Geron Corporation Reports Business Highlights and Second Quarter 2023 Financial Results

August 3, 2023

Submitted U.S. New Drug Application in lower risk MDS in June 2023

Additional data and analyses from IMerge Phase 3 presented at medical meetings further strengthen value proposition and differentiation of imetelstat

Potential U.S. commercial launch in lower risk MDS expected in first half of 2024

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 highlights and financial results for the second quarter of 2023.

“We progressed our business significantly this quarter, as we evolve into a commercial company. Most notably, we submitted the first New Drug Application to the FDA for a telomerase inhibitor, a pioneering achievement that reflects our teams’ dedication to ground-breaking and innovative drug development,” said John A. Scarlett, M.D., Chairman and Chief Executive Officer. “Importantly, new data and analyses from IMerge Phase 3 presented at ASCO and EHA further strengthen the value proposition of imetelstat by highlighting differentiated attributes of the drug, such as unprecedented continuous durable transfusion independence, responses across subgroups, patient-reported outcomes of improved fatigue and strong evidence of disease-modifying activity.”

Dr. Scarlett also noted, “With approximately $400 million on the balance sheet as of the end of the quarter, we have the financial resources to not only fund a potential successful launch, but also to support the first year of launch.”

Business Highlights

- Submitted New Drug Application (NDA) to the FDA based on results from IMerge Phase 3 in lower risk myelodysplastic syndromes (MDS).
- Presented new data and analyses from IMerge Phase 3 at ASCO and EHA reporting robust durability of transfusion independence, evidence of disease-modifying activity and favorable fatigue patient-reported outcomes in imetelstat-treated lower risk MDS patients versus placebo.
- Initiated Expanded Access Protocol (EAP) in June 2023, making imetelstat available to clinicians and patients prior to potential FDA approval.
- Achieved >40% enrollment in IMpactMF, Geron’s Phase 3 trial of imetelstat in patients with myelofibrosis (MF) relapsed/refractory to JAK-inhibitors. Based on projected planning assumptions for enrollment and death rates in the trial, interim analysis is expected in the first half of 2025 and final analysis is expected in the first half of 2026.
- Dosed first patient in June 2023 in the investigator-led Phase 2 IMpress trial, evaluating imetelstat in patients with relapsed/refractory acute myeloid leukemia or higher risk MDS.
- Obtained and reported significant market research insights highlighting a potentially substantial commercial opportunity for imetelstat in lower risk MDS.
- Appointed Scott Samuels as Executive Vice President, Chief Legal Officer and Corporate Secretary, following Stephen Rosenfield’s retirement at the end of July 2023. Mr. Samuels recently served as the General Counsel of BeiGene, Ltd., where he built a large, global legal and compliance team, oversaw launches of three internally developed drug products in the U.S., Europe and China and development of a global healthcare compliance program, and led key strategic transactions with Amgen Inc., Novartis AG and Celgene Corporation (now Bristol Myers Squibb Inc.).

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

As of June 30, 2023, the Company had $400.2 million in cash, cash equivalents, restricted cash and marketable securities. In the second quarter of 2023, the Company received $17.8 million upon the cash exercise of outstanding warrants. As of June 30, 2023, warrants remaining outstanding are exercisable for potential future proceeds of $31.5 million. Based on the Company’s current operating plans and expectations regarding the timing of regulatory approval and commercialization of imetelstat in the United States (U.S.) in the first half of 2024, as well as revised guidance on interim and final analyses from IMpactMF, Geron projects that its existing financial resources plus potential future proceeds from remaining warrants outstanding and estimated revenues from commercialization will be sufficient to fund its projected operating requirements through the end of 2025.

Second Quarter 2023 Financial Results

Revenues for the three and six months ended June 30, 2023, were $29,000 and $50,000, respectively, compared to $73,000 and $196,000 for the comparable 2022 periods. Revenues in both years primarily reflect estimated royalties from sales of cell-based research products from the Company's divested stem cell assets.

