Krystal Biotech Reports Fourth Quarter and Full Year 2021 Financial Results and Provides Update on Operational Progress

February 28, 2022

- Following successful completion of GEM-3 pivotal trial, Krystal is on track to file BLA for Vyjuvek™ for the treatment of dystrophic epidermolysis bullosa in 1H 2022; MAA filing anticipated in 2H 2022
- Phase 1 trial of KB407 in cystic fibrosis patients in Australia expected to begin in 1H 2022; IND filing and U.S. trial initiation anticipated in 2H 2022
- Jeune Aesthetics on track to announce Phase 1 proof-of-concept efficacy data from KB301, being developed for aesthetic indications, in 1Q 2022
- Strong balance sheet with December 31, 2021 cash, cash equivalents and investments of $502.5 million

PITTSBURGH, Feb. 28, 2022 (GLOBE NEWSWIRE) -- Krystal Biotech Inc., (“Krystal” or the "Company") (NASDAQ: KRYS), the leader in redosable gene therapy, today reported financial results and key operational updates for the fourth quarter and year ending December 31, 2021.

“I would like to thank the entire Krystal team for their dedication in 2021. This was an important year for Krystal with the announcement of positive topline data from the Phase 3 trial of Vyjuvek™ for the treatment of dystrophic epidermolysis bullosa. We are now working diligently toward global regulatory filings, including submitting our biologics license application, and preparing for commercialization,” said Krish S. Krishnan, Chairman and CEO of Krystal Biotech, Inc. He added, “The positive Phase 3 data provides strong validation of our approach and our platform as we advance new medicines to treat other debilitating diseases.”

Fourth Quarter Program Highlights & Upcoming Events:

Vyjuvek for the treatment of Dystrophic Epidermolysis Bullosa (EB)

- In November 2021, the Company announced positive topline data from the pivotal GEM-3 trial of topical Vyjuvek (beremagene geperpavec or B-VEC) for the treatment of dystrophic EB. The Company intends to present more detailed results at upcoming medical congresses.
- The Company is on track to file a biologics license application (BLA) with the U.S. Food and Drug Administration (FDA) in 1H 2022 and a marketing authorization application with the European Medicines Agency (EMA) in 2H 2022.

KB407 for the treatment of Cystic Fibrosis (CF)

- The Company expects to initiate a Phase 1 clinical trial of inhaled KB407 in patients with CF in Australia in 1H 2022. Details of the Phase 1 study can be found at www.clinicaltrials.gov under NCT identifier NCT05095246.
- The Company plans to expand the Phase 1 trial clinical program to the U.S. in 2H 2022.

KB105 for the treatment of Autosomal Recessive Congenital Ichthyosis (ARCI)

- Dosing in the next cohort in the ongoing Phase 2 clinical trial of KB105 for the treatment of TGM1-deficient ARCI is on track to resume in 2022.
- Details of the Phase 1/2 study can be found at www.clinicaltrials.gov under NCT identifier NCT04047732.

KB104 for Netherton Syndrome

- The Company continues to work towards an investigational new drug filing (IND), which is anticipated in 2022.

KB301 for Aesthetic Indications

- Jeune Aesthetics, Inc., the Company’s wholly-owned subsidiary, expects to announce safety and proof-of-concept efficacy data from the Phase 1 study (PEARL-1) of intradermal KB301 in 1Q 2022. Details of the study can be found at www.clinicaltrials.gov under NCT identifier NCT04540900.

Corporate Highlights:

- In February 2022, Suma Krishnan was promoted to President, Research and Development. Suma was the chief architect for the Company’s differentiated redosable gene therapy platform and has been leading research and development efforts

since Krystal's inception. This promotion is a testament to her outstanding accomplishment in driving the science and innovation leading to recent positive results from B-VEC, our lead asset from this platform. With this promotion, Suma will focus on building and strengthening an industry-leading research and development team and further expanding the Company's efforts to deliver life-changing medicines for patients.

- On December 3, 2021, the Company completed a public offering of 2,866,667 shares of its common stock, including 200,000 shares purchased by the underwriters, at $75.00 per share. Net proceeds to the Company from the offering were $201.9 million after deducting underwriting discounts.

Fourth Quarter and Full Year 2021 Financial Results:
Cash, cash equivalents and investments totaled $502.5 million on December 31, 2021, compared to $271.3 million as of December 31, 2020. The increase of $231.2 million is inclusive of net proceeds from our February 2021 and December 2021 public offerings.

Research and development expenses for the fourth quarter ended December 31, 2021 were $9.0 million, compared to $5.7 million for the fourth quarter 2020, and $27.9 million for the year ended December 31, 2021, compared to $17.9 million for the year ended December 31, 2020.

General and administrative expenses for the fourth quarter ended December 31, 2021 were $12.9 million, compared to $4.8 million for the fourth quarter 2020, and $40.4 million for the year ended December 31, 2021, compared to $15.1 million for the year ended December 31, 2020.

Net losses for the quarters ended December 31, 2021 and 2020 were $21.8 million and $10.5 million, or $(0.94) and $(0.53) respectively, per common share (basic and diluted). Net losses for the years ended December 31, 2021 and 2020 were $69.6 million and $32.2 million or $(3.13) and $(1.71) respectively, per common share (basic and diluted).

For additional information on the Company's financial results for the year ended December 31, 2021, refer to form 10-K filed with the SEC.

About Krystal Biotech
Krystal Biotech, Inc. (NASDAQ:KRYS) is a pivotal-stage gene therapy company leveraging its proprietary, redosable gene therapy platform and in-house manufacturing capabilities to potentially bring life-changing treatment options to patients with serious diseases, including rare diseases in skin, lung, and other areas.

For more information please visit:
https://www.krystalbio.com, and follow @KrystalBiotech on LinkedIn and Twitter

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 pre-clinical and clinical trials of its products; Krystal's plans for filing regulatory and efforts to bring its products to market; 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, 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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Consolidated Balance Sheet Data:

(In thousands)	December 31, 2021	December 31, 2020
Balance sheet data:		
Cash and cash equivalents	$ 341,246	$ 268,269
Working capital	416,531	259,606
Total assets	626,295	310,844
Total liabilities	32,719	18,760

Total stockholders' equity	$ 593,576	$ 292,084

Consolidated Statement of Operations:

	Years Ended December 31,		
(In thousands, except shares and per share data)	**2021**	**2020**	**Change**
Expenses			
Research and development	$ 27,884	$ 17,936	$ 9,948
General and administrative	40,391	15,063	25,328
Total operating expenses	68,275	32,999	35,276
Loss from operations	(68,275)	(32,999)	(35,276)
Other Expense			
Interest and other income, net	197	832	(635)
Interest expense	(1,492)	—	(1,492)
Total interest and other income	(1,295)	832	(2,127)
Net loss applicable to stockholders	$ (69,570)	$ (32,167)	$ (37,403)
Net loss attributable to common stockholders per share: Basic and diluted	$ (3.13)	$ (1.71)	
Weighted-average common shares outstanding: Basic and diluted	22,196,846	18,787,161	

Source: Krystal Biotech, Inc.