Geron Corporation Reports Fourth Quarter and Full Year 2022 Financial Results and Upcoming Milestones

3/16/2023

Positive Phase 3 Top-Line Results in Lower Risk MDS Reported in January 2023

Planned 2023 Regulatory Submissions in the U.S. and EU On Track

Preparations for Potential Commercial Launch in U.S. Ongoing

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 malignancies, today reported business updates, upcoming milestones and financial results for the fourth quarter and year ended December 31, 2022.

“With positive top-line results having been reported for IMerge Phase 3, we now have a charted path toward several potentially significant regulatory and commercial catalysts, which we expect will further enhance the value of imetelstat. As the first step, we are focused on completing and submitting a U.S. New Drug Application (NDA) and a European Marketing Authorization Application (MAA) for imetelstat in lower risk MDS in 2023,” said John A. Scarlett, M.D., Chairman and Chief Executive Officer. “Also in 2023, we will be implementing many of the long-lead time operational items needed to prepare for potential commercial launch of imetelstat in lower risk MDS in the U.S., such as establishing key sales-related systems, engaging a third-party logistics provider, manufacturing sufficient commercial supply of drug for launch and beyond, and hiring deeply experienced commercial talent.”

Dr. Scarlett also noted, “On top of our efforts to advance imetelstat toward commercialization in lower risk MDS, we continue to make progress on recruiting and enrolling patients into IMpactMF, our imetelstat Phase 3 trial in relapsed/refractory MF. Reaching a sufficient number of events to enable an interim analysis readout from this trial in 2024 depends on sufficient enrollment, as well as the rate at which actual death events occur during the course of the trial. We expect to have a better view on timing of the interim analysis in the second half of this year.”

Dr. Scarlett added, “As a result of robust and compelling data from IMerge Phase 3, we believe there will be renewed attention on telomerase inhibition as an oncology approach. Thus, we have positioned our exploratory

programs in other hematologic malignancies to provide data over the next several years to add strategic value to the imetelstat franchise."

Financial Resources to Support Potential Commercial Launch of Imetelstat in Lower Risk Myelodysplastic Syndromes (MDS)

The Company ended 2022 with $173.1 million in cash and marketable securities. In January 2023, the Company closed an underwritten public offering of common stock and pre-funded warrant, plus the full exercise of the underwriters' option to purchase additional shares of common stock, for net cash proceeds of $213.3 million, after deducting the underwriting discount and other offering expenses. In addition, the Company received $59.8 million upon the cash exercise of outstanding warrants in January and February 2023.

Key Upcoming Milestones Expected

- Additional presentations at medical conferences and publication in peer-reviewed journal of data on imetelstat in lower risk MDS from IMerge Phase 3, including evidence of potential disease modification – throughout 2023.
- Complete submission of the NDA for imetelstat in lower risk MDS – in mid-2023.
- Complete submission of an MAA for imetelstat in lower risk MDS – in second half of 2023.
- Assuming NDA acceptance on a timely basis, FDA approval of the NDA and U.S. commercial launch – in first half of 2024.
- Assuming a 14 month review timeline, approval of the MAA and commercial launch in the EU – by the end of 2024.
- Interim analysis from IMpactMF Phase 3 trial in relapsed/refractory myelofibrosis (MF) – 2024.
- Significant life cycle management program readouts – 2023-2025.

Planned Next Steps for Imetelstat in Lower Risk MDS

Geron plans to present additional data from IMerge Phase 3 at medical meetings later this year. These potential presentations are expected to report data that may be indicative of the potential for disease modification with imetelstat, including exploring correlations of decreases in mutation burden and abnormal bone marrow cytogenetics with clinical responses; the results of patient reported outcomes (PRO) in the trial; hTERT and telomerase activity biomarker data and continued follow-up of patients for durability of transfusion independence. In addition, the Company plans to submit the IMerge Phase 3 data for publication in a peer-reviewed journal in 2023.

Imetelstat has been granted Fast Track designation by the U.S. Food and Drug Administration (FDA) for the

treatment of adult patients with transfusion dependent anemia due to Low or Intermediate-1 risk MDS that is not associated with del(5q) who are refractory or resistant to an erythroid stimulating agent (ESA). Based on that designation, Geron's request for a rolling submission of the NDA was granted, and the Company is submitting various modules of the NDA as they are completed. In January 2023, the Company submitted the module on non-clinical study reports.

Expected Interim Analysis in 2024 from IMpactMF in Relapsed/Refractory MF

IMpactMF, the only Phase 3 clinical trial in relapsed/refractory MF with overall survival (OS) as a primary endpoint, is planned to engage approximately 180 clinical sites across North America, South America, Europe, Australia and Asia to facilitate patient recruitment and enrollment into the trial.

