Jaguar Health, Inc. Reports 2019 First Quarter Financial Results

May 24, 2019

Mytesi® Net Sales and Gross Sales Grew 154% and 161%, Respectively, in Q1 2019 Compared to Q1 2018

SAN FRANCISCO, CA / ACCESSWIRE / May 24, 2019 / Jaguar Health, Inc. (NASDAQ: JAGX) ("Jaguar" or the "Company"), a commercial stage pharmaceutical company focused on developing novel, sustainably derived gastrointestinal products on a global basis, today reported first quarter 2019 results and issued the following highlights.

Financial Highlights

(In thousands except for per share amounts and percentages)		Q1 2019		Q1 2018	% Change
Net product revenue	$	1,590	$	627	154%
Gross product sales (non-GAAP measure)	$	2,190	$	839	161%
Collaboration income	$	-	$	177	-100%
Loss from operations	$	(5,775)	$	(5,128)	13%
Net loss attributable to common shareholders	$	(8,304)	$	(6,692)	24%

2019 First Quarter Company Financial Results

- **Mytesi Net Product Revenue:** Mytesi net sales in the first quarter of 2019 were approximately $1.5 million, and Mytesi gross sales were approximately $2.1 million, an increase of 154% and 161% of net and gross sales, respectively, over the first quarter of 2018. Total Mytesi prescription volume, which is the combination of new prescriptions and refills, as reported by IQVIA, a provider of analytics, technology solutions and contract research services to the life sciences industry, increased 98% in the first quarter of 2019 over the first quarter of 2018, and grew 1% in the first quarter of 2019 versus the fourth quarter of 2018. Jaguar's animal-related sales for the first quarter of 2019 and 2018 were flat at $47K and $44K, respectively, due to minimal marketing and sales efforts.
- **Operating Expenses:** The total operating expense for the quarter ended March 31, 2019 was $7.4 million as compared to $5.9 million for the quarter ended March 31, 2018, a 25% increase or a $1.5 million increase quarter over quarter. The 25% increase in total operating expense quarter over quarter is a combination of the $0.4 million increase in cost of product revenue, $0.7 million increase in Research and Development, and a $0.5 million increase in General and Administrative expense offset by a $0.1 million decrease in Marketing and Sales.
- **Cost of Product Revenue:** The total Cost of Product Revenue for the quarters ended March 31, 2019 and March 31, 2018 was $0.8 million compared to $0.4 million, respectively. The increase of $0.4 million was a direct result of an increase of Mytesi sales coupled with additional distributor expense due to a change in service provider to Cardinal Health in the first quarter of 2019.
- **Research and Development**: The Research and Development expense was $1.4 million for the quarter ended March 31, 2019 compared to $0.7 million for the quarter ended March 31, 2018. The increase of $0.7 million in R&D for the first quarter of 2019 was primarily due to a $0.6 million investment in commercial manufacturing to enhance process improvements for future cost reduction in manufacturing and a $0.2 million increased spend in regulatory activities in support of cancer therapy-related diarrhea (CTD) pivotal trial design, partially offset by a $0.1 million reduction in headcount related expense.
- **Sales and Marketing**: The Sales and Marketing expense for the quarter ended March 31, 2019 was relatively flat with a $1.6 million spend in the three months ended March 31, 2019 as compared to $1.7 million for the quarter ended March 31, 2018. The major difference between the two periods is that the quarter ended March 31, 2019 headcount expense was 77% of the total spend, while the quarter ended March 31, 2018 headcount expense was 40% of the total spend. The increased sales representatives for the quarter ended 2019 and the 'boots on ground' strategy was implemented to enhance the face to face presence with designated high decile prescribers; and at the same time supplementing efforts with marketing, medical education, and sales promotion.
- **General and Administrative**: The General and Administrative expense for the quarter ended March 31, 2019 totaled $3.5 million compared to $3.0 million for the quarter ended March 31, 2018, a 17% increase quarter over quarter. The G&A spend of $3.5 million for the quarter ended March 31, 2019 consisted of the continued G&A support functions such as audit, legal, compliance, accounting, human resources, IT, public company expense, financing and facilities. The increase in G&A quarter over quarter was primarily due to third-party consulting fees for the support of public company regulatory reporting and financing activities, and an increase in non-cash stock-based compensation expense.

