Jaguar Health Provides Company Updates and Reports 2022 Second Quarter Financials

August 22, 2022

Prescription product net revenue of $2.9 million in Q2 2022 increased approximately 12.0% Quarter over Quarter, over Q1 2022; and increased approximately 641% Year over Year, over Mytesi® net revenue in Q2 2021

Core initiatives:

- ***OnTarget*** *Phase 3 clinical trial of crofelemer for prophylaxis of cancer therapy-related diarrhea (CTD) adding international sites, targeting completion of enrollment 1H 2023*
- *Expected presentation in December 2022 of results of a third-party, investigator-initiated proof-of-concept trial of crofelemer for short bowel syndrome (SBS), supporting the potential for expanded patient access through programs in Europe in 2023*
- *Ongoing launch of Canalevia®-CA1 for treatment of chemotherapy-induced diarrhea (CID) in dogs*

REMINDER: *Jaguar to host investor webcast Monday, August 22nd at 8:30 a.m. Eastern regarding second quarter 2022 financials and company updates; Click **here** to register for webcast*

SAN FRANCISCO, CA / ACCESSWIRE / August 22, 2022 / Jaguar Health, Inc. (NASDAQ:JAGX) ("Jaguar" or the "Company") today provided Company updates and reported consolidated second-quarter 2022 financial results.

Prescription product net revenue was approximately $2.9 million in the second quarter of 2022, representing an increase of approximately 12% over Mytesi net revenue in the first quarter of 2022, which totaled approximately $2.6 million, and an increase of approximately 641% over Mytesi net revenue in the second quarter of 2021, which totaled approximately $0.4 million.

"We are very pleased that growth in Mytesi (crofelemer) revenue continued in the second quarter of 2022," said Lisa Conte, Jaguar's president and CEO. "We completed the full shift this past January to a patient access strategy that involves transitioning to a limited distribution network of specialty pharmacies, which reduced our distribution costs and improved our Mytesi gross-to-net ratio dramatically. It is wonderful to see Mytesi growth continuing following this transition and the other components of our Mytesi patient access program, including our ongoing educational and promotional activities in 2022 and the launch this past May of our telehealth initiative for Mytesi. Most importantly, we are pleased with the realization of our mission of providing relief with a novel, plant-based, first-in-class mechanism of action to patients in need - including patients for whom no alternative therapeutic options exist."

"Jaguar is focused on two late-stage clinical events in the next approximately 6 to 12 months that we expect to be transformational in terms of value creation and recognition for the Company. We anticipate the completion in 2022 of an investigator-initiated proof-of-concept study of crofelemer for short bowel syndrome (SBS), supporting the potential for expanded patient access to crofelemer in Europe in 2023 for this devastating and often catastrophic disease for these patients, who are frequently on parenteral nutrition for as long as 20 hours a day, seven days a week. The third-party investigator, Dr. Mohamad Miqdady, Division Chief of the Pediatric Gastroenterology, Hepatology & Nutrition Division at Sheikh Khalifa Medical City, is targeting the presentation in December 2022 of results from the SBS study at a global GI conference in Dubai. Our second key clinical activity is our Phase 3 pivotal **OnTarget** trial of crofelemer for our core follow-on indication of prophylaxis of cancer therapy-related diarrhea (CTD). We expect enrollment in this pivotal trial to complete in the first half of 2023," Conte said.

2022 MILESTONES, UPDATES & ACCOMPLISHMENTS:

- **Phase 3 clinical trial of crofelemer for cancer therapy-related diarrhea (CTD) in humans:** The pivotal **OnTarget** Phase 3 clinical trial of crofelemer for prophylaxis of CTD was initiated in October 2020and is ongoing. The Company is in the process of adding additional clinical trial sites - both in the US and outside the US - to accelerate patient enrollment. Further details about the trial can be viewed **here** on the clinicaltrials.gov website. Is it estimated that 50-80% of chemotherapy patients experience diarrhea,[1] and diarrhea has the potential to cause dehydration, potential infections, and non-adherence to treatment in cancer patients. Patients with CTD are 40% more likely to discontinue their chemotherapy or targeted therapy than patients without CTD,[2] and the cost of care of CTD patients is estimated to be 2.9 times higher than for patients who are not experiencing CTD.[3]
- **2022 & 2023 Milestones: Completion of investigator-initiated proof-of-concept studies of crofelemer for SBS and**

