Krystal Biotech Completes Construction of Ancoris - A New GMP Facility for Commercial Manufacturing of a Viral Vector-Based Gene Therapy to Treat Dystrophic Epidermolysis Bullosa

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PITTSBURGH, Jan. 15, 2019 (GLOBE NEWSWIRE) -- Krystal Biotech Inc., ("Krystal") (NASDAQ: KRYS), a gene therapy company developing topical and intradermal "off-the-shelf" treatments for rare dermatological diseases, today announces that construction of Ancoris, a new state-of-the-art Good Manufacturing Practice (GMP) facility, is complete. The new facility is located near the Company's headquarters in Pittsburgh and will support clinical and commercial manufacturing of Krystal's lead product candidate, KB103, for the treatment of dystrophic epidermolysis bullosa (DEB). The facility will be officially open in 1Q 2019 following completion of the first engineering run.

"Our development of internal manufacturing capabilities bolsters our position for commercial readiness as we execute on our vision to bring our therapies to the patient communities in need," said Krish S Krishnan, chairman and chief executive officer of Krystal Biotech. "We thank the City of Pittsburgh and the Mayor's office for helping us complete construction in a timely manner and we intend to have a formal inauguration following completion of a trial run in 1Q 2019."

The 4,500 square foot facility has been designed to satisfy the necessary manufacturing requirements for commercial development of KB103 and the highest current GMP standards governing commercial production for biopharmaceutical use. The Ancoris facility will be the primary production site to meet projected commercial demand for KB103. In addition, a second phase of the manufacturing strategy has been initiated with plans to build a second, larger GMP manufacturing facility in Pittsburgh that will support the anticipated commercial demand for future developmental pipeline programs. The second facility is anticipated to be complete in 2020.

"Having our own GMP facility will enable our STAR-D HSV-1 based platform to be fully integrated and allow us to keep important proprietary process development and associated intellectual property in-house," said Suma Krishnan, founder and chief operating officer of Krystal. "Ancoris and the second GMP facility we have planned will ensure that we are able to meet the manufacturing demands of all our research and potential commercial programs."

About KB103
KB103 is Krystal's lead product candidate that 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 employing Krystal's STAR-D platform to deliver functional human COL7A1 genes directly to the patients' dividing and non-dividing skin cells. HSV-1 is Krystal's replication-deficient, non-integrating viral vector that 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. Recent interim Phase 1/2 trial results showed fast and durable wound closure in two adult DEB patients as well as a promising safety profile.

About the STAR-D Gene Therapy Platform
Krystal's **S**kin **TAR**geted **D**elivery platform, or STAR-D platform, is a proprietary gene therapy platform consisting of an engineered viral vector and skin-optimized gene transfer technology that Krystal is employing to develop off-the-shelf treatments for dermatological diseases for which there are no known effective treatments. 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 topical and intradermal "off-the-shelf" novel treatments for patients suffering from rare 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 potential of KB103 to treat the underlying causes of DEB, the timetable for bringing GMP manufacturing in-house and the potential for rapid development of the company's clinical programs. 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 filings with the Securities and Exchange Commission, including its registration statement on Form S-1 and Form 10-K, as amended from time to time, under the caption "Risk Factors."

CONTACTS:

Investors:
Ashley R. Robinson
LifeSci Advisors
arr@lifesciadvisors.com

Media:
Darren Opland, Ph.D.
LifeSci Public Relations
darren@lifescipublicrelations.com

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