Jaguar Health, Inc. Reports 2018 Fourth Quarter and Year End Financial Results

April 10, 2019

Mytesi® Gross Sales and Net Sales Grew 237% and 185%, Respectively, in the Year End 2018 Compared to Year End 2017

SAN FRANCISCO, CA / ACCESSWIRE / April 10, 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 fourth quarter 2018 results and issued the following highlights.

Financial Highlights	**Three Months Ended December 31,**		**Twelve Months Ended December 31,**	
(In thousands)	**2018**	**2017**	**2018**	**2017**
Gross product sales	$ 2,158	$ 1,261	$ 5,847	$ 1,737
Net product revenue	$ 1,596	$ 903	$ 4,239	$ 1,485
Collaboration income	$ 0	$ 639	$ 177	$ 2,876
Net income (loss) from operations	$ (20,681)	$ (12,110)	$ (30,824)	$ (34,274)

2018 Fourth Quarter and Year-End Company Financial Results

- **Mytesi Net Product Revenue:** Mytesi gross sales in the fourth quarter of 2018 were approximately $2.2 million, and Mytesi net sales were approximately $1.6 million, an increase of 71% and 77% of gross and net sales, respectively, over the fourth quarter of 2017. Total Mytesi prescription volume, which is the combination of new prescriptions and refills, as reported by IQVIA, grew 20% in the fourth quarter of 2018 versus the prior quarter, and increased 94% over the fourth quarter of 2017. Mytesi gross sales for the year ended 2018 were approximately $5.7 million, and Mytesi net sales were approximately $4.1 million, an increase of 237% and 185%, respectively year over year. In 2018, the Company's animal product research and development efforts were intentionally minimal, and Jaguar's animal-related sales were also minimal.

- **Operating Expenses:** The total operating expense for the quarter ended December 31, 2018, was $13.7 million as compared to $22.2 million for the quarter ended December 31, 2017, a 38% decrease quarter over quarter. The total operating expenses for the year ended December 31, 2018, was $35.2 million as compared to $38.6 million for the year ended December 31, 2017. The operating expense for year-end 2017 included an impairment expense of goodwill and acquired in-process research and development of $19.1 million and the fourth quarter 2017 included an impairment expense of goodwill and acquired in-process research and development impairment of $15.5 million. The fourth quarter 2018 impairment and year-end 2018 impairment expense was $5.2 million. The 38% decrease in total operating expense quarter over quarter is a combination of the $10.0 million decrease in impairment expense offset by an increase of $1.6 million marketing and sales efforts operational expense in the fourth quarter enhancing our Mytesi sales and marketing efforts. The annual $3.4 million operating expense decrease from 2017 to 2018 is due to a $13.9 million reduction in impairment of goodwill and acquired in-process research and development, offset by a $6.7 million in Mytesi marketing and sales headcount expense; a $1.9 million increase in cost of product revenue due to increased Mytesi sales year over year; a $0.9 million increase in clinical studies for cancer therapy-related diarrhea (CTD) and manufacturing and serialization developments; and a $1.0 million increase for general and administrative expense and support for increased sales force headcount.

- The R&D expense was $1.3 million for the quarter ended December 31, 2018, compared to $1.2 million for the quarter ended December 31, 2017. The total R&D expense for the quarter ended December 31, 2017, consisted of animal health clinical trials and regulatory expenses for the development of Canalevia ™ for the possible indication of chemotherapy-induced diarrhea (CID) in dogs. The $1.3 million spend of R&D during the fourth quarter of 2018 represents the Company's investment in commercial manufacturing serialization requirements and enhanced manufacturing process improvements the Company is developing to reduce the cost of revenue and prepare for future pipeline projects; as well as clinical study

support for cancer therapy-related diarrhea (CTD) studies. The total 2018 R&D expense was $5.2 million compared to a 2017 R&D expense of $4.3 million. This growth once again represents the Company's investment in commercial manufacturing serialization requirements and enhanced manufacturing process improvements the Company is developing for future cost reduction in manufacturing.

- The sales and marketing expense for the quarter ended December 31, 2018 was $2.7 million as compared to $2.1 million for the quarter ended December 31, 2017. The $.6 million increase represents the Company's continued effort in selling and marketing Mytesi in the fourth quarter of 2018. The total 2018 marketing and sales spend was $9.8 million compared to $3.1 million for the year ended 2017. The $6.7 million increase represents the growth of the sales force to approximately 21 sales representatives and management; as well as an approximate $5.2 million spend in commercial marketing activities for Mytesi marketing and promotional spend.

- The general and administrative expense for the quarter ended December 31, 2018, totaled $3.5 million compared to $2.7 million for the quarter ended December 31, 2017, a 30% increase quarter over quarter. The G&A spend of $3.5 million for the quarter ended December 31, 2018 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 financing fees and third-party consulting fees for the support of public company regulatory reporting and financing activities.

- **Operating Income (Loss) from Operations:** For the fourth quarter of 2018, the net loss from operations was $20.7 million, compared to a net loss of $12.1 million in the fourth quarter of 2017. This was a 42% decrease in operating loss from operations quarter over quarter due to a 77% increase in net product revenue coupled with a 38% decrease in operating expense in fourth quarter 2018 primarily due to the $15.2 million impairment charges in fourth quarter 2017. Net loss from operations for the year ended 2018 was $30.8 million compared to a net loss from operations of $34.3 million for the year ended 2017. The $3.5 million decrease in loss is due to increased net product revenue of $2.8 million year over year coupled with the decreased operating expense of $3.4 million in 2018, offset by a $2.7 million decrease in collaboration revenue in 2018 due to the termination of the animal segment collaboration agreement in January 2018.

- **Other Income (expense), net:** A $1.2 million settlement from the Napo-Valeant purchase agreement executed in March 2016 was received in the fourth quarter of 2017 and recorded as a gain on settlement.

- **Income Tax Rate:** The effective tax rate for the year ended December 31, 2018 and 2017, respectively was zero percent, primarily as a result of the estimated tax loss for the year and the change in valuation allowance.

Mytesi Commercial and Promotional Activities Updates

- As announced January 24, 2019, Mytesi 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 we recently announced, our wholly-owned subsidiary, 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 our focus on the potential CTD indication, two ongoing investigator initiated trials (IITs) utilizing Mytesi are underway:

    - Enrollment is ongoing for the HALT D study at Georgetown University in breast cancer patients receiving regimens containing Herceptin and Perjeta, which is being funded by Genentech Roche, and interim results are expected to be read out in the first half of 2019.
    - An IIT being 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 for the indication of cholera along with efforts to pursue a tropical disease priority review voucher from FDA for this potential indication. Cholera is an acute diarrheal illness that kills thousands of people worldwide each year due to rapid dehydration in the first few to 48 hours after infection. Lechlemer, Jaguar's second-generation anti-secretory botanical drug product candidate, 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.

- 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 cash flow 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, 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.

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