congenital diarrheal disorders (CDD) with intestinal failure: Napo Therapeutics, the Italy-based company Jaguar established under exclusive license to crofelemer in Europe, is supporting planned investigator-initiated studies of crofelemer in patients with SBS or CDD with intestinal failure, with a planned primary endpoint of reduction of weekly volume of parenteral nutrition. On December 13, 2021, the EMA granted Orphan Drug Designation (ODD) for crofelemer for SBS in the European Union, and crofelemer has received ODD in the U.S. for SBS. The EMA is committed to enabling early patient access to new medicines, particularly those that target an unmet medical need, and ODD status in the EU is expected to support Napo Therapeutics' plans to make crofelemer available through Early Access Programs in the EU for SBS. Participation in Early Access Programs provides a potential opportunity for meaningful revenue generation in addition to the ability to impact important morbidity, mortality, and the cost of care for chronically ill patients for whom no good therapeutic options exist. SBS affects approximately 10,000 to 20,000 people in the U.S.,[4] according to the Crohn's & Colitis Foundation, and it is estimated that the population of SBS patients in Europe is approximately the same size.[5] Despite limited treatment options, the global SBS market exceeded $568 million in 2019 and is expected to reach $4.6 billion by 2027, according to a report by Vision Research Reports.

- **May 2022 submission of an Orphan Drug Designation (ODD) application to the European Medicines Agency (EMA) for crofelemer for a rare congenital diarrheal disorder (CDD):** Napo Therapeutics, the Italian corporation established by the Company in Italy in 2021 that focuses on expanding crofelemer access in Europe, submitted a CDD ODD application for crofelemer to the EMA. CDDs are a group of inherited chronic enteropathies characterized by heterogeneous etiology, and each type of CDD is thus a different disease with a different pathogenetic mechanism. CDD is a life-threatening and rare autosomal recessive disease that affects newborns and children and leads to significant morbidity and even death from severe secretory diarrhea.
- **Q3 2022 Milestone: Filing of an Investigational New Drug (IND) application with the FDA for NP-300 (lechlemer) for the symptomatic relief of diarrhea from cholera:** Lechlemer is the Company's drug product candidate for symptomatic relief of diarrhea from cholera. It is a standardized and proprietary botanical drug product that is sustainably derived from the same source as crofelemer - the *Croton lechleri* tree - and works by the same mechanism of action as crofelemer. In support of the planned IND application filing for lechlemer, the Company received comprehensive animal toxicity preclinical services supported by the National Institute of Allergy and Infectious Diseases for four preclinical studies. The Company intends to pursue a tropical disease priority review voucher under the FDA's financial incentive program to develop drugs for tropical diseases such as cholera. Priority review vouchers are transferable, and in past transactions by other companies have sold for prices ranging from $67 million to $350 million, which provides for a potential immediate return on investment upon approval of the product for the symptomatic relief of diarrhea from cholera.
- **2022, Jaguar's Year of the Dog:** Launch activities remain underway for Canalevia-CA1 in the U.S. veterinary market for the treatment of chemotherapy-induced diarrhea (CID) in dogs, and the second quarter of 2022 is the first Canalevia-CA1 revenue recognition period for the Company. Canalevia-CA1 was the focus of Jaguar Animal Health's activities at April's Veterinary Cancer Society Mid-Year Conference in Puerto Vallarta, Mexico. Jaguar Animal Health exhibited at the June 23-25, 2022 American College of Veterinary Internal Medicine (ACVIM) Forum in Austin, Texas, and will be exhibiting at the September 7-11, 2022 International Veterinary Emergency and Critical Care Symposium (IVECCS) in San Antonio, Texas, and at the October 13-15, 2022 Veterinary Cancer Society (VCS) Annual Conference in Norfolk, Virginia. Dogs, as with humans, go off their disease modifying chemotherapy approximately 40% of the time due to diarrhea, and dogs are a predictive model of the human situation. Jaguar expects that Canalevia could additionally receive FDA conditional approval, under the name Canalevia®-CA2, for the treatment of exercise-induced diarrhea (EID) in dogs in the next 6-8 months.
- **Jaguar's Canine Cancer: *Take C.H.A.R.G.E.* (Canine Health And ReGistry Exchange) initiative** launched with a special media event and performance in New York City on May 23, 2022. *Take C.H.A.R.G.E.* established the first-ever U.S. canine cancer national registry and cancer care index to assess the prevalence and incidence of cancer in dogs. The mission is important, because protecting dogs from cancer begins with knowing its impact by breed, type, age, gender, and location. The data may also provide insights to help better understand cancer in humans and the importance of managing side effects in human cancer therapy. On August 10, 2022, Gallup published an **article** providing their analysis of results from *Take Charge of Canine Cancer*, the first-ever nationally representative survey of U.S. dog owners' experiences with the disease. The survey, which comprises the Index component of the *Take C.H.A.R.G.E.* initiative, found that of the 67% of Americans who have had at least one dog in the past 10 years, nearly one in five - equating to approximately 30 million people - say at least one of their dogs has experienced cancer. Gallup's article, which can be viewed by clicking **here**, also describes the *Take C.H.A.R.G.E.* initiative.

