Geron Corporation Reports Fourth Quarter and Full Year 2019 Financial Results and 2020 Milestones

3/12/2020

Conference Call Scheduled for 4:30 p.m. ET today
MENLO PARK, Calif., March 12, 2020 (GLOBE NEWSWIRE) -- 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, 2019 as well as 2020 milestones. The Company ended fiscal year 2019 with $159.2 million in cash and marketable securities.

“2019 was a pivotal year for Geron as we completed the imetelstat program transition, assembled an impressive in-house team with a proven track record in drug development, and advanced imetelstat into late-stage development with the opening of our IMerge Phase 3 clinical trial in lower risk myelodysplastic syndromes,” said John A. Scarlett, M.D., Chairman and Chief Executive Officer. “In 2020, we plan to complete enrollment in IMerge, announce our decision regarding any potential late-stage development plans for myelofibrosis by mid-year, and commence a proof of concept study in additional hematologic myeloid malignancies. With a strong team in place to execute these plans, we look forward to further advancing the development of imetelstat.”

Planned 2020 Milestones

Geron is planning for the following milestones in 2020:

- Complete enrollment for the Phase 3 IMerge clinical trial in lower risk myelodysplastic syndromes (MDS) by the end of 2020

Recently reported Phase 2 data continued to indicate meaningful and durable transfusion independence potentially achievable with imetelstat treatment in high transfusion burdened patients (> 4 units per 8 weeks). The Phase 3 IMerge clinical trial was opened for enrollment in August 2019, and the first patient was dosed in October 2019. As of the end of February 2020, 63% of planned clinical sites were opened for enrollment. Topline results are expected by mid-year 2022.
• Determine a potential registration strategy for imetelstat in myelofibrosis (MF)

As a follow up to an End of Phase 2 meeting with the U.S. Food and Drug Administration (FDA) in the fourth quarter of 2019, Geron plans to submit Phase 3 trial design proposals to the FDA and, in the second quarter, discuss with the FDA a potential regulatory approval path for imetelstat in MF. Geron expects to announce its decision regarding any potential late-stage development plans for MF by mid-year 2020.

• Expect to present updated data and new analyses from the Phase 2 IMerge and IMbark clinical trials at future medical conferences

Geron expects to present more mature data from the Phase 2 IMerge clinical trial in lower risk MDS for the continued treatment and follow-up of remaining patients, including durability of transfusion independence.

Geron also expects to present new analyses from the IMbark Phase 2 clinical trial that correlate the median overall survival observed with other clinical endpoints from the trial. In addition, the new analyses are expected to provide further support for the potential improvement in overall survival as an indication of disease-modifying activity of imetelstat treatment in myelofibrosis.

• Commence a proof of concept study of imetelstat in additional hematologic myeloid malignancies

Geron plans to expand imetelstat’s clinical development program with a proof of concept study in Intermediate-2 or High-risk, or higher risk, MDS and acute myeloid leukemia (AML) and expects to commence such a study by the end of the fourth quarter 2020.

2019 Accomplishments

• Clinical – Advanced MDS development and presented data supporting potential late-stage development in MDS and MF

  • Presented updated data from the Phase 2 IMerge clinical trial at the European Hematology Association (EHA) meeting in June 2019 that reported continued meaningful and durable transfusion independence.
  • Commenced screening and enrollment for the Phase 3 IMerge clinical trial in August 2019 and dosed the first patient in October 2019.
  • Presented Phase 2 IMbark data at EHA corroborating potential survival benefit of imetelstat in relapsed/refractory MF patients when compared to closely matched patients from real-world data treated with best available therapy.
The FDA granted Fast Track designation to imetelstat for the treatment of adult patients with Intermediate-2 or High-risk relapsed/refractory MF in September 2019.

Conducted an End of Phase 2 meeting with the FDA in the fourth quarter of 2019.

Operational – Completed transition of imetelstat development program and enhanced development capabilities

Transitioned the imetelstat program back to Geron in the third quarter of 2019, including transfer of imetelstat investigational new drug (IND) sponsorship in May 2019.

Throughout 2019, recruited hematology-oncology research and development expertise, including many team members with prior experience with imetelstat, as well as both early- and late-stage development experience, to establish a multi-functional development team to support current and future development plans.

Re-established manufacturing supply chain to manufacture imetelstat.

Fourth Quarter and Full Year 2019 Results

For the fourth quarter of 2019, the Company reported a net loss of $29.1 million, or $0.15 per share, compared to $7.3 million, or $0.04 per share, for the fourth quarter of 2018. Net loss for the full year of 2019 was $68.5 million, or $0.36 per share, compared to $27.0 million, or $0.15 per share, for the full year of 2018.