- **Loss from Operations:** For the first quarter of 2019, the net loss from operations was $5.8 million, compared to a net loss of $5.1 million in the first quarter of 2018. This was a 13% increase in operating loss quarter over quarter due to a net increase in total net revenue of $0.8 million offset by a $1.4 million increase in operating expense.

- **Net Loss Attributable to Common Shareholders:** For the first quarter of 2019, the net loss attributable to common shareholders was $8.3 million compared to $6.7 million for the first quarter of 2018. The first quarter of 2019 includes a $1.9 million loss on extinguishment of debt, and the first quarter of 2018 includes a deemed dividend attributable to preferred stockholders in the amount of $1.0 million, resulting in a net increase in loss of $0.9 million. The deemed dividend charge attributable to preferred stockholders represents the accretion of the discount on the Series A preferred shares in the first quarter of 2018 due to a beneficial conversion factor in the transaction. The loss on extinguishment of debt is included in the net loss for the first quarter of 2019, while the deemed dividend charge is reflected below net loss to arrive at net loss available to common stockholders on the Company's condensed consolidated statement of operations.

- **Income Tax Rate:** The effective tax rate for the first quarter of 2019 and 2018 was zero percent, respectively, primarily as a result of the estimated tax loss for the year and a full valuation allowance.

Mytesi Commercial and Promotional Activities Updates

- As announced January 24, 2019, Mytesi (crofelemer) has been added to the formulary for Florida's AIDS Drug Assistance Program (ADAP). As a result of this addition, based on data from healthcare research firm Decision Resource Group, approximately 86% of ADAP-eligible US lives now have access to Mytesi, Jaguar's FDA-approved drug product indicated for the symptomatic relief of noninfectious diarrhea in adult patients with HIV/AIDS on antiretroviral therapy.
- Jaguar is seeking partners that share the Company's commitment to making its crofelemer anti-secretory agent available to relieve suffering across patient populations around the world.

Human Pipeline Updates

- As Jaguar recently announced, the Company's wholly-owned subsidiary, Napo Pharmaceuticals, Inc. (Napo), met with the U.S. Food & Drug Administration (FDA) on March 28, 2019 to discuss the protocol for Napo's planned Phase 3 clinical trial in cancer subjects to evaluate the effects of Mytesi (crofelemer) in prevention and/or relief of cancer therapy-related diarrhea (CTD). The meeting, which included academic key opinion leaders/Napo Scientific Advisory Board members from leading oncology treatment institutions, resulted in a productive regulatory discussion about design refinements for the anticipated pivotal trial. Napo's planned next step is to continue its interactions with the FDA and incorporate the input from this dialog into the Phase 3 protocol following this very informative discussion.

- In support of the Company's focus on the potential CTD indication, two ongoing investigator initiated trials (IITs) utilizing Mytesi are underway:

- Enrollment is ongoing for the HALT-D study in breast cancer patients receiving regimens containing Herceptin and Perjeta. Interim results from the study, which is sponsored by Georgetown University and funded by Genentech, a member of the Roche Group, are expected to be read out in the first half of 2019. The study's primary endpoint has an 81% power to detect a 40% difference in the percent and/or number of patients experiencing any grade of diarrhea for two consecutive days at a p value of 0.1. (The statistical power of a study, sometimes referred to as a study's sensitivity, is a measure of how likely the study is to distinguish an actual effect from one of chance). For the sake of clarity, the estimates of the percent of patients experiencing such diarrhea is postulated to be 60% in the placebo patients and 20% in the study's crofelemer-treated arms. The interim analysis, which is being conducted to ensure that the study has a chance to ultimately achieve the primary endpoint, will determine whether or not the study has a power of at least 20% to detect such a difference when 23 patients have been randomized. The interim analysis will be deemed positive and the trial will continue if the power is 20% or greater.

- The second ongoing IIT, funded by Puma Biotechnology, is evaluating the use of crofelemer in breast cancer patients receiving neratinib-containing regimens, which are reported to have extremely high rates of diarrhea.