Ongoing business development initiatives in 2022:

- In June 2022, as announced, Jaguar entered an exclusive license and services agreement with Ontario, Canada-based SynWorld Technologies Corporation (SynWorld) for the treatment of diarrhea in dogs in the China market with Jaguar's Canalevia drug product. Per the terms of the agreement, Jaguar has engaged SynWorld as a service provider to obtain regulatory approval of the product for Jaguar in China and granted SynWorld a license to commercialize and sell this product following such approval in China. As consideration for the license, Jaguar is entitled to receive 60% of any profits

from sales of the product in China. If Jaguar reimburses SynWorld for the direct expense of obtaining regulatory approval in China, the profit sharing will be 80% and 20%, respectively, for Jaguar and SynWorld. The agreement also entails monthly license fee payments by SynWorld to Jaguar amounting to US $5.0 million in total during the initial two-year term of the agreement, realized as a commitment by SynWorld to make quarterly purchases of Jaguar common stock (purchased at market price in unregistered stock at the time of purchase). As consideration for the regulatory services to be provided by SynWorld, Jaguar will pay SynWorld a monthly service fee up to U.S. $5.0 million in total over the initial two-year term of the agreement in the form of unregistered Jaguar stock.

- In June 2022, as announced, Jaguar and Filament Health signed a letter of intent to enter a collaboration agreement to develop botanical prescription drugs for specific psychoactive target indications in the United States. The goal of the collaboration is to extend the botanical drug development skillsets of both companies in order to develop pharmaceutical-grade, standardized drug candidates and partner with a potential future licensee regarding the development and commercialization of these novel plant-based drugs for indications such as attention-deficit/hyperactivity disorder (ADHD) and social anxiety disorder. Jaguar's Entheogen Therapeutics Initiative (ETI) aims to discover and develop groundbreaking, novel, natural medicines derived from psychedelic and psychoactive plants for treatment of mood disorders, neurodegenerative diseases, addiction, and mental health disorders. Jaguar is in discussions with potential partners for this initiative.
- The Company is continuing to manage its relationship with Quadri Pharmaceuticals Store LLC (Quadri Pharma) following the execution on March 31, 2022 of an exclusive crofelemer distribution and license agreement for multiple target indications in Middle East markets. As announced, the agreement grants Quadri Pharma exclusive promotional, commercialization, and distribution rights for specified human indications of crofelemer in Bahrain, Kuwait, Qatar, Saudi Arabia, the United Arab Emirates, and Oman following regulatory approval to market crofelemer in these countries for the specified indications, including the indication currently approved in the U.S. for HIV-related diarrhea, and cancer therapy-related diarrhea. In addition, the agreement grants Quadri Pharma exclusive rights to distribute crofelemer in these countries in the immediate future under Named Patient Programs. Jaguar expects patients in this territory to be able to access crofelemer before the end of 2022.
- Jaguar is continuing efforts to forge additional license and business development relationships in key markets around the globe.

