Kymera Therapeutics Announces First Quarter 2023 Financial Results and Provides a Business Update

May 4, 2023

Phase 1 clinical trial of MDM2 degrader (KT-253) initiated

KT-474 (SAR444656) Phase 2 planned to start in 2023;
Kymera to present Phase 1 clinical data at EADV Symposium in May

Phase 1 trials for STAT3 (KT-333) and IRAKIMiD (KT-413) degraders ongoing, with program updates at ICML in June

March 31, 2023 cash balance approximately $516 million, with cash runway into second half of 2025

Company to hold quarterly results call at 8:30 a.m. ET

WATERTOWN, Mass., May 04, 2023 (GLOBE NEWSWIRE) -- Kymera Therapeutics, Inc. (NASDAQ: KYMR), a clinical-stage biopharmaceutical company advancing targeted protein degradation (TPD) to deliver novel small molecule protein degrader medicines, today reported business highlights and financial results for the first quarter ended March 31, 2023.

“Kymera made important progress in the first quarter against our ambitious goal of building a fully integrated degrader medicines company, and 2023 promises to be a year rich in data and milestones that build upon our prior scientific achievements and further establish the potential impact of our pipeline,” said Nello Mainolfi, PhD, Founder, President and CEO. “We have recently initiated the Phase 1 study of our MDM2 degrader KT-253, our fourth clinical program, where we believe targeted protein degradation has the potential to overcome the limitations of small molecule inhibitors, and we plan to investigate the potential of KT-253 for patients with liquid and solid tumors. With a growing pipeline, including the first-in-class IRAK4 degrader KT-474 currently in development with our partner Sanofi in hidradenitis suppurativa and atopic dermatitis, a robust discovery engine focused heavily on immunology, and a cash runway into the second half of 2025, we are well positioned to continue to deliver first in class therapies for patients around the world.”

Business Highlights and Recent Developments

- In January, at the J.P. Morgan Healthcare Conference, Kymera shared its key research, development and corporate goals for 2023 and newly highlighted multiple programs, heavily focused on immunology, that Kymera is advancing toward clinical development.
- In February, Kymera presented an overview of its innovative platform capabilities at the Society for Laboratory Automation and Screening Annual International Conference & Exhibition, including quantitative proteomics techniques and highly optimized fragment libraries, which enable the Company’s proprietary drug discovery engine to design and develop best-in-class precision degrader medicines for undrugged and inadequately drugged targets.
- In March, Kymera initiated a Phase 1 clinical trial evaluating Kymera’s investigational MDM2 degrader KT-253.The Phase 1 study will evaluate the safety, tolerability, pharmacokinetics/pharmacodynamics and clinical activity of KT-253 in patients with relapsed or refractory high grade myeloid malignancies, including acute myeloid leukemia (AML), acute lymphocytic leukemia (ALL), lymphoma and solid tumors.

Anticipated Upcoming Milestones

- Kymera will deliver an oral presentation of the previously disclosed clinical data from the KT-474 Phase 1 trial at the European Academy of Dermatology and Venereology (EADV) Symposium in Seville on May 18 at 11:45 AM CEST, sharing these data for the first time at a scientific meeting.
- Kymera will present preclinical data highlighting KT-253’s pharmacological profile at the European Hematology Association (EHA) Congress in June and plans to share initial safety and proof-of-mechanism data from the Phase 1 clinical trial later in 2023.
- The Company will provide clinical trial updates focused on PK/PD and safety on its KT-333 and KT-413 programs at the International Conference on Malignant Lymphoma (ICML) in June. Kymera, as previously announced, intends to present data evaluating anti-tumor activity in the target patient populations for KT-333 and KT-413 later this year.
- Kymera’s partner Sanofi plans to initiate Phase 2 clinical studies of the IRAK4 degrader KT-474 (SAR444656) in hidradenitis suppurativa (HS) and atopic dermatitis (AD), with the first study in HS planned for initiation in 2023.