Revenues for the three and twelve months ended December 31, 2019 were $171,000 and $460,000, respectively, compared to $375,000 and $1.1 million for the same periods in 2018. Revenues for the three and twelve months ended December 31, 2019 and 2018 included royalty and license fee revenues under various non-imetelstat license agreements. The decline in revenues reflects a reduction in the number of active research license agreements in 2019 related to the Company’s human telomerase reverse transcriptase, or hTERT, technology as a result of patent expirations on the underlying technology.

Total operating expenses for the three and twelve months ended December 31, 2019 were $30.2 million and $73.0 million, respectively, compared to $10.0 million and $32.1 million for the same periods in 2018. Research and development expenses for the three and twelve months ended December 31, 2019 were $24.9 million and $52.1 million, respectively, compared to $5.1 million and $13.4 million for the same periods in 2018. The increase in research and development expenses, compared to the same periods in 2018, primarily reflects costs for the transition of the imetelstat program, including resuming sponsorship of the ongoing imetelstat clinical trials;
expenses for start-up activities for the IMerge Phase 3 clinical trial; purchase of inventories of drug product, drug substance and raw materials from Janssen; and higher personnel-related costs for the expanding development team. General and administrative expenses for the three and twelve months ended December 31, 2019 were $5.3 million and $20.9 million, respectively, compared to $4.9 million and $18.7 million for the same periods in 2018. The increase in general and administrative expenses, compared to the same periods in 2018, primarily reflects higher corporate and patent legal costs and increased personnel-related expenses for additional general and administrative headcount to support the development organization.

Interest and other income for the three and twelve months ended December 31, 2019 was $925,000 and $4.2 million, respectively, compared to $1.1 million and $3.3 million for the same periods in 2018. The overall increase in interest and other income in 2019 when compared to 2018 primarily reflects higher yields on the Company's marketable securities portfolio.

The Company ended the 2019 fiscal year with $159.2 million in cash and marketable securities. The Company expects these funds to be sufficient to continue the IMerge clinical trial in 2020 and to commence a proof of concept study in 2020.

**Projected 2020 Financial Guidance**

For fiscal year 2020, the Company expects its operating expense burn to range from $70 to $75 million, which includes costs related to the global Phase 3 IMerge clinical trial in MDS; validation of supply chain vendors for the manufacturing of imetelstat; further interactions with the FDA in connection with the planned submission of Phase 3 trial design proposals in MF and discussion regarding a potential regulatory approval path in MF; and commencement of a proof of concept study of imetelstat.

As of December 31, 2019, the Company had 46 employees. The Company plans to grow to a total of approximately 55 to 60 employees by year-end 2020, of which the majority will be research and development personnel.

**Conference Call**

Geron will host a conference call to discuss fourth quarter and full year 2019 financial results and 2020 milestones at 4:30 p.m. ET on Thursday, March 12, 2020.

Participants may access the conference call live via telephone by dialing domestically +1 (866) 393-4306 or internationally +1 (734) 385-2616. The conference ID is 5528886. A live, listen-only webcast will also be available on the Company's website at [www.geron.com/investors/events](http://www.geron.com/investors/events). If you are unable to listen to the live call, an archived webcast will be available on the Company's website for 30 days.
About Imetelstat