Updates about recent and currently active investigator-initiated trials of crofelemer:

- Investigator-initiated HALT-D trial evaluating crofelemer for preventing chemotherapy-induced diarrhea (CID) in HER2-positive breast cancer patients: The full results of this study, which were presented at the San Antonio Breast Cancer Symposium (SABCS 2021) in December 2021, are being submitted to a medical journal in 2022 for consideration for publication.
- Chronic idiopathic diarrhea in non-HIV adult patients
  - Study Name: *Yield of Diagnostic Tests and Management of Crofelemer for Chronic Idiopathic Diarrhea in Non-HIV Patients: A Pilot Study*
  - Location: University of Texas Health Science Center at Houston
- Functional diarrhea in non-HIV adult patients
  - Study Name: *A randomized, double-blind, placebo-controlled study to evaluate the safety, tolerability, and efficacy of crofelemer in subjects with functional diarrhea*
  - Location: Beth Israel Deaconess Medical Center, a Harvard Medical School institution in Boston

2022 SECOND QUARTER COMPANY FINANCIAL RESULTS:

Prescription product net revenue was approximately $2.9 million in the second quarter of 2022, representing an increase of approximately 12% over Mytesi net revenue in the first quarter of 2022, which totaled approximately $2.6 million, and an increase of approximately 641% over Mytesi net revenue in the second quarter of 2021, which totaled approximately $0.4 million.

"Mytesi total prescription volume increased 8.2% in the second quarter of 2022 over the first quarter of 2022," said Ian Wendt, Jaguar's Chief Commercial Officer. "As previously announced, the transition we completed this past January to a limited distribution network of specialty pharmacies resulted in a meaningful reduction in Mytesi distribution costs as well as a higher average net price. I am very pleased to report that we significantly outperformed the industry gross-to-net average in the second quarter of 2022 - as we did in both of the two previous quarters - for sales of our human prescription product. This improvement in our gross-to-net was largely a result of the efficiencies realized by the transition to a closed network of specialty pharmacies. This transition assists in the preparation of the Company's U.S. commercial distribution network for potential future indication expansion of crofelemer to other populations of patients with complex medical needs, such as CTD, inflammatory bowel disease, and SBS. Additionally, the transition has allowed us to begin utilizing sales and prescription data directly provided by our network of specialty pharmacies to more accurately track prescription metrics."

The Company believes the availability of Mytesi through specialty pharmacies represents a significant benefit to patients, as such pharmacies focus on complex and chronic conditions and offer a higher level of support for prior authorizations, appeals, adherence reminders and counseling, and home delivery options.

- **Mytesi Prescription Volume:** As stated above, Mytesi prescription volume increased 8.2% in the second quarter of 2022

over the first quarter of 2022. Prescription volume differs from invoiced sales volume, which reflects, among other factors, varying buying patterns among specialty pharmacies in the closed network as they manage their inventory levels.

- **Mytesi Net Product Revenue:** Mytesi net revenue during the second quarter of 2022 was approximately $2.8 million and approximately $2.6 million in the first quarter of 2022, an increase of approximately $0.2 million, or approximately 10%, quarter over quarter, and an increase of approximately 644% over Mytesi net revenue in the second quarter of 2021, which totaled approximately $0.4 million. The transition to a limited distribution network of specialty pharmacies, which was completed this past January, resulted in a meaningful reduction in Mytesi distribution costs and a higher average net price. As part of the process of transitioning to the closed specialty pharmacy network, the third and fourth quarters of 2021 were significantly impacted by the inventory draw-down of approximately 1,300 bottles of Mytesi across the Company's third-party logistics warehouse, wholesalers, distributors, and retail stores.
- **Mytesi Gross Product Revenue (Non-GAAP):** Mytesi gross revenue was approximately $3.7 million in the second quarter of 2022 and $3.4 million in the first quarter of 2022, representing an increase of approximately $0.3 million or 9% quarter over quarter, and a decrease of approximately 24% over Mytesi gross revenue in the second quarter of 2021, which totaled approximately $4.9 million.
- **Canalevia-CA1 Net Product Revenue:** Canalevia-CA1 (crofelemer delayed-release tablets), the Company's prescription drug product for the treatment of chemotherapy-induced diarrhea (CID) in dogs, became commercially available to veterinarians across the U.S. at the end of April 2022. Canalevia-CA1 net and gross revenue during the second quarter of 2022 were approximately $87.4 thousand.
- **Neonorm ™:** Revenues for the non-prescription Neonorm products and Jaguar's Animal Health business unit were minimal for the second quarters of 2022 and 2021, in accordance with the Company's primary focus on human health and prescription products.

