Geron Corporation Reports Fourth Quarter and Full Year 2020 Financial Results and Operational Highlights

3/11/2021

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 fourth quarter and year ended December 31, 2020. The Company ended fiscal year 2020 with $260 million in cash and marketable securities, which is expected to fund operations until the end of 2022.

“Geron’s vision is to be recognized as a leader in the treatment of hematologic malignancies by changing the course of these diseases and thereby improving and extending the lives of patients,” said John A. Scarlett, M.D., Chairman and Chief Executive Officer. “In 2020, we made important progress toward realizing that vision through two ongoing Phase 3 clinical trials, presentation of new data and analyses providing strong evidence of imetelstat’s disease-modifying potential that differentiates imetelstat from other treatments today, and raising the capital necessary to support future activities. With this momentum from 2020, in 2021, we plan to complete enrollment in IMerge Phase 3, advance site initiation and enrollment in IMpactMF, and begin activities to prepare for Geron’s first NDA filing and potential commercial launch. With a strong team in place and the financial resources to support these plans, we believe our vision can be attained.”

Dr. Scarlett added, “We are hopeful that clinical site operations will normalize in the next several months since vaccine distribution has commenced in many countries and the number of COVID-19 cases is declining. However, the fluid and dynamic nature of the pandemic continues to create uncertainty and unpredictability on our clinical trial activities. Taking into account these challenges and under current planning assumptions, we expect IMerge Phase 3 to be fully enrolled in the second half of 2021. Depending on the timing of full enrollment, we expect top-line results from IMerge Phase 3 to be available from the end of 2022 to the first half of 2023. For IMpactMF, under current planning assumptions, we expect the pace of enrollment to be slower and now project the event-driven analyses for the trial to occur in 2024 for the interim analysis and 2025 for the final analysis.”

Company Highlights and Upcoming Milestones

Ongoing Phase 3 Clinical Trials

IMerge in Lower Risk Myelodysplastic Syndromes (MDS)

In December 2020, 50% of the planned enrollment in IMerge was achieved and today, 65% have been enrolled. In the fourth quarter of 2020, the first meeting of the Independent Data Monitoring Committee (IDMC) was held, and the IDMC recommended that the trial continue without modification.

In the past few winter months, the resurgence of COVID-19 cases caused delays in clinical site openings, as well as patient screening and enrollment, and such delays may be ameliorated with broader vaccine distribution and other public health safety measures. With the current decline in the number of COVID-19 cases, the Company expects its trial operations to begin to normalize in the next several months. However, the pace at which any normalization may occur remains uncertain and unpredictable. Taking into account these dynamic and evolving circumstances, under current planning assumptions, the Company expects IMerge Phase 3 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 first half of 2023. To address the delays in enrollment, the Company continues to pursue enrollment boosting activities, including opening new sites, engaging clinical science liaisons and employing a social media campaign. Currently, 105 sites are open for enrollment, and the Company expects to open the remaining 15 additional planned sites over the next few months.

IMpactMF in Refractory Myelofibrosis (MF)

IMpactMF, the only Phase 3 clinical trial in MF with overall survival (OS) as a primary endpoint, opened for screening and enrollment in December 2020 with three clinical sites in the United States. However, as with IMerge Phase 3, COVID-19 has negatively impacted clinical trial activities. In addition, in 2020 a number of competing trials were initiated in MF and other oncology indications in the countries where IMpactMF is planned to be conducted. As a result of these factors, site personnel resources are constrained at many clinical sites, causing delays in site initiation activities. Although the Company has expanded the number of countries and sites planned to conduct the trial, the Company now expects IMpactMF to be fully enrolled in 2024. The Company currently plans to engage over 180 sites to participate in IMpactMF across North America, South America, Europe, Australia and Asia.

Under current planning assumptions around enrollment and median overall survival for each treatment arm, the Company expects to conduct the interim analysis in 2024 and the final analysis in 2025. The final analysis for OS is planned to be conducted after more than 50% of the patients enrolled in the trial have died. An interim analysis of OS is planned to be conducted after approximately 70% of the total projected number of events for the final

analysis have occurred. If the pre-specified, statistically significant difference in OS between the two treatment arms is met at the interim analysis, it is possible that data from the interim analysis could support a registration filing. Both the planned interim and final analyses are event-driven and could occur on different timelines than currently expected.

