Geron Corporation Reports Greater Than 90% Enrollment in IMerge Phase 3 and Expected Top-Line Results Accelerated to First Quarter of 2023

8/16/2021

Completion of Enrollment in IMerge Phase 3 Expected in the Fourth Quarter of 2021

Investor Day Planned for November

Second Quarter and Year to Date 2021 Financial Results Also Reported

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, today reported updates on the IMerge Phase 3 trial in lower risk MDS and financial results for the second quarter ended June 30, 2021. The Company will host a conference call today at 4:30 p.m. ET to discuss these updates and current events. As of June 30, 2021, the Company had $239.1 million in cash and marketable securities. These financial resources, combined with expected future non-dilutive funding under the current debt facility, are expected to fund operations through the end of the first quarter of 2023.

“We are pleased with the achievement of 91% of the planned enrollment in IMerge Phase 3 and expect the trial to be fully enrolled in the fourth quarter of 2021. In addition, the expected timing for top-line results in IMerge Phase 3 has been accelerated by three months to the first quarter of 2023,” said John A. Scarlett, M.D., Chairman and Chief Executive Officer. “By confirming the results from IMerge Phase 2 in the current IMerge Phase 3, including the depth, breadth and durability of transfusion independence, as well as the potential for disease modification, we expect imetelstat to be a highly differentiated product in lower risk MDS in comparison to drugs currently approved or in development today. We look forward to bringing this innovative and important drug to lower risk MDS patients, for whom there remain limited treatment options.”

Phase 3 Clinical Development

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

As of August 12, 2021, the Company had achieved 91% of the planned enrollment in IMerge Phase 3. The Company expects the trial to be fully enrolled in the fourth quarter of 2021. In July 2021, a regularly scheduled Independent Data Monitoring Committee (IDMC) meeting was held, and the IDMC recommended that the trial continue without modification.

The significantly longer enrollment period caused by the COVID-19 pandemic has enabled a longer follow-up period than previously projected. As a result, the Company determined that the clinical cut-off date for the primary analysis could occur three months earlier than originally planned, which the Company expects will still provide a sufficiently mature data set to assess the benefit-risk profile of imetelstat. The Company has shortened the follow-up period after the last patient has been enrolled from 15 months to 12 months to enable the earlier clinical cut-off date for the primary analysis. With the revised 12-month follow-up period for the primary analysis, the Company now projects that top-line results from IMerge Phase 3 will be available in the first quarter 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)

The Company plans to engage over 180 sites to participate in IMpactMF across North America, South America, Europe, Australia, and Asia, of which 55 sites are currently open for enrollment. In the second quarter of 2021, the first patient was dosed in IMpactMF. The Company continues to expect the interim analysis to occur in 2024 and the final analysis in 2025.

As the only MF Phase 3 trial with overall survival (OS) as the primary endpoint, the Company expects that success in this trial would provide unequivocal proof of clinical benefit for patients, as well as further evidence of disease-modifying activity with imetelstat treatment.

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

Investor Day

In November 2021, Geron plans to host a virtual event for investors and analysts at which management and key opinion leaders will discuss the following topics:

- Imetelstat's potential for disease modification in LR MDS and refractory MF;
- Expected path to commercializing imetelstat;

- Expansion of imetelstat development plans, including new studies in additional indications; and
- An early discovery program in second generation telomerase inhibitors.

Recently Reported Data in June 2021

Poster Presentations at EHA2021 Virtual Congress

In June 2021, two poster presentations of imetelstat Phase 2 data were made at the European Hematology Association (EHA) Virtual Congress. These presentations, available on Geron's website, further support imetelstat's potentially differentiated approach to inhibiting telomerase activity to target the malignant stem and progenitor cells in the bone marrow responsible for the underlying hematologic myeloid malignancies.