Financial Highlights (in thousands)	Three Months Ended June 30,			
Gross product sales	2022	2021	$ change	% change
Mytesi	$ 3,671	$ 4,922	$ (1,251)	-34 %
Neonorm	15	6	9	60 %
Canalevia	87		87	100 %
Total gross product sales	3,773	4,928	(1,155)	-31 %
Sales rebates	(523)	(1,354)	831	-159 %
Sales discounts	(318)	(2,600)	2,282	-718 %
Sales returns	(11)	(48)	37	-336 %
Wholesaler fee	-	(541)	541	0 %
Net product sales	$ 2,921	$ 385	$ 2,536	87 %
Mytesi Sales: Gross to Net				
Gross sales	$ 3,671	$ 4,922	$ (1,251)	-34 %
Sales rebates, discounts and returns	(852)	(4,543)	3,691	-433 %
Net Mytesi Sales	2,819	379	2,440	87 %

Financial Highlights	Three Months Ended June 30,			
(in thousands, except per share amounts)	2022	2021	$ change	% change
Net product revenue	$ 2,921	$ 385	2,536	87 %
Loss from operations	$ (6,479)	$ (11,580)	5,101	-79 %
Net loss	$ (9,390)	$ (14,081)	4,691	-50 %
Net loss per share, basic and diluted	$ (0.12)	$ (0.31)		

- **Cost of Product Revenue:** Total cost of product revenue for the quarter ended June 30, 2022 was $0.5 million compared to $0.7 million for the quarter ended June 30, 2021. The decrease of $0.2 million was largely due to lower distribution and channel rebate/discount costs that resulted from the shift to the specialty pharmacies distribution model.
- **Research and Development:** The R&D expense was $2.5 million for the second quarter of 2022 compared to $3.9 million for the second quarter of 2021, a decrease of $1.4 million. Clinical, contract manufacturing, personnel and related benefits

decreased approximately $1.0 million in the second quarter of 2022 compared to the same period in 2021. During the second quarter of 2022 certain personnel and related benefits were capitalized as internally developed software costs for the Canine Cancer: *Take C.H.A.R.G.E.* Registry. Consulting, formulation and regulatory fees decreased $0.7 million from $0.9 million in the three months ended June 30, 2021 to $0.2 million in the same period in 2022. The decrease was due to lower clinical trial consulting costs.

- **Sales and Marketing:** The Sales and Marketing expense was $2.1 million for the second quarter of 2022 compared to $2.2 million for the second quarter of 2021, a decrease of $0.1 million.
- **General and Administrative:** The G&A expense was $4.3 million for the second quarter of 2022 compared to $5.1 million for the second quarter of 2021. The decrease of $0.8 million was largely due to a reduction of $0.1 million in personnel and related benefits, $0.5 million in public company expense and $0.1 in consulting costs. This is offset by increases of $0.03 million in travel expenses due to loosening of Covid-related travel restrictions, $0.1 million in rent and $0.7 million in Company financing activities.
- **Loss from Operations:** For the second quarter of 2022, the loss from operations was $6.5 million compared to a loss of $11.6 million in the second quarter of 2021, a decrease of $5.1 million.
- **Net Loss:** For the second quarter of 2022, the net loss attributable to common shareholders was approximately $9.4 million, compared to a net loss of $14.1 million in the second quarter of 2021, a decrease of approximately $4.7 million quarter over quarter. In addition to the loss from operations:
- Interest expense increased by $0.5 million from $2.0 million in the three months ended June 30, 2021 to $2.5 million for the same period in 2022 primarily due to interest from the royalty and note agreements.
- Change in fair value of financial instruments and hybrid instruments designated at fair value option (FVO) losses increased $1.2 million from a loss of $0.5 million in the three months ended June 30, 2021 to a gain of $0.7 million for the same period in 2022.
- Other expense increased by $1.1 million from $0.02 in the three months ended June 30, 2021 to $1.1 million for the same period in 2022 due to the foreign currency transactions.
- **Non-GAAP EBITDA:** Non-GAAP EBITDA for the second quarter of 2022 and the second quarter of 2021 was a net loss of $5.4 million and $10.8 million, respectively.