- Additionally, a third-party cancer agent manufacturer is funding Napo's implementation of a nonclinical study, which is underway to evaluate the effects of crofelemer treatment on diarrhea induced by tyrosine kinase inhibitors (TKIs) in healthy female dogs. The evaluation of crofelemer effects in dogs receiving TKIs is intended to provide additional scientific rationale and support for the use of crofelemer in providing symptomatic relief of noninfectious diarrhea in human patients receiving TKI-containing regimens in future human clinical investigations.

- The Company is planning to initiate formulation and regulatory activities to support an investigational new drug application for lechlemer, Napo's second-generation anti-secretory drug product candidate, for the indication of cholera along with efforts to pursue a tropical disease priority review voucher from FDA for this potential indication. Lechlemer, which is a drug candidate under the botanical guidance of the FDA, is approximately one-tenth the price to manufacture as crofelemer and therefore more economically feasible than Mytesi for marketing in resource-constrained countries. Priority review vouchers are granted by the FDA to drug developers as an incentive to develop treatments for neglected diseases and rare pediatric diseases. These vouchers are transferable and, in recent transactions by other companies, have sold for $67 million to $350 million, because they provide third-party purchasers a six-month priority review with the FDA for any product candidate in development.

- According to the Centers for Disease Control and Prevention of the U.S. Department of Health & Human Services, cholera is an acute diarrheal illness caused by infection of the intestine with the bacterium *Vibrio cholerae*. An estimated 3-5 million cholera cases and more than 100,000 cholera-related deaths occur each year around the world. The infection is often mild or without symptoms, but can sometimes be severe. Approximately one in 10 (5-10%) of infected persons will have severe disease characterized by profuse watery diarrhea, vomiting, and leg cramps. In these people, rapid loss of body fluids leads to dehydration and shock. Without treatment, death can occur within hours. At this time, the largest cholera outbreak in recorded history is occurring in Yemen.

- As previously announced, Napo has accepted a request for support submitted by Dr. Mohamad Miqdady, Chief of Pediatric Gastroenterology, Hepatology and Nutrition at Sheikh Khalifa Medical City (SKMC) in Abu Dhabi, for an investigator-initiated trial of crofelemer for congenital diarrheal disorders (CDDs) in children. Enrollment for this trial is planned in the second half of 2019 as the Company completes stability studies for a pediatric liquid formulation. CDDs are a group of rare, chronic intestinal channel diseases, occurring in early infancy, that are characterized by severe, lifelong diarrhea and a lifelong need for nutritional intake either parenterally or with a feeding tube. CDDs are related to specific genetic defects inherited as autosomal recessive traits, and the incidence of CDDs is much more prevalent in regions where consanguineous marriage is part of the culture. CDDs are directly associated with serious secondary conditions including dehydration, metabolic acidosis, and failure to thrive, prompting the need for immediate therapy to prevent death and limit lifelong disability.

- Napo recently approved a request for an investigator-initiated trial of crofelemer for idiopathic/functional diarrhea, and the Company's pipeline of potential follow-on indications also includes supportive care for diarrhea related to inflammatory bowel disease. Diarrhea stemming from irritable bowel syndrome is another target indication for Mytesi, for which Jaguar has completed two phase 2 studies. The chronic safety of Mytesi is an important distinguishing attribute for these possible indications.

Canalevia™ Updates

- As announced March 20, 2019, Jaguar has completed the filing with the FDA's Center for Veterinary Medicine (CVM) of the Chemistry, Manufacturing, and Controls (CMC) technical section in support of the Company's application for conditional approval of Canalevia (crofelemer delayed-release tablets) for treatment of chemotherapy - induced diarrhea (CID) in dogs. Jaguar has now completed three of the four required technical sections - the CMC, Effectiveness, and Environmental Impact technical sections-of the Company's application for conditional approval of Canalevia for CID in dogs. Jaguar anticipates filing the Target Animal Safety technical section with CVM in the second quarter of this year. With receipt of conditional approval for this indication, the Company expects to conduct the commercial launch of Canalevia for CID in dogs in the first quarter of 2020.

