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

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PITTSBURGH, Aug. 06, 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 second quarter ended June 30, 2018, and provided an update on the company's corporate progress.

Commenting on second quarter results, Krish S. Krishnan, chairman and chief executive officer of Krystal Biotech, said, "2018 is a year of execution for Krystal as we strive to achieve three important value-creating catalysts. First and foremost, in the clinic, we intend to announce interim safety and efficacy results from the KB103 Phase 1/2 study for the treatment of dystrophic epidermolysis bullosa (DEB) by Q4 2018. In addition, we completed our pre-IND meeting with the FDA on KB105, our second pipeline product for the treatment of TGM-1 deficient autosomal recessive congenital ichthyosis (ARCI), and anticipate filing our IND in Q4. Finally, construction of the GMP facility to manufacture clinical grade products for Krystal's pipeline programs has begun and is anticipated to be complete by the end of 2018." Mr. Krishnan continued, "I believe Krystal's approach of using an 'off-the-shelf' topical gene therapy approach to treating debilitating skin diseases is unique in the industry and we are only beginning to unlock the value of our technology and pipeline."

Recent Corporate Highlights

- First two patients enrolled in Phase 1/2 clinical study of KB103, a first-in-class topical gene therapy for the treatment of DEB.
- U.S. FDA grants Fast Track Designation for Krystal Biotech's KB103 for the treatment of DEB.
- IND on KB105, a topical gene therapy for the treatment of TGM-1 deficient ARCI, to be filed in Q4 2018 following completion of pre-IND meeting with the U.S. FDA.
- Construction of the GMP facility to manufacture clinical grade products for Krystal's pipeline programs to be complete in Q4 2018.
- David Maheu joins the Krystal team as vice-president, process development and manufacturing operations.
    - 17+ years at Amgen working on process development and manufacturing work on Imlygic, a genetically modified HSV-1 virus, approved for commercial distribution in US and Europe and targeted against metastatic melanoma.
    - 2 years at MilliporeSigma Inc. as head of virus and gene therapy bioprocessing.

Financial results for the quarter ended June 30, 2018

- Cash, cash equivalents and short-term investments totaled $45.5 million at June 30, 2018, compared with $47.2 million at March 31, 2018.
- Research and development expenses for the second quarter were $1.5 million.
- General and administrative expenses for the second quarter were $0.9 million.
- Net losses for the quarters ended June 30, 2018 and 2017 were $2.3 million and $0.8 million, respectively, or $0.22 per common share (basic and diluted) for both periods.

For further details on the company's financials, please refer to Form 10Q filed with the SEC.

About KB103
KB103 is Krystal's lead product candidate, currently in preclinical development and seeks to use gene therapy to treat dystrophic epidermolysis bullosa, or 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's STAR-D platform to deliver functional human COL7A1 genes directly to the patients' dividing and non-dividing skin cells. Krystal'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, or DEB
Dystrophic epidermolysis bullosa, or DEB, 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 knock. 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 is developing KB-103 for the treatment of the broad DEB population, including both recessive and dominant forms of the disease.

About Lamellar Ichthyosis
Lamellar ichthyosis (LI) is an autosomal recessive disorder that is apparent at birth and is present throughout life. There are 22 known types of LI, a number of which are known to be caused by defects in one of several skin-related genes. LI usually appears in the first few days of life, lasts lifelong and in certain variants can be very severe. A newborn with LI is born encased in a collodion membrane that sheds within 10-14 days. The shedding of the membrane reveals generalized scaling with variable redness of the skin. The scaling may be fine or plate-like, resembling fish skin. Although the disorder is not life threatening, it is quite disfiguring and causes considerable psychological stress to affected patients. There are no approved treatments for LI and the current standard of care remains palliative treatments to manage symptoms.

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 includes certain disclosures that contain “forward-looking statements,” including, without limitation, statements regarding the development of our product candidates, including KB103 and KB105, including statements regarding our plans to initiate a clinical trial of KB103 in 2018 and to file an IND for KB105 during this calendar year and our plans to develop a GMP manufacturing facility over the next 12 months. You can identify forward-looking statements because they contain words such as “believes” and “expects.” Forward-looking statements are based on Krystal’s current expectations and assumptions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that may differ materially from those contemplated by the forward-looking statements, which are neither statements of historical fact nor guarantees or assurances of future performance. Important factors that could cause actual results to differ materially from those in the forward-looking statements are set forth in Krystal’s periodic filings with the Securities and Exchange Commission, including its registration statement on Form S-1 and its Form 10-K, under the caption “Risk Factors.”

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Source: Krystal Biotech, Inc.