Krystal Biotech Announces First Quarter 2023 Financial Results and Operational Highlights

May 8, 2023

- *PDUFA date of May 19, 2023*
- *Presented clinical data at ARVO on topical application of B-VEC to the eye to treat ocular complications in a patient with recessive dystrophic epidermolysis bullosa under Compassionate Use Program*
- *Strong balance sheet, closing the quarter with $355.5 million in cash, cash equivalents and investments*

PITTSBURGH, May 08, 2023 (GLOBE NEWSWIRE) -- Krystal Biotech, Inc. (the "Company") (NASDAQ: KRYS), a biotechnology company focused on developing and commercializing genetic medicines for patients with rare diseases, today reported financial results and key operational progress updates for the first quarter ended March 31, 2023.

"Krystal had a strong start to 2023, marked by significant progress in commercial preparation activities for our anticipated FDA approval of B-VEC later this month, as well as advancements across our pipeline, which lay the groundwork for long-term value creation," said Krish S. Krishnan, Chairman and CEO of Krystal Biotech. He added, "We are also encouraged by the remarkable vision improvements seen in the RDEB patient who was dosed with B-VEC topically in the eye to treat cicatrizing conjunctivitis under our compassionate use program, which supports expansion of our platform beyond skin and pulmonology into ophthalmological indications."

Dermatology

B-VEC (beremagene geperpavec) for the treatment of Dystrophic Epidermolysis Bullosa (DEB)

- In January, the Company was notified by the U.S. Food & Drug Administration (FDA) that the Prescription Drug User Fee Act (PDUFA) date for the Company's Biologics License Application for B-VEC for the treatment of patients with DEB, will be May 19, 2023. In April, the Company began labeling discussions with the FDA.
- The Company was informed by the European Medicines Agency in January 2023 to modify the Pediatric Investigation Plan (PIP) waiver request to include patients between birth and 6 months. The Company has modified and submitted the PIP waiver so that the Marketing Authorization Application procedure can officially start in the second half of 2023 with an approval expected in early 2024.
- The Company was informed by the Ministry of Health, Labour and Welfare (MHLW) of Japan that B-VEC was confirmed as safe for importation under the Cartagena Act. With the approval for the importation of B-VEC under the Cartagena Act, we intend to start an open label extension study of B-VEC in Japan in 2023 with an approval in Japan expected in early 2025.
- In April 2023, the Company presented new data on the compassionate use of topical B-VEC to treat a patient with RDEB with recurrent cicatrizing conjunctivitis at the Association for Research in Vision and Ophthalmology (ARVO) 2023 Annual Meeting. The data presented describes the first application of B-VEC to treat ocular complications in a patient with RDEB under a compassionate use program. The patient underwent surgical symblepharon lysis with pannus removal in the right eye. B-VEC was administered to the patient's right eye at regular intervals following surgery in addition to routine post-surgical management. B-VEC was well tolerated and associated with full corneal healing by 3 months as well as significant visual acuity improvement from hand motion to 20/40 at 7 months, the latest time point of the ongoing treatment effect evaluation.

Rare dermatological pipeline

- The Company plans to initiate the Phase 2 cohort of its KB105-02 (JADE-1) trial in the first half of 2023. The Phase 2 cohort will enroll both pediatric and adult patients with TGM1 deficient autosomal recessive congenital ichthyosis for assessment of KB105 safety and efficacy. Details of the Phase 1/2 study can be found at www.clinicaltrials.gov under NCT identifier NCT04047732.
- The Company is working on an investigational new drug (IND) filing for KB104 for the treatment of Netherton Syndrome. The Company is on track to file an IND for KB104 in 2023.

Respiratory

KB407 for the treatment of Cystic Fibrosis

- In August 2022, we announced that the FDA had accepted our IND application to evaluate KB407 in a clinical trial to treat patients with Cystic Fibrosis. We are closely working with the Therapeutics Development Network of the Cystic Fibrosis Foundation to validate our Phase 1 clinical protocol. We plan to initiate a Phase 1 clinical trial in the U.S. in the first half of 2023. Details of the Phase 1 study can be found at www.clinicaltrials.gov under NCT identifier NCT05504837.
- Screening activities are ongoing for a Phase 1 clinical trial in Australia to study safety and determine frequency of dosing

application. Details of the Phase 1 study can be found at www.clinicaltrials.gov under NCT identifier NCT05095246.

KB408 for the treatment of Alpha-1 Antitrypsin Deficiency (AATD)

- The Company is performing preclinical and manufacturing activities and is on track to initiate a Phase 1 clinical trial of KB408 for the treatment of AATD in the second half of 2023.

