Geron Corporation Reports First Quarter 2021 Financial Results and Recent Highlights

5/10/2021

IMerge Phase 3 Clinical Trial in Myelodysplastic Syndromes 75% Enrolled and On Track to Complete Enrollment in Second Half of 2021

Two Abstracts Accepted by European Hematology Association for 2021 Virtual Congress

Conference Call Scheduled for 4:30 p.m. ET Today

FOSTER CITY, Calif.--(BUSINESS WIRE)-- Geron Corporation (Nasdaq: GERN), a late-stage clinical biopharmaceutical company developing a first-in-class telomerase inhibitor, imetelstat, to treat hematologic myeloid malignancies, today reported financial results for the first quarter ended March 31, 2021, as well as company highlights and upcoming events. As of March 31, 2021, the Company had $244.7 million in cash and marketable securities, which is expected to fund operations until the end of 2022.

“We have worked diligently over the past quarter to advance our two Phase 3 clinical trials with registrational intent, and we remain laser focused on improving outcomes for patients and delivering significant value to our shareholders,” said John A. Scarlett, M.D., Geron’s Chairman and Chief Executive Officer.

“Completing 75% of the planned enrollment in our MDS trial coupled with the recent dosing of the first patient in our MF trial indicate the continued progress we are making in our two Phase 3 clinical trials for imetelstat,” said Aleksandra Rizo, M.D., Ph.D., Geron’s Chief Medical Officer. “We continue to have confidence in imetelstat’s differentiating clinical benefits seen throughout the course of its development, including strong evidence of disease-modifying activity. We’re excited to have another opportunity to highlight imetelstat’s strong data profile through the two abstracts accepted for presentation at the upcoming European Hematology Association meeting. We look forward to achieving top-line results from our IMerge Phase 3 study and the promising path ahead for imetelstat.”

Dr. Scarlett concluded, “We are excited about the progress we are making to bring this important drug to patients. We are planning for Geron to become a commercial company in 2023 with the potential launch of imetelstat in

lower risk MDS. The markets for both lower risk MDS and refractory MF are highly attractive. We continue to make preparations and manage our cash appropriately to support the future buildout of our manufacturing and commercial infrastructure."

Company Highlights and Upcoming Data Presentations

Ongoing IMerge Phase 3 Clinical Trial in Myelodysplastic Syndromes (MDS)

Screening and enrollment for IMerge Phase 3 in MDS continued to progress in the first quarter. In early December 2020, the Company had completed 50% of the planned patient enrollment in IMerge Phase 3. As of the end of April 2021, enrollment has increased to 75%. The Company continues to expect the trial to be fully enrolled in the second half of 2021. Depending on the timing of full enrollment, the Company expects top-line results from IMerge Phase 3 to be available during the time period from the end of 2022 to the first half of 2023.

For further information about IMerge Phase 3, including enrollment criteria, locations, and current status, please visit **ClinicalTrials.gov/NCT02598661**.

Ongoing IMpactMF Phase 3 Clinical Trial in Refractory Myelofibrosis (MF)

On April 13, the Company announced that the first patient had been dosed in IMpactMF, the only Phase 3 clinical trial in MF with overall survival (OS) as a primary endpoint evaluating imetelstat, a first-in-class telomerase inhibitor. The Company plans to engage over 180 sites to participate in IMpactMF across North America, South America, Europe, Australia, and Asia. The Company continues to expect the interim analysis to occur in 2024 and the final analysis in 2025.

For further information about IMpactMF, including enrollment criteria, locations, and current status, please visit **ClinicalTrials.gov/NCT04576156**.

Upcoming Data Presentations

Two abstracts reporting new clinical data and analyses from the Phase 2 trials of imetelstat in lower risk MDS and refractory MF have been accepted for presentation at the European Hematology Association (EHA) Annual Congress meeting to be held virtually from June 9 – 17, 2021. Both of the abstracts will be published on May 12, 2021 at 16:00 CEST on **ehaweb.org**.