Total operating expenses for the three and six months ended June 30, 2023, were $52.0 million and $92.1 million, respectively, compared to $28.0 million and $56.8 million for the comparable 2022 periods.

Research and development expenses for the three and six months ended June 30, 2023, were $35.5 million and $62.7 million, respectively, compared to $20.6 million and $42.7 million for the comparable 2022 periods. The increase in research and development expenses for the three and six months ended June 30, 2023, compared to the same periods in 2022, primarily reflects higher clinical trial costs related to supporting IMerge Phase 3 and IMpactMF, increased personnel-related expenses for additional headcount, higher consulting costs to support regulatory submissions and greater imetelstat manufacturing costs in preparation for potential commercialization in lower risk MDS.

General and administrative expenses for the three and six months ended June 30, 2023, were $16.5 million and $29.4 million, respectively, compared to $7.4 million and $14.1 million for the comparable 2022 periods. The increase in general and administrative expenses for the three and six months ended June 30, 2023, compared to the same periods in 2022, primarily reflects new costs for commercial preparatory activities and higher personnel-related expenses for additional headcount.

Interest income was $4.7 million and $8.6 million for the three and six months ended June 30, 2023, respectively, compared to $330,000 and $442,000 for the same periods in 2022. The increase in interest income for the three and six months ended June 30, 2023, compared to the same periods in 2022, primarily reflects higher yields on the Company's marketable securities as a result of rising interest rates, as well as a larger investment portfolio with the cash proceeds from the January 2023 public offering and warrant exercises in the first half of 2023.

Interest expense was $2.0 million and $3.9 million for the three and six months ended June 30, 2023, respectively, compared to $1.6 million and $3.1 million for the same periods in 2022. The increase in interest expense for the three and six months ended June 30, 2023, compared to the same periods in 2022, primarily reflects higher interest rates. Currently, the Company has $50.0 million in principal debt outstanding.

Projected 2023 Financial Guidance Reaffirmed

For fiscal year 2023, under generally accepted accounting principles (GAAP), the Company continues to expect 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 June 30, 2023, the Company had 133 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, August 3, 2023 to discuss business updates, and second quarter 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.

Inducement Grants Under Nasdaq Listing Rule 5635(c)(4)

In connection with the commencement of Mr. Samuels' employment with the Company on August 1, 2023, the Company granted him non-statutory stock options to purchase an aggregate of 1,600,000 shares of Geron common stock. Stock options representing an aggregate of 1,350,000 shares have a 10-year term and vest over four years, with 12.5% of the shares underlying the options vesting on the six-month anniversary of commencement of employment and the remaining shares vesting over the following 42 months in equal installments of whole shares, subject to continued employment with Geron through the applicable vesting dates. Stock options representing an aggregate of 250,000 shares have a 10-year term and vest in full upon achievement of a certain regulatory milestone, subject to continued employment with Geron through the applicable vesting date. All of the stock options were granted as a material inducement to employment in accordance with Nasdaq Listing Rule 5635(c)(4) and are subject

to the terms and conditions of the stock option agreements covering the grants and Geron's 2018 Inducement Award Plan, which was adopted December 14, 2018 and provides for the granting of stock options to new employees.

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 (FDA) 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. Geron submitted a New Drug Application (NDA) in the U.S. in June 2023 and expects to submit a Marketing Authorization Application (MAA) in the EU in the fourth quarter of 2023 in the lower risk MDS indication. Imetelstat is currently not approved by any regulatory authority.

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 red blood cell transfusion independence (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 under 2006 IWG criteria 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 Phase 3

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 relapsed after or refractory to prior treatment with a JAK inhibitor, also referred to as relapsed/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 IMpress Phase 2

IMpress Phase 2 (NCT05583552) is an open-label, single-arm, multicenter study aiming to enroll approximately 45 AML and higher risk MDS patients who are relapsed, refractory, or intolerant to HMAs. The objective of this trial is to evaluate the efficacy, in terms of hematologic improvement, of imetelstat in this patient population. The primary endpoint of this trial is overall response rate. The combined response assessment criteria for MDS and AML based on IWG 2018 criteria (MDS) and the criteria of the European LeukemiaNet (AML) will be used to define responders. Study sites will be located in Australia, France and Germany.

