, 2018 and filed with the SEC on October 19, 2018, and in the company's future SEC filings and reports. Krystal Biotech undertakes no duty or obligation to update any forward-looking statements and information contained herein as a result of new information, future events or changes in its expectations or circumstances.

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Source: Krystal Biotech, Inc.