	Three Months Ending June 30,	
(in thousands)	2022	2021
	(unaudited)	
Net loss	$ (9,390)	$ (14,081)
Adjustments:		
Interest expense	2,536	2,009
Property and equipment depreciation	10	8
Amortization of intangible assets	422	422
Share-based compensation expense	1,017	892
Income taxes	-	-
Non-GAAP EBITDA	(5,405)	(10,750)
Impairment of indefinite-lived intangible assets		-
Loss on extinguishment of debt	-	
Series 3 warrants inducement expense		-
Series B convertible preferred stock inducement expense		
Non-GAAP Recurring EBITDA	$ (5,405)	$ (10,750)

Note Regarding Use of Non-GAAP Measures

The Company supplements its condensed consolidated financial statements presented on a GAAP basis by providing gross sales, non-GAAP EBITDA, and non-GAAP recurring EBITDA, which are considered non-GAAP under applicable SEC rules. Jaguar believes that the disclosure items of these non-GAAP measures provide investors with additional information that reflects the basis upon which Company management assesses and operates the business. These non-GAAP financial measures are not in accordance with GAAP and should not be viewed in isolation or as substitutes for GAAP net sales and GAAP net loss and are not substitutes for, or superior to, measures of financial performance in conformity with GAAP.

Gross sales percentages issued by the Company are based on gross sales figures that represent Mytesi orders placed by select Specialty

Pharmacies with Jaguar's third-party logistics warehouse, less allowances for rebates and discounts, which generate the cash flows for Napo Pharmaceuticals, Inc. ("Napo"), Jaguar's wholly owned subsidiary. Gross sales are 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. Gross sales are 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 have 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 specialty pharmacy discounts, Medicare rebates, Medicaid rebates, 340B discounts, ADAP rebates, VA rebates, copay program costs, prompt pay discounts, and returns based on historical trends to determine net sales.

The Company defines non-GAAP EBITDA as net loss before interest expense and other expense, depreciation of property and equipment, amortization of intangible assets, share-based compensation expense and provision for or benefit from income taxes. The Company defines non-GAAP Recurring EBITDA as non-GAAP EBITDA adjusted for certain non-recurring revenues and expenses. Company management believes that non-GAAP EBITDA and non-GAAP Recurring EBITDA are meaningful indicators of Jaguar's performance and provide useful information to investors regarding the Company's results of operations and financial condition.

Participation Instructions for Webcast
When: Monday, August 22, 2022, at 8:30 AM Eastern Time
Participant Registration & Access Link: **Click Here**

Replay Instructions for Webcast
Replay of the webcast on the investor relations section of Jaguar's website: (click here)

About Jaguar Health, Jaguar Animal Health, Napo Pharmaceuticals, & Napo Therapeutics

Jaguar Health, Inc. is a commercial stage pharmaceuticals company focused on developing novel, plant-based, non-opioid, and sustainably derived prescription medicines for people and animals with GI distress, including chronic, debilitating diarrhea. Jaguar Animal Health is a tradename of Jaguar Health. Jaguar Health's wholly owned subsidiary, Napo Pharmaceuticals, Inc., focuses on developing and commercializing proprietary plant-based human pharmaceuticals from plants harvested responsibly from rainforest areas. Our crofelemer drug product candidate is the subject of the OnTarget study, an ongoing pivotal Phase 3 clinical trial for prophylaxis of diarrhea in adult cancer patients receiving targeted therapy. Jaguar Health is the majority shareholder of Napo Therapeutics S.p.A. (f/k/a Napo EU S.p.A.), an Italian corporation established by Jaguar Health in Milan, Italy in 2021 that focuses on expanding crofelemer access in Europe.