Under current planning assumptions around enrollment and median overall survival for each treatment arm, the Company expects to conduct an interim analysis in 2024 after approximately 35% of the total planned enrollment in trial 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. The final analysis for OS is planned to be conducted after more than 50% of the patients enrolled in the trial have died. Both the planned interim and final analyses are enrollment as well as event-driven and could occur on different timelines than currently expected.

Exploratory Programs to Expand Imetelstat Potential

In August 2022, the first patient was dosed in IMproveMF, a company-sponsored Phase 1 study of imetelstat in combination with ruxolitinib in frontline MF patients. The primary objective of the first part of IMproveMF is to identify a recommended dosing regimen for further evaluation. Upon identification of a tolerable dosing regimen for the combination treatment of imetelstat and ruxolitinib, the second part of IMproveMF is planned to evaluate the efficacy and safety of that dosing regimen. Two of three clinical sites in the U.S. are currently open for enrollment for IMproveMF with the remaining U.S. clinical site expected to open for enrollment in 2023.

In addition, in collaboration with key opinion leaders with expertise in acute myeloid leukemia (AML), the Company is supporting IMpress, an investigator-led study in patients with higher risk MDS and relapsed/refractory AML who have been previously treated with a hypomethylating agent (HMA). The first site for this trial is planned to open in 2023.

In November 2022, early data was published from the preclinical program in lymphoid malignancies being conducted at MD Anderson Cancer Center. Based on these early results, the Company is continuing the collaboration to assess the potential therapeutic effect of imetelstat in lymphoid malignancies and expects further

data by the end of 2023.

Progress continues to be made in the discovery program intended to identify a potential lead next generation oral telomerase inhibitor. The Company expects one or more lead compounds may be selected to advance to the next step of discovery research by the end of 2023.

Fourth Quarter and Full Year 2022 Results

For the fourth quarter of 2022, the Company reported a net loss of $42.6 million, or $0.10 per share, compared to $32.0 million, or $0.10 per share, for the fourth quarter of 2021. Net loss for the full year of 2022 was $141.9 million, or $0.37 per share, compared to $116.1 million, or $0.35 per share, for the full year of 2021.

Revenues for the three and twelve months ended December 31, 2022 were $103,000 and $596,000, respectively, compared to $1.0 million and $1.4 million for the same periods in 2021. Revenues in 2022 and 2021 primarily reflect estimated royalties from sales of cell-based research products from the Company's divested stem cell assets. In connection with the 2013 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.), Geron is entitled to receive royalties on sales from certain research or commercial products utilizing Geron's former intellectual property. The decrease in revenues in 2022 compared to 2021 primary reflects retroactive royalties in 2021 of approximately $911,000 on product sales of cell-based research products.

Total operating expenses for the three and twelve months ended December 31, 2022 were $42.1 million and $139.1 million, respectively, compared to $32.0 million and $115.4 million for the same periods in 2021.

Research and development expenses for the three and twelve months ended December 31, 2022 were $28.2 million and $95.5 million, respectively, compared to $24.2 million and $85.7 million for the same periods in 2021. The increase in research and development expenses in 2022 compared to 2021 primarily reflects the net result of increased personnel-related expenses for additional headcount and higher consulting costs related to preparation for top-line results and regulatory submissions in lower risk MDS, partially offset by decreased manufacturing costs due to the timing of imetelstat manufacturing batches and reduced clinical trial expenses due to the expected attrition of patients in IMerge Phase 3.

General and administrative expenses for the three and twelve months ended December 31, 2022 were $13.8 million and $43.6 million, respectively, compared to $7.9 million and $29.7 million, for the same periods in 2021. The increase in general and administrative expenses in 2022 compared to 2021 primarily reflects the net result of increased costs for commercial preparatory activities; higher personnel-related expenses for additional headcount; and the Company's portion of settlement costs related to the class action and derivative lawsuits; partially offset by

lower consulting expenses.

Interest income for the three and twelve months ended December 31, 2022 was, $1.2 million and $2.5 million, respectively, compared to $106,000 and $527,000 for the same periods in 2021. The increase in interest income in 2022 compared to 2021 primarily reflects higher yields on the Company's marketable securities portfolio due to increasing interest rates.

Interest expense for the three and twelve months ended December 31, 2022 was $2.0 million and $6.9 million, respectively, compared to $1.1 million and $3.7 million for the same periods in 2021. The increase in interest expense in 2022 compared to 2021 primarily reflects rising interest rates. Currently, $50.0 million in principal debt is outstanding.