IMpress Phase 2 is an investigator-led study being led by The European Myelodysplastic Neoplasms Cooperative Group (EMSCO) and Australasian Leukaemia & Lymphoma Group (ALLG).

About Geron

Geron is a late-stage clinical 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 plans to submit a Marketing Authorization Application in the EU in the fourth quarter of 2023 and is preparing for a potential launch in lower risk MDS in the U.S. in the first half of 2024; (ii) that imetelstat has the potential to demonstrate disease-modifying activity in patients; (iii) that for fiscal year 2023,

under GAAP the Company expects total expenses to be in the range of $210 to $220 million, and non-GAAP total expenses to be in the range of $200 to $210 million; (iv) that the Company believes the approximately $400 million on the balance sheet at the end of the second quarter provides the financial resources to fund a potential successful launch of imetelstat in lower risk MDS and also to support the first year of launch; (v) that the IMpactMF interim analysis is expected in the first half of 2025 and the final analysis is expected in the first half of 2026; (vi) that there is a potentially substantial commercial opportunity for imetelstat in lower risk MDS; (vii) that IMpactMF has registrational intent; (viii) that Geron projects its existing financial resources plus potential future proceeds from remaining warrants outstanding and estimated revenues from commercialization will be sufficient to fund its projected operating requirements through the end of 2025; 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 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) and (v) 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, efficacy and clinical benefit in IMerge Phase 3 to enable regulatory approval; (e) whether any future safety or efficacy results of imetelstat treatment 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 the expected timelines, planned milestones and expenses in (i) and (v) 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 that impact a commercial launch in lower risk MDS or the continuation of the IMpactMF trial; (j) whether the follow-up period of 12 months for the IMerge Phase 3 primary analysis was sufficient to demonstrate safety and efficacy, including transfusion independence and clinical benefit, and obtain regulatory approval; (k) 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; and (l) that the timing in (v) above for IMpactMF may vary depending on actual enrollment and death rates in the trial. 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, 2023 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)	Three Months Ended June 30, 2023	Three Months Ended June 30, 2022	Six Months Ended June 30, 2023	Six Months Ended June 30, 2022
Revenues:				
Royalties	$ 29	$ 73	$ 50	$ 196
Operating expenses:				
Research and development	35,490	20,606	62,709	42,705

General and administrative	16,490	7,443	29,384	14,142
Total operating expenses	51,980	28,049	92,093	56,847
Loss from operations	(51,951)	(27,976)	(92,043)	(56,651)
Interest income	4,738	330	8,591	442
Interest expense	(2,003)	(1,581)	(3,925)	(3,060)
Other income and expense, net	(11)	1,110	28	1,054
Net loss	$ (49,227)	$ (28,117)	$ (87,349)	$ (58,215)
Basic and diluted net loss per share:				
Net loss per share	$ (0.09)	$ (0.07)	$ (0.16)	$ (0.16)
Shares used in computing net loss per share	547,280,946	403,868,713	553,772,809	368,166,148

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands)	**June 30, 2023 (Unaudited)**	**December 31, 2022 (Note 1)**
Current assets:		
Cash, cash equivalents and restricted cash	$ 57,438	$ 57,209
Current marketable securities	314,475	115,901
Other current assets	5,366	7,136
Total current assets	377,279	180,246
Noncurrent marketable securities	28,281	—
Property and equipment, net	1,147	793
Deposits and other assets	8,589	9,536
	$ 415,296	$ 190,575
Current liabilities	$ 72,569	$ 76,694
Noncurrent liabilities	44,300	33,883
Stockholders' equity	298,427	79,998
	$ 415,296	$ 190,575

Note 1: Derived from audited financial statements included in the Company's annual report on Form 10-K for the year ended December 31, 2022.

Aron Feingold
Investor and Media Relations
investor@geron.com
media@geron.com

Source: Geron Corporation