New Drug Application (NDA) and Commercial Readiness Activities in 2021

The Company has begun preparations for the future submission of an NDA for imetelstat in lower risk MDS. Assuming the results of IMerge Phase 3 are supportive, the Company plans to submit the completed NDA in 2023.

The Company is beginning pre-commercial activities, including building the internal infrastructure to support a commercial launch. Assuming approval of the NDA, the Company forecasts the commercial launch of imetelstat in lower risk MDS in the United States to be in 2024.

Presentations and Publications of Phase 2 Data and Analyses

More Mature Clinical Data from IMerge Phase 2 Continue to Differentiate Imetelstat in Lower Risk MDS

In October 2020, more mature data of 38 patients in IMerge Phase 2 were published in the Journal of Clinical Oncology (JCO) highlighting the durability of transfusion independence achievable with imetelstat treatment in the trial. Durability of transfusion independence continues to differentiate imetelstat with 29% (11/38) of patients being transfusion-free for more than one year, and a median duration of transfusion independence of 20 months. Such durability provides significant and meaningful clinical benefit to lower risk MDS patients given their chronic anemia. In addition, the JCO publication reported observations from the IMerge Phase 2 of depletion of cytogenetic abnormalities and reductions in key driver mutations for lower risk MDS which provide strong evidence of disease-modifying activity of imetelstat. These observations were further strengthened through the correlation of molecular data with clinical benefits of transfusion independence.

The data from the JCO publication were also reported in an oral presentation at the American Society of Hematology (ASH) Annual Meeting in December 2020. Further analyses of IMerge Phase 2 data are expected to be presented at medical conferences in 2021.

New Analyses of IMbark Phase 2 Data Support OS Outcome and Disease-Modifying Potential of Imetelstat

In December 2020, new analyses of IMbark Phase 2 data were reported in oral and poster presentations at the ASH Annual Meeting. These analyses described dose-related improvements in OS that were correlated to other clinical benefits, such as symptom response and spleen volume reduction, which support previously reported

improvement in OS for MF patients in the trial. Furthermore, (i) reductions in the variant allele frequency of key driver mutations in MF, indicating imetelstat targets the underlying malignant clone, and (ii) improvements in bone marrow fibrosis were correlated to improvement in OS, which provide further evidence of imetelstat's disease-modifying potential.

Fourth Quarter and Full Year 2020 Results

For the fourth quarter of 2020, the Company reported a net loss of $23.8 million, or $0.07 per share, compared to $29.1 million, or $0.15 per share, for the fourth quarter of 2019. Net loss for the full year of 2020 was $75.6 million, or $0.28 per share, compared to $68.5 million, or $0.36 per share, for the full year of 2019.

Revenues for the three and twelve months ended December 31, 2020 were $50,000 and $253,000, respectively, compared to $171,000 and $460,000 for the same periods in 2019. Revenues in 2020 and 2019 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 former intellectual property.

Total operating expenses for the three and twelve months ended December 31, 2020 were $23.3 million and $77.2 million, respectively, compared to $30.2 million and $73.0 million for the same periods in 2019. Research and development expenses for the three and twelve months ended December 31, 2020 were $16.2 million and $51.5 million, respectively, compared to $24.9 million and $52.1 million for the same periods in 2019. The overall decrease in research and development expenses, compared to the same periods in 2019, primarily reflects the net result of closing of the IMbark Phase 2 clinical trial, completion of the transition of the imetelstat program and reduced purchases of raw materials, drug substance and drug product, partially offset by increased costs for IMerge Phase 3 and start-up costs for IMpactMF. General and administrative expenses for the three and twelve months ended December 31, 2020 were $7.1 million and $25.7 million, respectively, compared to $5.3 million and $20.9 million, for the same periods in 2019. The overall increase in general and administrative expenses, compared to the same periods in 2019, primarily reflects increased personnel-related expenses for additional general and administrative headcount to support the development organization and higher legal costs.