Note Regarding Use of Non-GAAP Measures

Gross sales percentages issued by the Company are based on gross sales figures that represent Mytesi orders placed by wholesalers with Jaguar's third-party logistics warehouse which generate invoiced sales and cashflow for Napo. Gross sales is used internally by management as an indicator of and to monitor operating performance, including sales performance of Mytesi, salesperson performance, and product growth or declines. The Company believes that the presentation of gross sales provides a closer to real-time useful measure of our operating performance. Gross sales is not a measure that is recognized under accounting principles generally accepted in the United States of America ("GAAP") and should not be considered as an alternative to net sales, which is determined in accordance with GAAP, and should not be used alone as an indicator of operating performance in place of net sales. Additionally, gross sales may not be comparable to similarly titled measures used by other companies, as gross sales has been defined by the Company's internal reporting practices. In addition, gross sales may not be realized in the form of cash receipts as promotional payments and allowances may be deducted from payments received from certain customers. Mytesi gross sales are reduced by Medicare, ADAP 340B chargebacks, returns, and wholesale distribution fees based on historical trends to determine net sales.

About Mytesi®

Mytesi (crofelemer) is an antidiarrheal indicated for the symptomatic relief of noninfectious diarrhea in adult patients with HIV/AIDS on antiretroviral therapy (ART). Mytesi is not indicated for the treatment of infectious diarrhea. Rule out infectious etiologies of diarrhea before starting Mytesi. If

infectious etiologies are not considered, there is a risk that patients with infectious etiologies will not receive the appropriate therapy and their disease may worsen. In clinical studies, the most common adverse reactions occurring at a rate greater than placebo were upper respiratory tract infection (5.7%), bronchitis (3.9%), cough (3.5%), flatulence (3.1%), and increased bilirubin (3.1%).

See full Prescribing Information at Mytesi.com. Crofelemer, the active ingredient in Mytesi, is a botanical (plant-based) drug extracted and purified from the red bark sap of the medicinal *Croton lechleri* tree in the Amazon rainforest. Napo has established a sustainable harvesting program for crofelemer to ensure a high degree of quality and ecological integrity.

About Jaguar Health, Inc.

Jaguar Health, Inc. is a commercial stage pharmaceuticals company focused on developing novel, sustainably derived gastrointestinal products on a global basis. Our wholly-owned subsidiary, Napo Pharmaceuticals, Inc., focuses on developing and commercializing proprietary human gastrointestinal pharmaceuticals for the global marketplace from plants used traditionally in rainforest areas. Our Mytesi® (crofelemer) product is approved by the U.S. FDA for the symptomatic relief of noninfectious diarrhea in adults with HIV/AIDS on antiretroviral therapy.

For more information about Jaguar, please visit jaguar.health. For more information about Napo, visit napopharma.com.

Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." These include statements regarding the expectation that Napo will continue interactions with the FDA regarding the protocol for Napo's planned Phase 3 clinical trial in cancer subjects to evaluate the effects of Mytesi (crofelemer) in prevention and/or relief of CTD, the expectation that interim results of the IIT of crofelemer in breast cancer patients suffering from CTD will be available in the first half of 2019, the belief that the nonclinical study underway to evaluate the effects of crofelemer treatment on diarrhea induced by TKIs in healthy female dogs will provide additional scientific rationale and support for the use of crofelemer in providing symptomatic relief of noninfectious diarrhea in human patients receiving TKI-containing regimens in future human clinical investigations, the Company's plans to initiate formulation and regulatory activities to support an investigational new drug application for lechlemer for the indication of cholera along with efforts to pursue a tropical disease PRV from FDA for this potential indication, the expectation that enrollment for the CDD IIT at SKMC in Abu Dhabi will take place in the second half of 2019, and the expectation that, with receipt of conditional approval for Canalevia for the indication of CID in dogs, the Company will conduct the commercial launch of Canalevia for CID in dogs in the first quarter of 2020. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "aim," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions. The forward-looking statements in this release are only predictions. Jaguar has based these forward-looking statements largely on its current expectations and projections about future events. These forward-looking statements speak only as of the date of this release and are subject to a number of risks, uncertainties and assumptions, some of which cannot be predicted or quantified and some of which are beyond Jaguar's control. Except as required by applicable law, Jaguar does not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

Contact:

Peter Hodge
Jaguar Health, Inc.
phodge@jaguar.health

SOURCE: Jaguar Health, Inc.