Krystal Biotech Announces Second Quarter 2023 Financial Results and Operational Highlights

August 7, 2023

• VYJUVEK™ approved in theU.S. as the first and only topical redosable gene therapy for the treatment of dystrophic epidermolysis bullosa

• 121 Patient Start Forms in the first six weeks of launch

• First cystic fibrosis patient dosed in Phase 1 Clinical Trial of KB407

• IND for KB707, Krystal's first oncology candidate for solid tumors, accepted by FDA and granted Fast Track Designation

• Strong balance sheet, closing the quarter with $505.9 million in cash, cash equivalents and investments

PITTSBURGH, Aug. 07, 2023 (GLOBE NEWSWIRE) -- Krystal Biotech, Inc. (the "Company") (NASDAQ: KRYS), a commercial-stage biotechnology company focused on the discovery, development and commercialization of genetic medicines to treat diseases with high unmet medical needs, today reported financial results and key operational progress updates for the second quarter ended June 30, 2023.

"2023 is off to a very strong start and we expect the momentum to continue for the rest of the year. In the first half of the year, we received FDA approval for VYJUVEK, dosed our first patient in the cystic fibrosis trial and obtained IND clearance for our first oncology candidate," said Krish S. Krishnan, Chairman and CEO of Krystal Biotech. "I am particularly thrilled with the enthusiasm that physicians and patients are expressing for VYJUVEK in these early days of launch. With 121 Patient Start Forms in the first six weeks since approval, I am pleased with the initial pace of the launch, and we look forward to promptly initiating treatment for these patients."

VYJUVEK™

- On May 19, the Company announced that VYJUVEK (beremagene geperpavec-svdt, or B-VEC) was approved by the U.S. Food & Drug Administration (FDA) for the treatment of patients six months of age or older with either recessive or dominant dystrophic epidermolysis bullosa (DEB) to be administered by a healthcare professional either in a healthcare professional setting (e.g., clinic) or a home setting.
- As of June 30, the Company received 121 Patient Start Forms of which 30 start forms were generated for patients with dominant dystrophic epidermolysis bullosa. The Company will continue to report on the number of Patient Start Forms submitted to the Company for the first three quarters following VYJUVEK approval and will transition to reporting on the number of Patients on Therapy beginning in the first quarter of 2024.
- The Company also received positive coverage determinations from several of the national health plans, including UnitedHealthcare, as well as regional plans such as BlueCross BlueShield, state Medicaid plans and other smaller regional health plans. The Company expects that additional payer policies will continue to publish that cover VYJUVEK for both recessive and dominant DEB patients.
- In July, the Company received a positive opinion from the European Medical Agency (EMA) on the Pediatric Investigation Plan for B-VEC for the treatment of DEB with no additional studies required. The Company plans to submit a market authorization application to the EMA in the second half of 2023 and anticipates a potential launch in the EU in the second half of 2024.
- In July, the Pharmaceuticals and Medical Agency in Japan accepted the open label extension study of B-VEC, and the Company intends to start an open label extension study of B-VEC in Japan in the second half of 2023 and file for approval in Japan in 2024. The Company will provide details of the open label extension study when it doses the first patient in Japan.

Respiratory

KB407 for the treatment of Cystic Fibrosis (CF)

- In July, the Company announced that the first patient had been dosed at the Cystic Fibrosis Institute of Chicago in the Company's Phase 1 CORAL-1/ U.S. study evaluating KB407, a mutation agnostic genetic medicine, delivered via a nebulizer, for the treatment of patients with CF. The Phase 1/CORAL-1 study is a multi-center, dose-escalation trial of KB407 in patients with CF, regardless of their underlying genotype. The Company anticipates announcing data from the Phase 1 study in 2024. Details of the Phase 1 study can be found at www.clinicaltrials.gov under NCT identifier NCT05504837.

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

- The Company intends to file an Investigational New Drug (IND) application with the FDA and initiate a Phase 1 clinical trial of KB408 for the treatment of AATD in the second half of 2023.

Oncology

KB707 for the treatment of solid tumors

- In July, the Company announced that the FDA had accepted its IND application to evaluate intratumoral KB707 in a clinical trial to treat patients with locally advanced or metastatic solid tumor malignancies. KB707 targets solid tumors that are accessible via intratumoral injection or inhalation, and we intend to advance both routes of administration into clinical studies. Details of the Phase 1 (OPAL-1) study can be found www.clinicaltrials.gov under NCT identifier NCT05970497. The Company expects to dose the first patient in the second half of 2023.
- The FDA also granted KB707 fast track designation to delay disease progression in the treatment of patients with anti-PD-1 relapsed/refractory locally advanced or metastatic melanoma.
- The Company plans to file an amendment to the existing KB707 IND in the second half of 2023 to allow the Company to evaluate inhaled (nebulized) KB707 in a clinical trial to treat tumors in a patient's lungs. The Company expects to dose the first patient with inhaled KB707 in the first half of 2024.