Program Background Information

IRAK4 Degrader Program (KT-474/SAR444656)

KT-474 is a potent, highly selective, orally bioavailable IRAK4 degrader, in development for the treatment of IL-1R/TLR-driven complex inflammatory diseases where there is an opportunity to significantly advance the standard of care in a broad variety of diseases. In the Phase 1 trial, KT-474 showed evidence of robust IRAK4 degradation in the blood and active skin lesions of HS and AD patients and was generally well tolerated. Treatment with KT-474 was associated with a systemic anti-inflammatory response and meaningful improvement in skin lesions and symptoms in both HS and AD patients, with internal consistency between the effect on inflammatory biomarkers and impact on clinical endpoints. KT-474 was generally safe and well-tolerated, with no serious adverse events, no drug-related infections, and no dose interruptions or discontinuations due to adverse events. Sanofi, which is collaborating with Kymera on the development of KT-474 (SAR444656) outside of the oncology and immune-oncology fields, will initiate Phase 2 clinical trials of KT-474, with the first study in HS planned for initiation in 2023.

STAT3 Degrader Program (KT-333)

KT-333 is designed as a potent degrader of STAT3, a transcriptional regulator that has been linked to numerous cancers as well as to inflammatory and autoimmune diseases. KT-333 is being developed for the treatment of STAT3-dependent hematological malignancies and solid tumors. The Phase 1 clinical trial of KT-333 is designed to evaluate the safety, tolerability, PK/PD and clinical activity of KT-333 dosed weekly in adult patients with relapsed and/or refractory lymphomas, leukemias and solid tumors. In December 2022, Kymera shared that Dose Level (DL) 1 had been completed with a total of 4 patients enrolled. All patients were heavily pretreated with multiple prior regimens and included 3 with solid tumors and 1 with cutaneous T-cell lymphoma. Plasma PK and PD translated as expected in humans, with mean maximum STAT3 degradation in PBMC following the first 2 doses averaging 66% and with maximum STAT3 knockdown of up to 86% as measured by mass spectrometry. There were no dose-limiting toxicities or treatment-related serious adverse events reported at this dose. KT-333 has been granted orphan drug designation by the U.S. Food and Drug Administration for both the treatment of cutaneous T-cell lymphoma (CTCL) and peripheral T-cell lymphoma (PTCL).

The Phase 1a dose escalation stage is ongoing, recruiting broadly across solid and liquid tumors. Kymera will present a clinical update focused on PK/PD and safety at the ICML meeting in June and, as previously announced, intends to present data evaluating anti-tumor activity in the target patient population later this year.

More information on the Phase 1 study can be found at www.clinicaltrials.gov, identifier NCT05225584.

IRAKIMiD Degrader Program (KT-413)

KT-413 is a novel heterobifunctional degrader targeting both IRAK4 and the IMiD substrates Ikaros and Aiolos. Designed to address both the IL-1R/TLR and Type 1 IFN pathways synergistically with a single molecule, KT-413 is in development for the treatment of MYD88-mutant B cell malignancies. The Phase 1 clinical trial of KT-413 is designed to evaluate the safety, tolerability, PK/PD and clinical activity of KT-413 administered as an IV infusion once every 3 weeks to adult patients with relapsed and/or refractory B-cell non-Hodgkin's lymphomas. In December 2022, Kymera announced that the first two dose levels had been completed. Patients were heavily pretreated with multiple prior regimens and included follicular lymphoma and DLBCL, which were both wild-type for MYD88. Plasma PK and PD translated as expected in humans with both dose levels showing dose-dependent degradation of IRAK4, Ikaros and Aiolos in PBMC, with up to 95/100% knockdown of Ikaros/Aiolos and 40% knockdown of IRAK4 at the second dose level. Serial tumor biopsies at Cycle 3/Day 4 in the patient treated at DL1 showed comparable knockdown of Ikaros/Aiolos and IRAK4 as in plasma. There were no dose-limiting toxicities or treatment-related serious adverse events and no neutropenia observed in the two patient cohorts.

The Phase 1a dose escalation portion of the trial is ongoing, recruiting a broad population of B cell lymphoma patients. Kymera will provide a clinical update focused on PK/PD and safety at the ICML meeting in June and, as previously announced, intends to present data evaluating anti-tumor activity in the target patient population later this year.

More information on the Phase 1 study can be found at www.clinicaltrials.gov, identifier NCT05233033.

MDM2 Degrader Program (KT-253)

KT-253 targets MDM2, the crucial regulator of the most common tumor suppressor, p53. p53 remains intact (wild type) in close to 50% of cancers, meaning that it retains its ability to modulate cancer cell growth. While small molecule inhibitors have been developed to stabilize and upregulate p53 expression, they induce a feedback loop that increases MDM2 protein levels, which can repress p53 and limit their efficacy. In preclinical studies, KT-253 has demonstrated the ability to overcome the MDM2 feedback loop and rapidly induce cancer cell death, even with brief exposures. This may also enable an improved therapeutic index, resulting in a superior efficacy/safety profile.