Projected 2023 Financial Guidance

For fiscal year 2023, under generally accepted accounting principles (GAAP), the Company expects total expenses in the range of approximately $210 million to $220 million, which includes non-cash items such as: stock-based compensation expense, amortization of debt discounts and issuance costs and depreciation and amortization. The Company expects non-GAAP total expenses for fiscal year 2023 to be in the range of approximately $200 million to $210 million. This guidance excludes estimated non-cash items such as: stock-based compensation expense, amortization of debt discounts and issuance costs, as well as depreciation and amortization.

The fiscal year 2023 financial guidance reflects costs to support planned regulatory submissions in 2023; continued support of ongoing clinical trials, IMerge Phase 3, IMpactMF, IMproveMF and IMpress, as well as preclinical studies in lymphoid malignancies and discovery research for a next generation telomerase inhibitor; manufacturing commercial inventory of imetelstat; preparations for potential U.S. commercial launch of imetelstat in lower risk MDS; projected increases in headcount and interest payments on outstanding debt.

As of December 31, 2022, the Company had 107 employees. The Company plans to grow to a total of approximately 150 to 160 employees by year-end 2023.

Conference Call

Geron will host a conference call at 4:30 p.m. ET on Thursday, March 16, 2023 to discuss business updates, expected upcoming milestones and fourth quarter and full year 2022 financial results.

A live webcast of the conference call and related presentation 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 webcast by registering online using the following link, **https://conferencingportals.com/event/SmvlMvWL**.

About Imetelstat

Imetelstat is a novel, first-in-class telomerase inhibitor exclusively owned by Geron and being developed in hematologic malignancies. Data from non-clinical studies and clinical trials of imetelstat provide strong evidence that imetelstat targets telomerase to inhibit the uncontrolled proliferation of malignant stem and progenitor cells in myeloid hematologic malignancies resulting in malignant cell apoptosis and potential disease-modifying activity. Imetelstat has been granted Fast Track designation by the U.S. Food and Drug Administration for both the treatment of adult patients with transfusion dependent anemia due to Low or Intermediate-1 risk MDS that is not associated with del(5q) who are refractory or resistant to an erythropoiesis stimulating agent, and for adult patients with Intermediate-2 or High-risk MF whose disease has relapsed after or is refractory to janus associated kinase (JAK) inhibitor treatment.

About IMerge Phase 3

The Phase 3 portion of the IMerge Phase 2/3 study is a double-blind, 2:1 randomized, placebo-controlled clinical trial to evaluate imetelstat in patients with IPSS Low or Intermediate-1 risk (lower risk) transfusion dependent MDS who were relapsed after, refractory to, or ineligible for, erythropoiesis stimulating agent (ESA) treatment, had not received prior treatment with either a HMA or lenalidomide and were non-del(5q). To be eligible for IMerge Phase 3, patients were required to be transfusion dependent, defined as requiring at least four units of packed red blood cells (RBCs), over an eight-week period during the 16 weeks prior to entry into the trial. The primary efficacy endpoint of IMerge Phase 3 is the rate of RBC-TI lasting at least eight weeks, defined as the proportion of patients without any RBC transfusion for at least eight consecutive weeks since entry to the trial (8-week TI). Key secondary endpoints include the rate of RBC-TI lasting at least 24 weeks (24-week TI), the duration of TI and the rate of hematologic improvement erythroid (HI-E), which is defined as a rise in hemoglobin of at least 1.5 g/dL above the pretreatment level for at least eight weeks or a reduction of at least four units of RBC transfusions over eight weeks compared with the prior RBC transfusion burden. A total of 178 patients were enrolled in IMerge Phase 3 across North America, Europe, Middle East and Asia.

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 (MF) 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 remission, partial remission, 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 biopharmaceutical company pursuing therapies with the potential to extend and enrich the lives of patients living with hematologic malignancies. The Company's investigational first-in-class telomerase inhibitor, imetelstat, harnesses Nobel Prize-winning science in a treatment that may alter the underlying drivers of disease. Geron currently has a Phase 3 clinical trial underway evaluating imetelstat in each of: (i) lower risk myelodysplastic syndromes (LR MDS), and (ii) relapsed/refractory myelofibrosis (MF). To learn more, visit **www.geron.com** or follow us on **LinkedIn**.