The first poster presented new data and analyses of the clinical efficacy of imetelstat in molecularly defined subtypes based on cytogenetic and mutation profiles for patients in the IMerge Phase 2 clinical trial in lower risk MDS. As reported at previous EHA meetings, meaningful and durable transfusion independence was observed in patients from IMerge Phase 2, including transfusion-free periods greater than one year, as well as substantial increases in hemoglobin. The new poster presentation reported clinical responses across different cytogenetic and molecularly defined categories, and these responses were independent of mutation status or number of mutations. These data support the unique telomerase inhibition mechanism of action of imetelstat and the potential to target the malignant stem and progenitor cells of the underlying disease. The Company is exploring these observations further in the ongoing IMerge Phase 3.

The second poster at EHA presented new analyses of safety data from the IMbark Phase 2 trial in MF and the IMerge Phase 2 trial in lower risk MDS to understand the characteristics of hematologic and non-hematologic adverse events. These analyses highlighted that the imetelstat-related cytopenias are short, reversable and with limited clinical consequence when managed with the dose modification guidelines in the protocols.

Publication of IMbark Phase 2 Data in Journal of Clinical Oncology

Efficacy, safety and biomarker results from the IMbark Phase 2 clinical trial were published in the Journal of Clinical Oncology in a paper entitled "Randomized, Single-Blind, Multicenter Phase II Study of Two Doses of Imetelstat in Relapsed or Refractory Myelofibrosis." The publication, which is available online, highlights the clinical benefits observed in the study, including symptom response and OS, as well as evidence of disease-modifying activity from biomarker and bone marrow fibrosis assessments.

The trial design for IMpactMF is intended to confirm the IMbark Phase 2 results and to enable imetelstat to be a potential treatment option for MF patients who no longer respond to currently approved JAK inhibitor therapies.

Currently, there is no approved drug for patients who fail or no longer respond to JAK inhibitor therapies, and median survival for such MF patients after discontinuation from ruxolitinib is only approximately 14 – 16 months, representing a significant unmet medical need.

Second Quarter and Year-to-Date 2021 Results

For the second quarter of 2021, the Company reported a net loss of $29.6 million, or $0.09 per share, compared to $15.8 million, or $0.06 per share, for the comparable 2020 period. Net loss for the first six months of 2021 was $57.4 million, or $0.18 per share, compared to $32.2 million, or $0.14 per share, for the comparable 2020 period.

Revenues for the three and six months ended June 30, 2021 were $107,000 and $244,000, respectively, compared to $43,000 and $95,000 for the comparable 2020 periods. 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 three and six months ended June 30, 2021 were $29.0 million and $57.6 million, respectively, compared to $16.8 million and $33.7 million for the comparable 2020 periods.

Research and development expenses for the three and six months ended June 30, 2021 were $21.9 million and $43.1 million, respectively, compared to $10.8 million and $21.6 million for the comparable 2020 periods. The increase in research and development expenses for the three and six months ended June 30, 2021, compared to the same periods 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 three and six months ended June 30, 2021 were $7.1 million and $14.5 million, respectively, compared to $6.0 million and $12.1 million for the comparable 2020 periods. The increase in general and administrative expenses for the three and six months ended June 30, 2021, compared to the same periods 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 three and six months ended June 30, 2021 was $136,000 and $309,000, respectively, compared to $475,000 and $1.2 million for the comparable 2020 periods. The decrease in interest income for the

three and six months ended June 30, 2021, compared to the same periods in 2020, primarily reflects lower yields on the Company's marketable securities portfolio.

Interest expense for the three and six months ended June 30, 2021 was $804,000 and $1.5 million, respectively and reflects the Company's debt facility secured in September 2020 for up to $75 million. In June 2021, the Company completed a drawdown of $10.0 million in accordance with the loan agreement. Currently, a total of $35.0 million has been drawn down under the facility.

Financial Resources

Previously, the Company provided guidance that its financial resources were sufficient to fund its operations through the end of 2022. As of June 30, 2021, the Company had $239.1 million in cash and marketable securities. These financial resources, combined with expected future non-dilutive funding under the current debt facility, are now expected to fund operations through the end of the first quarter of 2023.