Dermatology

KB105 for the treatment of TGM1 deficient autosomal recessive congenital ichthyosis

- The Company plans to initiate the Phase 2 cohort of its KB105-02 (JADE-1) trial in 2024 and is currently working with the FDA to ensure alignment on the clinical endpoints in the pivotal trial prior to initiating a Phase 2 study in pediatric patients. 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.

KB104 for the treatment of Netherton Syndrome

- With an expanding pipeline portfolio, the Company now anticipates filing an IND application with the FDA and initiating a clinical trial of KB104 to treat patients with Netherton Syndrome in late 2024.

Aesthetics

KB301 for the treatment of aesthetic indications

- In April, Jeune Aesthetics, Inc., 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 study is on-going, and the Company plans to announce results from this study in the second half of 2023. Details of the Phase 1 study can be found at www.clinicaltrials.gov under NCT identifier NCT04540900.

Financial results for the quarter ended June 30, 2023:

- Cash, cash equivalents, and investments totaled $505.9 million on June 30, 2023.
- Research and development expenses for the quarter ended June 30, 2023 were $12.1 million, inclusive of $2.9 million of stock-based compensation, compared to $10.9 million, inclusive of stock-based compensation of $2.0 million for the quarter ended June 30, 2022.
- General and administrative expenses for the quarter ended June 30, 2023 were $25.9 million, inclusive of stock-based compensation of $8.5 million, compared to $17.9 million, inclusive of stock-based compensation of $6.2 million, for the quarter ended June 30, 2022.
- Net losses for the quarters ended June 30, 2023 and 2022 were $33.2 million and $28.1 million, or $(1.25) and $(1.10), respectively, per common share (basic and diluted).
- For additional information on the Company's financial results for the quarter ended June 30, 2023, please refer to the Form 10-Q filed with the SEC.

Financial results for the six months ended June 30, 2023:

- Research and development expenses for the six months ended June 30, 2023 were $24.4 million, inclusive of stock-based compensation of $5.4 million, compared to $20.2 million, inclusive of stock-based compensation of $3.4 million for the six months ended June 30, 2022.
- General and administrative expenses for the six months ended June 30, 2023 were $49.9 million, inclusive of stock-based compensation of $16.4 million, compared to $33.8 million, inclusive of stock-based compensation of $11.3 million for the six months ended June 30, 2022.
- Net losses for the six months ended June 30, 2023 and 2022 were $78.5 million and $78.1 million or $(3.00) and $(3.08), respectively, per common share (basic and diluted).
- For additional information on the Company's financial results for the six months ended June 30, 2023, please refer to the Form 10-Q filed with the SEC.

About VYJUVEK

VYJUVEK is a non-invasive, topical, redosable gene therapy designed to deliver two copies of the *COL7A1* gene when applied directly to DEB wounds. VYJUVEK was designed to treat DEB at the molecular level by providing the patient's skin cells the template to make normal COL7 protein, thereby addressing the fundamental disease-causing mechanism.

Indication

VYJUVEK is a herpes-simplex virus type 1 (HSV-1) vector-based gene therapy indicated for the treatment of wounds in patients six months of age and older with dystrophic epidermolysis bullosa with mutation(s) in the collagen type VII alpha 1 chain (*COL7A1*) gene.

IMPORTANT SAFETY INFORMATION

Adverse Reactions

The most common adverse drug reactions (incidence >5%) were itching, chills, redness, rash, cough, and runny nose. These are not all the possible side effects with VYJUVEK. Call your healthcare provider for medical advice about side effects.

To report SUSPECTED ADVERSE REACTIONS, contact Krystal Biotech, Inc. at 1-844-557-9782 or FDA at 1-800-FDA-1088 or http://www.fda.gov/medwatch.

Contraindications

None.

Warnings and Precautions

VYJUVEK gel must be applied by a healthcare provider.

After treatment, patients and caregivers should be careful not to touch treated wounds and dressings for 24 hours.

Wash hands and wear protective gloves when changing wound dressings. Disinfect bandages from the first dressing change with a virucidal agent, and dispose of the disinfected bandages in a separate sealed plastic bag in household waste. Dispose of the subsequent used dressings in a sealed plastic bag in household waste.