First Quarter 2021 Results

For the first quarter of 2021, the Company reported a net loss of $27.8 million, or $0.09 per share, compared to

$16.4 million, or $0.08 per share, for the same period in 2020.

Revenues for the first quarter of 2021 were $137,000 compared to $52,000 for the same period in 2020. Royalty revenues in 2021 and 2020 primarily reflect estimated royalties from sales of cell-based research products from the Company's divested stem cell assets. In connection with the divestiture of Geron's human embryonic stem cell assets, including intellectual property and proprietary technology, to Lineage Cell Therapeutics, Inc. (formerly BioTime, Inc., which acquired Asterias Biotherapeutics, Inc.) in 2013, Geron is entitled to receive royalties on sales from certain research or commercial products utilizing Geron's divested intellectual property.

Total operating expenses for the first quarter of 2021 were $28.6 million compared to $16.9 million for the same period in 2020. Research and development expenses for the first quarter of 2021 were $21.1 million compared to $10.8 million for the same period in 2020. The increase in research and development expenses in the first quarter of 2021 compared to the same period in 2020 primarily reflects increased clinical development costs associated with conducting two Phase 3 clinical trials, higher imetelstat manufacturing costs for producing validation batches at contract manufacturers to enable future production of imetelstat for clinical and commercial purposes and higher personnel-related costs for additional headcount. General and administrative expenses for the first quarter of 2021 were $7.5 million compared to $6.1 million for the same period in 2020. The increase in general and administrative expenses in the first quarter of 2021 compared to the same period in 2020 primarily reflects new costs in connection with pre-commercial activities, including modernizing the internal infrastructure to support a commercial launch, and higher legal costs.

Interest income for the first quarter of 2021 was $173,000 compared to $754,000 for the same period in 2020. The decrease in interest income in the first quarter of 2021 compared to the same period in 2020 primarily reflects lower yields on the Company's reduced marketable securities portfolio.

Interest expense for the first quarter of 2021 was $743,000 and reflects the Company's debt facility secured in September 2020 for up to $75 million. Currently, $25.0 million has been drawn down under the facility.

Net other income for the first quarter of 2021 was $1.2 million compared to net other expense of $44,000 for the same period in 2020. During the first quarter of 2021, the Company sold all of its holdings in an equity investment resulting in a net realized gain of $1.2 million, including foreign currency translation adjustments.

2021 Financial Guidance Reaffirmed

For fiscal year 2021, the Company continues to expect its operating expense burn to range from $108 to $112 million, which includes costs for the two ongoing Phase 3 clinical trials; producing validation batches of imetelstat at contract manufacturers to enable future production of imetelstat for clinical and commercial purposes; and

preparatory activities for regulatory filings to enable drug approval and commercial readiness.

As of March 31, 2021, the Company had 63 employees. The Company plans to grow to a total of approximately 80 to 85 employees by year-end 2021, of which the majority will be development and manufacturing personnel.

Conference Call

The Company will host a conference call today, May 10, 2021 at 4:30 p.m. ET to review its first quarter financial results and provide an update on the ongoing imetelstat Phase 3 clinical trials, IMerge in MDS and IMpactMF in MF.

A live, listen-only webcast will be available on the Company's website at **www.geron.com/investors/events**. An archive of the webcast will be available on the Company's website for 30 days.

Participants may access the conference call live via telephone by pre-registering online using the following link, **http://www.directeventreg.com/registration/event/2456438**. Upon registration, a phone number, Direct Event Passcode and unique Registrant ID will be sent via email. This information will be needed in order to enter the conference call. Participants are advised to pre-register at least 10 minutes prior to joining the call.

About Imetelstat

Imetelstat is a novel, first-in-class telomerase inhibitor exclusively owned by Geron and being developed in hematologic myeloid malignancies. Data from Phase 2 clinical trials provide strong evidence that imetelstat targets telomerase to inhibit the uncontrolled proliferation of malignant stem and progenitor cells in hematologic myeloid malignancies resulting in malignant cell apoptosis and potential disease-modifying activity. Imetelstat has been granted Fast Track designation by the United States Food and Drug Administration for both the treatment of patients with non-del(5q) lower risk MDS who are refractory or resistant to an erythropoiesis-stimulating agent and for patients with Intermediate-2 or High-risk MF whose disease has relapsed after or is refractory to janus kinase (JAK) inhibitor treatment.