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 for IMerge Phase 3, Geron expects regulatory filings in the U.S. in mid-2023 and the EU in the second half of 2023, and a potential launch in lower risk MDS in the U.S. in the first half of 2024 and in the EU by the end of 2024; (ii) that for IMpactMF, Geron plans to engage approximately 180 clinical sites and expects to conduct an interim analysis in 2024 and a final analysis after more than 50% of the patients enrolled in the trial have died; (iii) that for the next generation telomerase inhibitor program, by the end of 2023 Geron expects to select one or more lead compounds to advance; (iv) 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; (v) that the Company expects the remaining IMproveMF U.S. clinical site to open in 2023; (vi) that the first site for IMpress is planned to open in 2023; (vii) that the Company expects further data from the preclinical program in lymphoid malignancies to be available by the end of 2023; (viii) that for fiscal year 2023, under GAAP the Company expects total expenses to be $210 to $220 million and non-GAAP total expenses to be $200 to $210 million; and (ix) 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/or geopolitical events 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/or geopolitical events, as well as 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, planned milestones and expenses in (i) to (iii) and (v) to (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 has demonstrated sufficient safety and efficacy in IMerge Phase 3 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 additional capital in order to complete the development and commercialization of imetelstat to meet all of the expected timelines and planned milestones in (i) to (iii) and (v) to (vii) above; (h) whether regulatory authorities require an additional imetelstat lower risk MDS clinical trial for approval, or post-approval; (i) whether there are failures or delays in manufacturing or supplying sufficient quantities of imetelstat or other clinical trial materials; (j) whether imetelstat is able to obtain and maintain the exclusivity terms and scopes provided by patent and patent term extensions, orphan drug, data and marketing and pediatric coverages and have freedom to operate; (k) whether the follow-up period of 12 months for the IMerge Phase 3 primary analysis is sufficient to demonstrate safety and efficacy, including transfusion independence, and obtain regulatory approval; (l) whether Geron can accurately project the timing of enrollment in IMpactMF or in its other or investigator-led clinical trials, whether due to the current or evolving effects of the COVID-19 pandemic, geopolitical events, or otherwise; (m) whether Geron is able to enroll its clinical trials at a pace that meets the expected timelines and planned milestones in (ii), (iii) and (v) to (vii) above; (n) that the IMpactMF interim analysis may not occur in 2024 due to insufficient enrollment or insufficient death events; and (o) for IMerge Phase 3, the FDA may require Geron to submit additional information or require advisory committee procedures that could cause a regulatory approval, if any, to be delayed. 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, 2022 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.

Non-GAAP Financial Measure

To supplement our financial results and guidance presented in accordance with GAAP, the Company is presenting non-GAAP total expenses, which excludes stock-based compensation expense, amortization of debt discounts and issuance costs and depreciation and amortization, from GAAP total expenses. The Company believes this non-GAAP financial measure, when considered together with other financial information prepared in accordance with GAAP, can enhance investors' and analysts' ability to meaningfully compare Geron's results from period to period and to projected forward-looking guidance, and to identify operating trends in Geron's business. The exclusion of non-cash items, such as stock-based compensation expense, amortization of debt discounts and issuance costs and depreciation and amortization, does not directly or immediately relate to the operational performance for the periods presented. This non-GAAP financial measure is in addition to, not a substitute for, or superior to, measures of financial performance prepared in accordance with GAAP. Geron encourages investors to carefully consider the Company's results under GAAP, as well as the supplemental non-GAAP financial information, to more fully understand Geron's business.

Financial table follows.

GERON CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except share and per share data)	(UNAUDITED) Three Months Ended December 31, 2022	2021	Year Ended December 31, 2022	2021
Revenues:				
License fees and royalties	$ 103	$ 1,040	$ 596	$ 1,393
Operating expenses:				
Research and development	28,210	24,150	95,518	85,727
General and administrative	13,844	7,872	43,628	29,665
Total operating expenses	42,054	32,022	139,146	115,392
Loss from operations	(41,951)	(30,982)	(138,550)	(113,999)
Interest income	1,235	106	2,529	527
Interest expense	(2,005)	(1,135)	(6,882)	(3,740)
Other income and (expense), net	86	(6)	1,002	1,100
Net loss	$ (42,635)	$ (32,017)	$ (141,901)	$ (116,112)
Basic and diluted net loss per share:				
Net loss per share	$ (0.10)	$ (0.10)	$ (0.37)	$ (0.35)
Shares used in computing net loss per share	408,143,890	330,833,782	380,784,846	327,631,814

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands)	December 31, 2022	December 31, 2021
Current assets:		
Cash, cash equivalents and restricted cash	$ 57,209	$ 35,235

Current marketable securities	115,901	148,851
Other current assets	7,136	3,120
Total current assets	180,246	187,206
Noncurrent marketable securities	—	28,651
Property and equipment, net	793	650
Other assets	9,536	9,527
	$ 190,575	$ 226,034
Current liabilities	$ 76,694	$ 45,521
Noncurrent liabilities	33,883	54,097
Stockholders' equity	79,998	126,416
	$ 190,575	$ 226,034

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Source: Geron Corporation