For more information about Jaguar Health, please visit https://jaguar.health. For more information about Napo Pharmaceuticals, visit www.napopharma.com.

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.

Important Safety Information About Canalevia®-CA1

For oral use in dogs only. Not for use in humans. Keep Canalevia-CA1 (crofelemer delayed-release tablets) in a secure location out of reach of children and other animals. Consult a physician in case of accidental ingestion by humans. Do not use in dogs that have a known hypersensitivity to crofelemer. Prior to using Canalevia-CA1, rule out infectious etiologies of diarrhea. Canalevia-CA1 is a conditionally approved drug indicated for the treatment of chemotherapy-induced diarrhea in dogs. The most common adverse reactions included decreased appetite, decreased activity, dehydration, abdominal pain, and vomiting.

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian. Use only as directed. **It is a violation of Federal law to use this product other than as directed in the labeling. Conditionally approved by FDA pending a full demonstration of effectiveness under application number 141-552.**

See full Prescribing Information at Canalevia.com.

Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." These include statements regarding the Company's expectation that Jaguar will host an investor webcast on August 22, 2022, the Company's expectation that the two late-stage clinical events on which the Company is focused in the next approximately 6 to 12 months will be transformational in terms of value creation and recognition for the Company, Jaguar's expectation that an investigator-initiated proof-of-concept study of crofelemer for SBS will be completed in 2022, supporting the potential for expanded patient access to crofelemer in Europe in 2023 for SBS patients, Jaguar's expectation that the third-party investigator for this SBS proof-of-concept study will present the study results in December 2022 at a global GI conference in Dubai, the Company's expectation that enrollment in the OnTarget trial will complete in the first half of 2023, Jaguar's expectation that ODD status in the EU for crofelemer for SBS will support Napo Therapeutics' plans to make crofelemer available through Early Access Programs in the EU for SBS, Jaguar's expectation that participation in Early Access Programs in the EU for SBS will provide a potential opportunity for meaningful revenue generation in addition to the ability to impact important morbidity, mortality, and the cost of care for chronically ill SBS patients for whom no good therapeutic options exist, the expectation that the global SBS market will reach

$4.6 billion by 2027, the Company's expectation that it will pursue a tropical disease priority review voucher under the FDA's financial incentive program to develop drugs for tropical diseases such as cholera, Jaguar's expectation that the Company will exhibit at IVECCS in 2022 and at the 2022 VCS Annual Conference, Jaguar's expectation that Canalevia could receive FDA conditional approval, under the name Canalevia-CA2, for the treatment of EID in dogs in the next 6-8 months, and Jaguar's expectation that patients in Bahrain, Kuwait, Qatar, Saudi Arabia, the United Arab Emirates, and Oman may be able to access crofelemer before the end of 2022 for specified indications once such indications. 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 several 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.

[1] Gibson RJ and Stringer AM. Chemotherapy-induced diarrhoea. Curr Opin Support Palliat Care 2009; 3: 31-35

[2] Pablo C. Okhuysen, M.D., *The impact of cancer-related diarrhea on changes in cancer therapy patterns: Real world evidence*

[3] Eric Roeland, M.D., FAAHPM, *Healthcare utilization and costs associated with cancer-related diarrhea*

[4] http://www.crohnscolitisfoundation.org/sites/default/files/legacy/assets/pdfs/short-bowel-disease-crohns.pdf

[5] http://www.pharmabiz.com/NewsDetails.aspx?aid=84221&sid=2

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SOURCE: Jaguar Health, Inc.

accesswire.com
https://www.accesswire.com/712975/Jaguar-Health-Provides-Company-Updates-and-Reports-2022-Second-Quarter-Financials