About IMerge Phase 3

IMerge Phase 3 is a double-blind, randomized, placebo-controlled Phase 3 clinical trial with registrational intent. The trial is designed to enroll approximately 170 transfusion dependent patients with Low or Intermediate-1 risk myelodysplastic syndromes (MDS), also referred to as lower risk MDS, who have relapsed after or are refractory to prior treatment with an erythropoiesis stimulating agent (ESA). The primary endpoint is the rate of red blood cell (RBC) transfusion independence (TI) for any consecutive period of eight weeks or longer, or 8-week RBC-TI rate. Key secondary endpoints include the rate of RBC-TI lasting at least 24 weeks, or 24-week RBC-TI rate, and the rate of

hematologic improvement-erythroid (HI-E), defined as a reduction of at least four units of RBC transfusions over eight weeks compared with the prior RBC transfusion burden.

IMerge Phase 3 is currently enrolling patients. For further information about IMerge Phase 3, including enrollment criteria, locations and current status, visit **ClinicalTrials.gov/NCT02598661**.

About IMpactMF

IMpactMF is an open label, randomized, controlled Phase 3 clinical trial with registrational intent. The trial is designed to enroll approximately 320 patients with Intermediate-2 or High-risk myelofibrosis who are refractory to prior treatment with a JAK inhibitor, also referred to as refractory MF. Patients will be randomized to receive either imetelstat or best available therapy. The primary endpoint is overall survival (OS). Key secondary endpoints include symptom response, spleen response, progression free survival, complete response, partial response, clinical improvement, duration of response, safety, pharmacokinetics, and patient reported outcomes.

IMpactMF is currently enrolling patients. For further information about IMpactMF, including enrollment criteria, locations and current status, visit **ClinicalTrials.gov/NCT04576156**.

About Geron

Geron is a late-stage clinical biopharmaceutical company focused on the development and potential commercialization of a first-in-class telomerase inhibitor, imetelstat, in hematologic myeloid malignancies. The Company currently is conducting two Phase 3 clinical trials: IMerge in lower risk myelodysplastic syndromes and IMpactMF in refractory myelofibrosis. For more information about Geron, visit **www.geron.com**.

Use of Forward-Looking Statements

Except for the historical information contained herein, this press release contains forward-looking statements made pursuant to the “safe harbor” provisions of the Private Securities Litigation Reform Act of 1995. Investors are cautioned that such statements, include, without limitation, those regarding: (i) that Geron’s two Phase 3 trials have registrational intent; (ii) that imetelstat has shown strong evidence of disease-modifying activity, meaning that imetelstat has the potential to demonstrate disease-modifying activity in patients; (iii) that Geron plans to engage over 180 sites for IMpactMF; (iv) that Geron plans to become a commercial company in 2023 with the potential launch of imetelstat in lower risk MDS; (v) that Geron expects IMerge Phase 3 to be fully enrolled in the second half of 2021; (vi) that Geron expects top-line results for IMerge Phase 3 to be available during the time period from the end of 2022 to the first half of 2023; (vii) that under current planning assumptions for IMpactMF, Geron expects to conduct an interim analysis in 2024 and a final analysis in 2025; (viii) that Geron’s 2021 operating expense burn will