The Phase 1 study initiated in March will evaluate the safety, tolerability, pharmacokinetics/pharmacodynamics, and clinical activity of KT-253 in patients with relapsed or refractory high grade myeloid malignancies, including acute myeloid leukemia (AML), acute lymphocytic leukemia (ALL), lymphoma and solid tumors. Patients in the KT-253 Phase 1a dose escalation study will receive IV doses of KT-253 administered once every 3 weeks. The open-label study is intended to identify the recommended Phase 2 dose for KT-253, and is comprised of two arms, with ascending doses of KT-253 in each arm. The first arm will consist of patients with lymphomas and advanced solid tumors and the second arm will consist of patients with high grade myeloid malignancies and ALL.

More information on the Phase 1 study can be found at www.clinicaltrials.gov, identifier NCT05775406.

Platform and Discovery Programs

Kymera is leveraging the Company’s proprietary E3 Ligase Whole-Body Atlas, including the differential expression profile of known E3 ligases, to pursue targets and indications that may benefit from tissue-restricted or -selective degradation. Kymera has also expanded the Company’s platform to develop a new generation of molecular glue degraders for high value undrugged and non-ligandable targets, exploiting a newly identified degron motif. Multiple programs are approaching development stage in 2023.

Conference Call

To access the conference call via phone, please dial +1 (833) 630-2127 (U.S.) or +1 (412) 317-1846 (International) and ask to join the Kymera Therapeutics call. A live webcast of the event will be available under “Events and Presentations” in the Investors section of the Company’s website at www.kymeratx.com. A replay of the webcast will be archived and available following the event.

First Quarter 2023 Financial Results

Collaboration Revenues: Collaboration revenues were $9.5 million for the first quarter of 2023 compared to $9.6 million the first quarter of 2022. Collaboration revenues include revenue from the Company’s Sanofi and Vertex collaborations.

Research and Development Expenses: Research and development expenses were $42.2 million for the first quarter of 2023 compared to $35.9 million for the first quarter of 2022. This increase was primarily due to increased expenses related to the investment in our STAT3, IRAKIMiD, and MDM2 clinical stage programs, platform and discovery programs, as well as an increase in occupancy and related costs due to continued growth in the research and development organization. Stock based compensation expenses included in R&D were $4.7 million for the first quarter of 2023 compared to $3.9 million for the first quarter of 2022.

General and Administrative Expenses: General and administrative expenses were $12.6 million for the first quarter of 2023 compared to $10.6 million for the first quarter of 2022. The increase was primarily due to increase in legal and professional service fees in support of the Company’s growth and an increase in personnel, facility, occupancy, and other expenses from an increase in headcount to support growth as a public company. Stock based compensation expenses included in G&A were $4.7 million for the first quarter of 2023 compared to $4.0 million for the first quarter of 2022.

Net Loss: Net loss was $40.9 million for the first quarter of 2023 compared to a net loss of $36.7 million for the first quarter of 2022.

Cash and Cash Equivalents: As of March 31, 2023, Kymera had approximately $516 million in cash, cash equivalents, and investments. Kymera expects that its cash and cash equivalents will provide the company with an anticipated cash runway into the second half of 2025 that is expected to take the company past the proof-of-concept Phase 2 data for KT-474, as well as early proof-of-concept data for KT-413, KT-333 and KT-253, while Kymera continues to identify opportunities to accelerate growth and expand its pipeline, technologies, and clinical indications.

About Kymera Therapeutics
Kymera is a biopharmaceutical company pioneering the field of targeted protein degradation, a transformative approach to address disease targets and pathways inaccessible with conventional therapeutics. Kymera’s Pegasus platform is a powerful drug discovery engine, advancing novel small molecule programs designed to harness the body’s innate protein recycling machinery to degrade dysregulated, disease-causing proteins. With a focus on undrugged nodes in validated pathways, Kymera is advancing a pipeline of novel therapeutic candidates designed to address the most promising targets and provide patients with more effective treatments. Kymera’s initial programs target IRAK4, IRAKIMiD, and STAT3 within the IL-1R/TLR or JAK/STAT pathways, and the MDM2 oncoprotein, providing the opportunity to treat patients with a broad range of immune-inflammatory diseases, hematologic malignancies, and solid tumors.