Aesthetics

KB301 for the treatment of Aesthetic Indications

- In April, Jeune Aesthetics, Inc. (Jeune), a wholly-owned subsidiary of the Company, announced the dosing of the first subject in the Phase 1, Cohort 3 study of KB301 for the improvement of lateral canthal lines at rest. The Phase 1, Cohort 3 study is being conducted at a single center as an open label study to assess two different doses of KB301 in up to 20 subjects. Improvement of lateral canthal lines at rest was selected as a target indication for KB301 based upon the Phase 1 safety, efficacy and durability studies, which evaluated KB301 in the lower and upper cheek, including the lateral canthal region. Subjects will be followed for three months after KB301 treatment, and the study is expected to be complete in the second half of 2023. Details of the Phase 1 study can be found at www.clinicaltrials.gov under NCT identifier NCT04540900.
- Jeune plans to initiate a Phase 2 multicenter, double-blind randomized study (PEARL-2) of KB301 for the improvement of lateral canthal lines at rest following completion of the Phase 1, Cohort 3 study.

Financial results for the quarter ended March 31, 2023:

- Cash, cash equivalents, and investments totaled $355.5 million on March 31, 2023.
- Research and development expenses for the quarter ended March 31, 2023 were $12.3 million, compared to $9.3 million for the quarter ended March 31, 2022.
- General and administrative expenses for the quarter ended March 31, 2023 were $24.0 million, compared to $15.9 million for the quarter ended March 31, 2022.
- Net losses for the quarters ended March 31, 2023 and 2022 were $45.3 million and $50.0 million, or $(1.76) and $(1.99), respectively, per common share (basic and diluted).
- For additional information on the Company's financial results for the quarter ended March 31, 2023, please refer to the Form 10-Q filed with the SEC.

About Krystal Biotech, Inc.
Krystal Biotech, Inc. (NASDAQ: KRYS) is a biotechnology company focused on developing and commercializing genetic medicines for patients with rare diseases. The Company's wide-ranging pipeline is based on its proprietary redosable HSV vector. Headquartered in Pittsburgh, Pennsylvania, the Company is led by an experienced management team, is fully-integrated and has core capabilities in viral vector design, vector optimization, gene therapy manufacturing and commercialization. For more information, please visit http://www.krystalbio.com, and follow @KrystalBiotech on LinkedIn and Twitter.

About Jeune Aesthetics, Inc.
Jeune Aesthetics, Inc., a wholly-owned subsidiary of Krystal Biotech, Inc., is a biotechnology company leveraging a clinically validated gene-delivery platform to develop products to fundamentally address – and reverse – the biology of aging and/or damaged skin. For more information, please visit http://www.jeuneinc.com.

Forward-Looking Statements
Any statements in this press release about future expectations, plans and prospects for Krystal Biotech, Inc., including statements about expansion of our platform beyond skin and pulmonology into ophthalmological indications, the timing of submission of the European Medicines Agency's marketing authorization application for B-VEC and approval in the EU, our plans to start an open label extension study of B-VEC in Japan in 2023 with an approval in Japan expected in early 2025, our plans to initiate the Phase 2 cohort of the KB105-02 (JADE-1) trial in the first half of 2023, our plans to file an IND for KB104 in 2023, the timing of the KB407 Phase 1 clinical trial program in Australia and the U.S., our plans to initiate a Phase 1 clinical trial of KB408 for the treatment of AATD in the second half of 2023, our expectation that the Phase 1, Cohort 3 study of KB301 will be complete in the second half of 2023 and our plans to initiate a Phase 2 study of KB301, 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: uncertainties associated with regulatory review of clinical trials and applications for marketing approvals, the availability or commercial potential of product candidates including B-VEC, 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 the Company'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 the Company's views as of the date of this release. The Company anticipates that subsequent events and developments will cause its views to change. However, while the Company 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 the Company's views as of any date subsequent to the date of this release.

CONTACT:
Investors and Media:
Meg Dodge
Krystal Biotech

mdodge@krystalbio.com

Consolidated Balance Sheet Data:

(In thousands)	March 31, 2023	December 31, 2022
Balance sheet data:		
Cash and cash equivalents	$ 140,745	$ 161,900
Short-term investments	209,642	217,271
Long-term investments	5,129	4,621
Total assets	531,847	558,450
Total liabilities	42,281	36,219
Total stockholders' equity	$ 489,566	$ 522,231

Consolidated Statement of Operations:

	Three Months Ended March 31,		
(In thousands, except shares and per share data)	**2023**	**2022**	**Change**
Expenses			
Research and development	$ 12,288	$ 9,314	$ 2,974
General and administrative	24,035	15,908	8,127
Litigation settlement	12,500	25,000	(12,500)
Total operating expenses	48,823	50,222	(1,399)
Loss from operations	(48,823)	(50,222)	1,399
Other Income			
Interest and other income, net	3,526	257	3,269
Net loss	$ (45,297)	$ (49,965)	$ 4,668
Net loss per common share: Basic and diluted	$ (1.76)	$ (1.99)	
Weighted-average common shares outstanding: Basic and diluted	25,712,220	25,114,453	

Source: Krystal Biotech, Inc.