As of June 30, 2021, the Company had 68 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

Geron will host a conference call at 4:30 p.m. ET on Monday, August 16, 2021 to provide an update on the ongoing imetelstat Phase 3 clinical trials, IMerge in MDS and IMpactMF in MF, as well as discuss second quarter financial results.

To view the Company's slide presentation and listen to the conference call live via webcast, visit the Company's website at **www.geron.com/investors/events** at the time of the conference call. An archive of the webcast will also 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/5548255**. 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 expects IMerge Phase 3 to be fully enrolled in the fourth quarter of 2021; (ii) that Geron expects top-line results for IMerge Phase 3 to be available in the first quarter of 2023; (iii) that Geron expects to conduct an interim analysis for IMpactMF in 2024 and a final analysis in 2025; (iv) that Geron expects its financial resources, with the expected non-dilutive funding under the current debt facility, to fund operations through the end of the first quarter of 2023; (v) that Geron expects to grow to 80-85 employees in 2021; (vi) that Geron plans to engage over 180 sites for IMpactMF; (vii) that IMerge Phase 3 and IMpactMF have registrational intent; (viii) that imetelstat has the potential to demonstrate disease-modifying activity in patients and to target the malignant stem and progenitor cells of the underlying disease; (ix) that the Company expects imetelstat to be a highly differentiated product in the lower risk MDS commercial marketplace; (x) that the Company expects that the shortened 12-month follow-up period will still provide a sufficiently mature data set to assess the benefit-risk profile of imetelstat; and (xi) 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 have the financial resources for, and to meet the expected timelines and planned milestones in (i) through (vi) 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 and the ability to target the malignant stem and progenitor cells of the underlying disease; (g) that Geron may seek 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 (i) through (vi) above; (h) whether regulatory authorities require an additional clinical trial for approval even if IMerge Phase 3 or IMpactMF meet their respective primary endpoints; (i) whether there are failures or delays in manufacturing or supplying sufficient quantities of imetelstat

or other clinical trial materials in a timely manner; (j) whether imetelstat is able to maintain patent protection and have freedom to operate; (k) whether the shortened follow-up period of 12 months for the IMerge Phase 3 primary analysis results in not obtaining sufficient data to demonstrate safety and efficacy, including transfusion independence, of imetelstat to support any application for regulatory approval; (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 the financial resources for, and to meet the expected timelines and planned milestones in (i) through (vi) 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 June 30, 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
(UNAUDITED)

(In thousands, except share and per share data)	Three Months Ended June 30, 2021	Three Months Ended June 30, 2020	Six Months Ended June 30, 2021	Six Months Ended June 30, 2020
Revenues:				
License fees and royalties	$ 107	$ 43	$ 244	$ 95
Operating expenses:				
Research and development	21,937	10,845	43,050	21,647
General and administrative	7,059	5,960	14,537	12,080
Total operating expenses	28,996	16,805	57,587	33,727
Loss from operations	(28,889)	(16,762)	(57,343)	(33,632)
Interest income	136	475	309	1,229
Interest expense	(804)	—	(1,547)	—
Change in fair value of equity investment.	—	422	—	227
Other income and expense, net	(17)	41	1,183	(3)
Net loss	$ (29,574)	$ (15,824)	$ (57,398)	$ (32,179)
Basic and diluted net loss per share:				
Net loss per share	$ (0.09)	$ (0.06)	$ (0.18)	$ (0.14)
Shares used in computing net loss per share	327,026,907	246,966,143	325,342,161	223,594,118

CONDENSED BALANCE SHEETS

(In thousands)	June 30, 2021 (Unaudited)	December 31, 2020 (Note 1)
Current assets:		
Cash, cash equivalents and restricted cash	$ 57,645	$ 10,288
Current marketable securities	140,959	186,350
Other current assets	3,158	3,219
Total current assets	201,762	199,857
Noncurrent marketable securities	40,521	63,387
Property and equipment, net	590	658
Other assets	9,302	6,826
	$ 252,175	$ 270,728
Current liabilities	$ 37,013	$ 30,940
Noncurrent liabilities	38,956	28,841
Stockholders' equity	176,206	210,947
	$ 252,175	$ 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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