Imetelstat is a novel, first-in-class telomerase inhibitor exclusively owned by Geron and being developed in hematologic myeloid malignancies. Early clinical data suggest imetelstat may have disease-modifying activity through the suppression of malignant progenitor cell clone proliferation, which allows potential recovery of normal hematopoiesis. Clinical studies of imetelstat sponsored by Geron include IMerge, a Phase 2/3 trial in lower risk myelodysplastic syndromes (MDS), and IMbark, a Phase 2 trial in Intermediate-2 or High-risk myelofibrosis (MF). 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 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. 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) Geron's plan to complete enrollment for IMerge by the end of 2020; (ii) that Geron expects topline results from IMerge by mid-year 2022; (iii) Geron's plan to meet with the FDA in the second quarter of 2020 to discuss a potential regulatory approval path in MF and subsequently provide a decision by mid-year 2020 regarding potential late-stage development of imetelstat in MF; (iv) Geron's plan to commence a proof of concept study in 2020 in additional hematologic myeloid malignancies; (v) that the Company expects its 2020 operating expenses to be $70 to $75 million; (vi) that the Company expects that its $159.2 million in cash and marketable securities at year-end 2019 will be sufficient in 2020 to continue to fund IMerge and commence a proof of concept study; (vii) that in 2020 Geron expects to present at medical conferences: (a) more mature data from the Phase 2 IMerge clinical trial, including durability of transfusion independence and (b) further analyses of Phase 2 IMbark data that provide additional support of the potential disease-modifying activity with imetelstat treatment in MF, as well as correlation of other endpoints in the trial to the median overall survival observed in the trial; (viii) that imetelstat may have disease-modifying activity; (ix) that the COVID-19 pandemic may significantly impact enrollment of patients in Geron's clinical trials and/or drug supply to clinical sites; and (x) other statements that are not historical facts, constitute forward looking statements.
These 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: (i) whether the Company overcomes all the clinical, safety, efficacy, technical, scientific, intellectual property, manufacturing and regulatory challenges to enable complete enrollment of IMerge in 2020, the availability of topline results from IMerge by mid-year 2022 and commencement of the proof of concept study; (ii) whether regulatory authorities permit the further development of imetelstat on a timely basis, or at all, without any clinical holds; (iii) whether imetelstat is demonstrated to be safe and efficacious in clinical trials; (iv) whether any future efficacy or safety results may cause the benefit-risk profile of imetelstat to become unacceptable; (v) whether there are unexpected operating expenses or events, or a change in Geron's plans that cause the $70 to $75 million 2020 financial guidance to be revised; (vi) whether the Company decides not to pursue late-stage development of imetelstat in MF; (vii) whether the MDS and MF data the Company plans to present at medical conferences strengthens the rationale for the Company to complete IMerge or pursue a Phase 3 clinical trial in MF; (viii) whether imetelstat actually demonstrates disease-modifying activity in patients; (ix) that Geron may not be able to prepare for discussions with the FDA in the second quarter of 2020, or at all, and its decision regarding potential late-stage development of imetelstat in MF, if any, may be delayed beyond mid-2020; and (x) whether imetelstat has adequate patent protection and freedom to operate. 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 periodic reports filed with the Securities and Exchange Commission under the heading “Risk Factors,” including Geron’s annual report on Form 10-K for the year ended December 31, 2019. Undue reliance should not be placed on forward-looking statements, which speak only as of the date they are made, and the facts and assumptions underlying the forward-looking statements may change. Except as required by law, Geron disclaims any obligation to update these forward-looking statements to reflect future information, events or circumstances.

Financial table follows.

GERON CORPORATION
CONDENSED STATEMENTS OF OPERATIONS

(In thousands, except share and per share data)

<table>
<thead>
<tr>
<th></th>
<th>Three Months Ended December 31, 2019</th>
<th>Year Ended December 31, 2019</th>
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<tbody>
<tr>
<td>Revenues:</td>
<td></td>
<td></td>
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<tr>
<td>License fees and royalties</td>
<td>$171</td>
<td>$460</td>
</tr>
<tr>
<td></td>
<td></td>
<td>$1,066</td>
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<tr>
<td>Operating expenses:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>$24,232</td>
<td>$53,972</td>
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<td>$24,232</td>
<td>$53,972</td>
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Research and development  24,325  3,987  52,012  13,462  
General and administrative  5,256  4,883  20,893  18,707  
Total operating expenses  30,179  9,864  72,905  32,139  
Loss from operations  (30,008)  (9,589)  (72,505)  (31,073)  
Interest and other income  925  1,120  4,221  3,291  
Gain on settlement  —  1,460  —  1,460  
Change in fair value of equity investment  —  (271)  (195)  (541)  
Other expense  13  (20)  (69)  (154)  
Net loss  $ (29,070)  $ (7,300)  $ (68,548)  $ (27,017)  

Basic and diluted net loss per share: 
Net loss per share  $ (0.15)  $ (0.04)  $ (0.36)  $ (0.15)  
Shares used in computing net loss per share 
198,447,315  186,348,551  190,160,311  176,504,996  

CONDENSED BALANCE SHEETS  

<table>
<thead>
<tr>
<th>December 31, 2019</th>
<th>December 31, 2018</th>
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<tbody>
<tr>
<td>Current liabilities</td>
<td>$ 28,162</td>
</tr>
<tr>
<td>Noncurrent liabilities</td>
<td>2,200</td>
</tr>
<tr>
<td>Stockholders' equity</td>
<td>135,155</td>
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<td>$ 165,517</td>
<td>$ 185,284</td>
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Source: Geron Corporation