Founded in 2016, Kymera is headquartered in Watertown, Mass. Kymera has been named a “Fierce 15” company by Fierce Biotech and has been recognized by both the Boston Globe and the Boston Business Journal as one of Boston’s top workplaces. For more information about our people, science, and pipeline, please visit www.kymeratx.com or follow us on Twitter or LinkedIn.

About Kymera’s Pegasus™ Platform
Kymera’s Pegasus platform is a powerful drug discovery engine that enables the discovery of novel small molecule protein degrader medicines designed to target and disrupt specific protein complexes and full signaling cascades in disease, placing once elusive disease targets within reach. The key components of the platform combine Kymera’s broad understanding of the localization and expression levels of the hundreds of E3 ligases in the human body with the Company’s proprietary E3 Ligase Binders Toolbox, and advanced chemistry, biology, and computational capabilities to develop protein degraders that address significant, unmet medical needs.

Cautionary Note Regarding Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, implied and express statements by Kymera Therapeutics regarding its: strategy, business plans and objectives for the IRAK4, IRAKIMiD, STAT3 and MDM2 degrader programs; plans and timelines for the preclinical and clinical development of its product candidates, including the therapeutic potential, clinical benefits and safety thereof; expectations regarding timing, success and data announcements of current ongoing preclinical and clinical trials; the ability to initiate new clinical programs; and Kymera’s financial condition and expected cash runway into the second half of 2025. The words "may," “might,” "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," “expect,” "estimate," “seek,” "predict," “future,” "project," "potential," "continue," "target" and similar words or expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, risks associated with: the impact of COVID-19 on countries or regions in which we have operations or do business, as well as on the timing and anticipated results of our current and future preclinical studies and clinical trials, supply chain, strategy and future operations; the delay of any current and future preclinical studies or clinical trials or the development of Kymera Therapeutics' drug candidates; the risk that the results of current preclinical studies and clinical trials may not be predictive of future results in connection with current or future preclinical and clinical trials, including those for KT-474, KT-333, KT-413 and KT-253; Kymera Therapeutics' ability to successfully demonstrate the safety and efficacy of its drug candidates; the timing and outcome of the Kymera Therapeutics' planned interactions with regulatory authorities; obtaining, maintaining and protecting its intellectual property; and Kymera Therapeutics' relationships with its existing and future collaboration partners. These and other risks and uncertainties are described in greater detail in the section entitled "Risk Factors" in the Annual Report on Form 10-K for the year ended December 31, 2022 filed on February 23, 2023, as well as discussions of potential risks, uncertainties, and other important factors in Kymera Therapeutics' subsequent filings with the Securities and Exchange Commission. In addition, any forward-looking statements represent Kymera Therapeutics' views only as of today and should not be relied upon as representing its views as of any subsequent date. Kymera Therapeutics explicitly disclaims any obligation to update any forward-looking statements. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements.

KYMERA THERAPEUTICS, INC.

Consolidated Balance Sheets
(In thousands, except share and per share amounts)
(Unaudited)

	March 31, 2023	December 31, 2022
Assets		
Cash, cash equivalents and marketable securities	$ 515,894	$ 559,494
Property and equipment, net	17,432	13,334
Right-of-use assets, operating lease	56,604	8,909
Other assets	23,975	21,397
Total assets	$ 613,905	$ 603,134
Liabilities and Stockholders' Equity		
Deferred revenue	$ 57,114	$ 63,260
Operating lease liabilities	66,429	14,681
Other liabilities	28,357	35,042
Total liabilities	151,900	112,983
Total stockholders' equity	462,005	490,151
Total liabilities and stockholders' equity	$ 613,905	$ 603,134

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

	Three Months Ended March 31,	
	2023	2022
Collaboration Revenue—from related parties	$ 9,466	$ 9,622
Operating expenses:		
Research and development	$ 42,227	$ 35,944
General and administrative	12,565	10,611
Total operating expenses	54,792	46,555
Loss from operations	(45,326)	(36,933)
Other income (expense):		
Interest and other income	4,453	290
Interest and other expense	(55)	(41)
Total other income	4,398	249
Net loss attributable to common stockholders	$ (40,928)	$ (36,684)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.70)	$ (0.71)
Weighted average common stocks outstanding, basic and diluted	58,187,038	51,651,125

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