Interest income for the three and twelve months ended December 31, 2020 was $243,000 and $1.8 million, respectively, compared to $925,000 and $4.2 million for the same periods in 2019. The overall decrease in interest income, compared to the same periods in 2019, primarily reflects lower yields on the Company's marketable securities portfolio due to declining interest rates.

Interest expense for the three and twelve months ended December 31, 2020 was $754,000 and $760,000, respectively. In September 2020, the Company secured a new debt facility for up to $75 million.

The Company ended the 2020 fiscal year with $260 million in cash and marketable securities, which the Company believes is sufficient for its operations until the end of 2022.

Projected 2021 Financial Guidance

For fiscal year 2021, the Company expects 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 NDA and commercial readiness.

As of December 31, 2020, the Company had 55 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 research and development personnel.

Conference Call

Geron will host a conference call at 4:30 p.m. ET on Thursday, March 11, 2021 to discuss fourth quarter and full year 2020 financial results and recent events.

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/3329959**. 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 imetelstat has potential disease-modifying activity; (ii) that Geron's current financial resources of $260 million in cash and marketable securities are expected to fund its operations until the end of 2022; (iii) that Geron plans to engage over 180 sites for IMpactMF; (iv) that Geron expects to submit the completed NDA for lower risk MDS in 2023, and assuming FDA approval of the NDA, forecasts a commercial launch of imetelstat in the United States in 2024; (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 will be available from the end of 2022 to first half of 2023; (vii) that the ten remaining additional IMerge Phase 3 sites will be open for screening and enrollment over the next few months; (viii) the possibility that data from the IMpactMF interim analysis could support a registration filing; (ix) that under current planning assumptions for IMpactMF, Geron projects and expects enrollment to be complete in 2024, to conduct an interim analysis in 2024 and a final analysis in 2025; (x) that Geron's 2021 operating expense burn will range from $108 to $112 million; (xi) that Geron expects to grow to 80-85 employees in 2021; (xii) that Geron expects to present further analyses of IMerge Phase 2 at medical conferences in 2021; and (xiii) 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), (vii) and (ix) 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 trials 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), (vi) and (ix) 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 IMpactMF at a pace that would enable an interim analysis in 2024 and a final analysis in 2025. 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 annual report on Form 10-K for the year ended December 31, 2020 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 December 31, 2020	Three Months Ended December 31, 2019	Year Ended December 31, 2020	Year Ended December 31, 2019
Revenues:				
License fees and royalties	$ 50	$ 171	$ 253	$ 460
Operating expenses:				
Research and development	16,228	24,923	51,488	52,072
General and administrative	7,088	5,256	25,678	20,893
Total operating expenses	23,316	30,179	77,166	72,965
Loss from operations	(23,266)	(30,008)	(76,913)	(72,505)
Interest income	243	925	1,828	4,221
Interest expense	(754)	—	(760)	—
Change in fair value of equity investment.	(49)	—	60	(195)
Other income and (expense), net	39	13	168	(69)
Net loss	$ (23,787)	$ (29,070)	$ (75,617)	$ (68,548)
Basic and diluted net loss per share:				
Net loss per share	$ (0.07)	$ (0.15)	$ (0.28)	$ (0.36)
Shares used in computing net loss per share	318,813,084	198,447,315	271,460,265	190,160,311

CONDENSED BALANCE SHEETS

(In thousands)	December 31, 2020	December 31, 2019
Current assets:		
Cash, cash equivalents and restricted cash	$ 10,288	$ 13,914

Current marketable securities	186,350	125,681
Other current assets	3,219	2,013
Total current assets	199,857	141,608
Noncurrent marketable securities	63,387	19,651
Property and equipment, net	658	408
Other assets	6,826	3,850
	$ 270,728	$ 165,517
Current liabilities	$ 30,940	$ 28,162
Noncurrent liabilities	28,841	2,200
Stockholders' equity	210,947	135,155
	$ 270,728	$ 165,517

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