Keros Therapeutics Reports Recent Business Highlights and Fourth Quarter and Full Year 2023 Financial Results

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LEXINGTON, Mass., Feb. 28, 2024 (GLOBE NEWSWIRE) -- Keros Therapeutics, Inc. (“Keros” or the “Company”) (Nasdaq: KROS), a clinical-stage biopharmaceutical company focused on developing and commercializing novel therapeutics to treat a wide range of patients with disorders that are linked to dysfunctional signaling of the transforming growth factor-beta (“TGF-ß”) family of proteins, today provided a business update and reported financial results for the fourth quarter and full year ended December 31, 2023.

“In 2023, Keros made continued clinical progress across our pipeline, including commencing our Phase 2 clinical trial evaluating KER-012 in patients with pulmonary arterial hypertension (“PAH”) and presenting exciting data from our two ongoing Phase 2 clinical trials of KER-050, one in patients with myelodysplastic syndromes (“MDS”) and one in patients with myelofibrosis,” said Jasbir S. Seehra, Ph.D., President and Chief Executive Officer. “We continue to build on that momentum in 2024, as highlighted by the advancement of our third clinical asset, KER-065, into a Phase 1 healthy volunteer clinical trial at the beginning of this year. We look forward to providing updates from the KER-050 and KER-012 programs in the first half of this year.”

Recent Corporate Highlights:

- **Cash position strengthened:** The Company closed an underwritten public offering of 4,025,000 shares of common stock on January 8, 2024, at a public offering price of $40.00 per share, inclusive of the underwriters’ exercise in full of their option to purchase up to an additional 525,000 shares of common stock at the public offering price (the “January 2024 Offering”). The Company expects that its cash and cash equivalents as of December 31, 2023, together with the net proceeds from the January 2024 Offering, will enable the Company to fund its planned operating expenses and capital expenditure requirements into 2027.

Selected Anticipated Program Milestones:

- **KER-050 (elritercept) for the treatment of ineffective hematopoiesis to address cytopenias:**
  - Engage with regulators on the design of the planned Phase 3 clinical trial of KER-050 in patients with MDS in the first half of 2024
  - Report additional data from Part 2 of the ongoing Phase 2 clinical trial of KER-050 in patients with MDS in the second and fourth quarters of 2024
  - Report additional data from the ongoing Phase 2 clinical trial of KER-050 in patients with myelofibrosis in the second and fourth quarters of 2024
- **KER-012 for the treatment of PAH and for the treatment of cardiovascular disorders:**
  - Provide an update on enrollment of the ongoing Phase 2 clinical trial evaluating KER-012 in patients with PAH (the “TROPOS trial”) in the first half of 2024
  - Report initial data from the ongoing Phase 2 open-label biomarker trial of KER-012 in patients with chronic heart failure with preserved injection and in such patients with reduced ejection fraction in the second half of 2024
- **KER-065 for the treatment of obesity and for the treatment of neuromuscular diseases:**
  - Report initial data from the ongoing Phase 1 clinical trial in healthy volunteers in the first quarter of 2025

2023 Financial Results

Keros reported a net loss of $40.2 million for the fourth quarter and $153.0 million for the year ended December 31, 2023, as compared to a net loss of $29.7 million for the fourth quarter and $104.7 million for the year ended December 31, 2022. The increase in net loss for the fourth quarter and the increase in net loss for the year was largely due to increased research and development efforts as well as additional investments to support the achievement of Keros' clinical and corporate goals.

Keros generated revenue of $0.2 million for the year ended December 31, 2023, related to a manufacturing technology transfer agreement Keros entered into with Hansoh (Shanghai) Healthtech Co., Ltd. (“Hansoh”) effective June 2023, in connection with the license agreement Keros entered into

with Hansoh in December 2021. Keros did not generate any revenue for the year ended December 31, 2022.

Research and development expenses were $37.5 million for the fourth quarter and $135.3 million for the year ended December 31, 2023, as compared to $24.9 million for the fourth quarter and $87.3 million for the year ended December 31, 2022. The increase in research and development expenses for the fourth quarter and the year was driven by the continued advancement of the Company's pipeline, notably the progression of its two Phase 2 clinical trials of KER-050, the advancement of KER-012 into the TROPOS trial, as well as an increase in personnel costs and infrastructure to support operations and expansion of its pipeline.

General and administrative expenses were $9.1 million for the fourth quarter and $34.8 million for the year ended December 31, 2023, as compared to $7.1 million and $27.5 million for the fourth quarter and year ended December 31, 2022. The increase was primarily due to an increase in personnel expenses to support the Company's organizational growth and achievement of its corporate goals, an increase in facilities, supplies and other office expenses due to growth of the Company's organization, and an increase in professional fees and director and officer insurance premiums.

Keros' cash and cash equivalents as of December 31, 2023 was $331.1 million compared to $279.0 million as of December 31, 2022. Keros expects that its cash and cash equivalents as of December 31, 2023, together with the net proceeds from the January 2024 Offering, will enable the Company to fund its planned operating expenses and capital expenditure requirements into 2027.

About Keros Therapeutics, Inc.