Patients should avoid touching or scratching wound sites or wound dressings.

In the event of an accidental exposure flush with clean water for at least 15 minutes.

For more information, see full U.S. Prescribing Information.

About Fast Track Designation

Fast Track Designation is designed to facilitate the development and expedite the review of drugs to treat serious conditions and treat a serious or unmet medical need, enabling drugs to reach patients sooner. Clinical programs with Fast Track designation may benefit from early and frequent communication with the FDA throughout the regulatory review process, and such clinical programs may be eligible to apply for Accelerated Approval and Priority Review if relevant criteria are met.

About Krystal Biotech, Inc.

Krystal Biotech, Inc. (NASDAQ: KRYS) is a commercial-stage biotechnology company focused on the discovery, development and commercialization of genetic medicines to treat diseases with high unmet medical needs. VYJUVEK™ is the Company's first commercial product, the first-ever redosable gene therapy, and the only medicine approved by the FDA for the treatment of dystrophic epidermolysis bullosa. The Company is rapidly advancing a robust preclinical and clinical pipeline of investigational genetic medicines in respiratory, oncology, dermatology, ophthalmology, and aesthetics. Krystal Biotech is headquartered in Pittsburgh, Pennsylvania. 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. or Jeune Aesthetics, Inc., including statements about our commercial launch of VYJUVEK; our plans to report on Patient Start Forms and Patients on Therapy; our plans to submit a market authorization application to the EMA in the second half of 2023 and our anticipation of a potential launch of B-VEC in the EU in the second half of 2024; our plans for an open label extension study of B-VEC in Japan in the second half of 2023, filing for approval in Japan in 2024, and the timing of our provision of details of the open label extension study; our expectation that we will announce data from the Phase 1 study of KB407 in 2024; our intention to file an IND application with the FDA and initiate a Phase 1 clinical trial of KB408 for the treatment of AATD in the second half of 2023; our expectations regarding dosing the first patient with KB707 in the second half of 2023; our plans to file an amendment to the existing KB707 IND in the second half of 2023 to evaluate inhaled KB707 in a clinical trial in the first half 2024; our plans to initiate the Phase 2 cohort of the KB105-02 (JADE-1) trial in 2024; our plans to file an IND application and initiate a clinical trial of KB104 in late 2024; our expectation that we will announce results of the Phase 1, Cohort 3 study of KB301 for the improvement of lateral canthal lines at rest in the second half of 2023, 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 VYJUVEK, 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.

Disclosures

The Company is using the Aerogen Solo® Nebulizer System and Aerogen® Ultra in its Phase 1 CORAL-1/U.S. study evaluating KB407.

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Consolidated Balance Sheet Data:

(In thousands)	June 30, 2023	December 31, 2022
Balance sheet data:		
Cash and cash equivalents	$ 275,875	$ 161,900
Short-term investments	201,642	217,271
Long-term investments	28,410	4,621
Total assets	684,026	558,450
Total liabilities	30,912	36,219
Total stockholders' equity	$ 653,114	$ 522,231

Consolidated Statements of Operations:

	Three Months Ended June 30,		
(In thousands, except shares and per share data)	**2023**	**2022**	**Change**
Expenses			
Research and development	$ 12,144	$ 10,890	$ 1,254
General and administrative	25,904	17,863	8,041
Total operating expenses	38,048	28,753	9,295
Loss from operations	(38,048)	(28,753)	(9,295)
Other Income			
Interest and other income, net	4,838	645	4,193
Net loss	$ (33,210)	$ (28,108)	$ (5,102)
Net loss per common share: Basic and diluted	$ (1.25)	$ (1.10)	
Weighted-average common shares outstanding: Basic and diluted	26,656,883	25,545,167	

	Six Months Ended June 30,	

(In thousands)	2023	2022	Change
	(unaudited)		
Expenses			
Research and development	$ 24,432	$ 20,204	$ 4,228
General and administrative	49,939	33,771	16,168
Litigation settlement	12,500	25,000	(12,500)
Total operating expenses	86,871	78,975	7,896
Loss from operations	(86,871)	(78,975)	(7,896)
Other Income			
Interest and other income, net	8,364	902	7,462
Net loss	$ (78,507)	$ (78,073)	$ (434)
Net loss per common share: Basic and diluted	$ (3.00)	$ (3.08)	
Weighted-average common shares outstanding: Basic and diluted	26,187,161	25,331,000	

Source: Krystal Biotech, Inc.