range from $108 to $112 million; (ix) that Geron expects to grow to 80-85 employees in 2021; and (x) other statements that are not historical facts, constitute forward-looking statements. These forward-looking statements involve risks and uncertainties that can cause actual results to differ materially from those in such forward-looking statements. These risks and uncertainties, include, without limitation, risks and uncertainties related to: (a) whether the current or evolving effects of the COVID-19 pandemic and resulting global economic and financial disruptions will materially and adversely impact Geron's business and business prospects, its financial condition and the future of imetelstat; (b) whether Geron overcomes all of the potential delays and other adverse impacts caused by the current or evolving effects of the COVID-19 pandemic, and overcomes all the enrollment, clinical, safety, efficacy, technical, scientific, intellectual property, manufacturing and regulatory challenges in order to meet the expected timelines and planned milestones in (iii), (iv), (v), (vi) and (vii) above; (c) whether regulatory authorities permit the further development of imetelstat on a timely basis, or at all, without any clinical holds; (d) whether imetelstat is demonstrated to be safe and efficacious in IMerge Phase 3 and IMpactMF to enable regulatory approval; (e) whether any future efficacy or safety results may cause the benefit-risk profile of imetelstat to become unacceptable; (f) whether imetelstat actually demonstrates disease-modifying activity in patients; (g) that Geron will need to raise substantial capital in order to complete the development and commercialization of imetelstat, including to meet all of the expected timelines and planned milestones in (iii), (iv), (v), (vi) and (vii) above; (h) whether regulatory authorities require an additional clinical trial for approval even if IMerge Phase 3 or IMpactMF meet their respective primary endpoint(s); (i) whether there are failures or delays in manufacturing or supplying sufficient quantities of imetelstat or other clinical trial materials in a timely manner, whether due to the current or evolving effects of the COVID-19 pandemic or otherwise; (j) whether imetelstat is able to maintain patent protection and have freedom to operate; (k) whether there are cost overruns in 2021 due to the current or evolving effects of the COVID-19 pandemic or otherwise; (l) whether Geron can accurately project the timing of, or attain complete enrollment in IMerge Phase 3 or IMpactMF, whether due to the current or evolving effects of the COVID-19 pandemic or otherwise; and (m) whether Geron is able to enroll IMerge Phase 3 and IMpactMF at a pace that would enable meeting the timelines in (iv), (v), (vi) and (vii) above. Additional information on the above risks and uncertainties and additional risks, uncertainties and factors that could cause actual results to differ materially from those in the forward-looking statements are contained in Geron's filings and periodic reports filed with the Securities and Exchange Commission under the heading "Risk Factors" and elsewhere in such filings and reports, including Geron's quarterly report on Form 10-Q for the quarter ended March 31, 2021 and future filings and reports by Geron. Undue reliance should not be placed on forward-looking statements, which speak only as of the date they are made, and the facts and assumptions underlying the forward-looking statements may change. Except as required by law, Geron disclaims any obligation to update these forward-looking statements to reflect future information, events or circumstances.

Financial table follows.

GERON CORPORATION
CONDENSED STATEMENTS OF OPERATIONS

(In thousands, except share and per share data)	UNAUDITED Three Months Ended March 31, 2021	2020
Revenues:		
License fees and royalties	$ 137	$ 52
Operating expenses:		
Research and development	21,113	10,802
General and administrative	7,478	6,120
Total operating expenses	28,591	16,922
Loss from operations	(28,454)	(16,870)
Interest income	173	754
Interest expense	(743)	—
Change in fair value of equity investment	—	(195)
Other income and expense, net	1,200	(44)
Net loss	$ (27,824)	$ (16,355)
Basic and diluted net loss per share:		
Net loss per share	$ (0.09)	$ (0.08)
Shares used in computing net loss per share	323,638,696	200,222,092

CONDENSED BALANCE SHEETS

(In thousands)	March 31, 2021 (Unaudited)	December 31, 2020 (Note 1)
Current assets:		
Cash, cash equivalents and restricted cash	$ 31,900	$ 10,288
Current marketable securities	179,490	186,350
Other current assets	3,874	3,219
Total current assets	215,264	199,857
Noncurrent marketable securities	33,289	63,387
Property and equipment, net	620	658
Deposits and other assets	9,435	6,826
	$ 258,608	$ 270,728
Current liabilities	$ 28,552	$ 30,940
Noncurrent liabilities	28,894	28,841
Stockholders' equity	201,162	210,947
	$ 258,608	$ 270,728

Note 1: Derived from audited financial statements included in the Company's annual report on Form 10-K for the year ended December 31, 2020.

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Source: Geron Corporation