Keros is a clinical-stage biopharmaceutical company focused on developing and commercializing novel therapeutics to treat a wide range of patients with disorders that are linked to dysfunctional signaling of the TGF-ß family of proteins. We are a leader in understanding the role of the TGF-ß family of proteins, which are master regulators of the growth, repair and maintenance of a number of tissues, including blood, bone, skeletal muscle, adipose and heart tissue. By leveraging this understanding, we have discovered and are developing protein therapeutics that have the potential to provide meaningful and potentially disease-modifying benefit to patients. Keros' lead product candidate, KER-050 (elritercept), is being developed for the treatment of low blood cell counts, or cytopenias, including anemia and thrombocytopenia, in patients with myelodysplastic syndromes and in patients with myelofibrosis. Keros' second product candidate, KER-012, is being developed for the treatment of PAH and for the treatment of cardiovascular disorders. Keros' third product candidate, KER-065, is being developed for the treatment of obesity and for the treatment of neuromuscular diseases.

Cautionary Note Regarding Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Words such as "anticipates," "believes," "continue," "expects," "enable," "potential" and "will" or similar expressions are intended to identify forward-looking statements. Examples of these forward-looking statements include statements concerning: Keros' expectations regarding its growth, strategy, progress and the design, objectives and timing of its clinical trials for KER-050, KER-012 and KER-065, including its regulatory plans; and Keros' expected cash runway. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. These risks and uncertainties include, among others: Keros' limited operating history and historical losses; Keros' ability to raise additional funding to complete the development and any commercialization of its product candidates; Keros' dependence on the success of its product candidates, KER-050, KER-012 and KER-065; that Keros may be delayed in initiating, enrolling or completing any clinical trials; competition from third parties that are developing products for similar uses; Keros' ability to obtain, maintain and protect its intellectual property; and Keros' dependence on third parties in connection with manufacturing, clinical trials and preclinical studies.

These and other risks are described more fully in Keros' filings with the Securities and Exchange Commission ("SEC"), including the "Risk Factors" section of the Company's Quarterly Report on Form 10-Q, filed with the SEC on November 6, 2023, and its other documents subsequently filed with or furnished to the SEC. All forward-looking statements contained in this press release speak only as of the date on which they were made. Except to the extent required by law, Keros undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

Investor Contact:
Justin Frantz
jfrantz@kerostx.com
617-221-6042

KEROS THERAPEUTICS, INC.
Consolidated Statements of Operations
(In thousands, except share and per share data)
(Unaudited)

	THREE MONTHS ENDED DECEMBER 31,		YEAR ENDED DECEMBER 31,	
	2023	2022	2023	2022
REVENUE:				
Service and other revenue	143	—	151	—
Total revenue	143	—	151	—
OPERATING EXPENSES:				
Research and development	(37,493)	(24,867)	(135,258)	(87,265)
General and administrative	(9,105)	(7,093)	(34,834)	(27,525)
Total operating expenses	(46,598)	(31,960)	(170,092)	(114,790)
LOSS FROM OPERATIONS	(46,455)	(31,960)	(169,941)	(114,790)
OTHER INCOME (EXPENSE), NET:				
Interest expense, net	—	—	—	(1)
Research and development incentive income	2,400	—	2,400	7,081
Dividend income	3,756	2,301	14,755	3,644
Other income (expense), net	56	(59)	(206)	(613)
Total other income (expense), net	6,212	2,242	16,949	10,111
Loss before income taxes	(40,243)	(29,718)	(152,992)	(104,679)

Income tax provision	—	—	—	—
Net loss	$ (40,243)	$ (29,718)	$ (152,992)	$ (104,679)
Net loss attributable to common stockholders—basic and diluted	$ (40,243)	$ (29,718)	$ (152,992)	$ (104,679)
Net loss per share attributable to common stockholders—basic and diluted	$ (1.34)	$ (1.09)	$ (5.20)	$ (4.15)
Weighted-average common stock outstanding—basic and diluted	30,126,578	27,326,726	29,447,119	25,241,030

KEROS THERAPEUTICS, INC.
Consolidated Balance Sheets
(In thousands, except share and per share data)
(Unaudited)

	DECEMBER 31,	
	2023	**2022**
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 331,147	$ 279,048
Accounts receivable	143	—
Prepaid expenses and other current assets	16,003	6,719
Total current assets	347,293	285,767
Operating lease right-of-use assets	15,334	15,548
Property and equipment, net	4,134	2,021
Restricted cash	1,212	1,327
Other long term asset	2,052	2,118
Total assets	$ 370,025	$ 306,781
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 5,450	$ 3,339
Current portion of operating lease liabilities	1,005	455
Accrued expenses and other current liabilities	17,918	12,753
Total current liabilities	24,373	16,547
Operating lease liabilities, net of current portion	13,439	12,811
Total liabilities	37,812	29,358
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY:		
Preferred stock, par value of $0.0001 per share; 10,000,000 shares authorized as of December 31, 2023 and December 31, 2022, respectively; no shares issued and outstanding	—	—
Common stock, par value of $0.0001 per share; 200,000,000 authorized as of December 31, 2023 and December 31, 2022; 31,841,084 and 27,543,453 shares issued and outstanding as of December 31, 2023 and December 31, 2022, respectively	3	2
Additional paid-in capital	713,636	505,855
Accumulated deficit	(381,426)	(228,434)
Total stockholders' equity	332,213	277,423
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 370,025	$ 306,781