Jaguar Health Comments on FDA's Decision to Set Packaging Limits for Anti-Diarrhea Medicine Loperamide (Imodium) to Encourage Safe Use

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Mytesi® Novel Anti-Diarrheal Mechanism of Action Distinguished as Non-Opioid

SAN FRANCISCO, CA / ACCESSWIRE / September 23, 2019 / Jaguar Health, Inc. (NASDAQ:JAGX) ("Jaguar" or the "Company") issued the following comments today regarding the September 20, 2019 announcement by the U.S. Food and Drug Administration (FDA) that it has set packaging limits for anti-diarrhea medicine loperamide (Imodium) to encourage safe use. As stated in the FDA's announcement, loperamide acts on opioid receptors in the gut to slow the movement in the intestines and decrease the number of bowel movements. It is safe at approved doses, but when much higher than recommended doses are taken, it can lead to serious problems, including severe heart rhythm problems and death.

"We applaud the FDA's decision to set packaging limits for loperamide to encourage safe use, and we would like to take this opportunity to issue a reminder that Mytesi, Jaguar's anti-secretory anti-diarrheal approved for the symptomatic relief of noninfectious diarrhea in adult patients with HIV/AIDS on antiretroviral therapy (ART), is a non-opioid, non-antibiotic, non-addictive drug approved for chronic use," Lisa Conte, Jaguar's president and CEO commented. "Unlike diarrhea medicines such as Imodium® and Lomotil® - opioids that work by slowing movement through the GI tract, which often causes constipation - Mytesi modulates and normalizes the functional imbalance of intestinal fluid and is locally acting in the gut. Mytesi's first-in-class mechanism of action and demonstrated safety profile is particularly important in anti-retroviral therapy patients, where maintenance of normal gut function is important to facilitate appropriate absorption of life-saving ART medications."

A Phase 3 study is planned to investigate the use of crofelemer for cancer therapy-related diarrhea, and crofelemer may hold promise for treating secretory diarrhea in patients receiving chemotherapy, novel targeted cancer therapy agents, and other life-saving chronic medications, if approved for other such indications.

Crofelemer is in development for multiple possible follow-on indications, including orphan-drug indications for infants and children with congenital diarrheal disorders (CDDs) and short bowel syndrome (SBS); supportive care for inflammatory bowel disease (IBD); irritable bowel syndrome (IBS); and for idiopathic/functional diarrhea.

"As someone living with HIV, I've experienced both chronic and episodic diarrhea since my diagnosis," commented Josh Robbins, an HIV activist and a consultant to Napo. "Over-the-counter opioids such as Imodium were unsatisfactory short-term stops because they caused me constipation, bloating, lower back pain, and essentially made things worse for me. It was like treating a headache by placing a bucket over my head. They were not effective for me. I've been taking Mytesi for 28 months, and besides the peace of mind that this medication is not absorbed in my blood steam, not affecting my viral load or CD4 counts, and has no drug-drug interactions, I now live a life with normal bowl movements and I feel great."

To help address loperamide abuse and misuse, per the FDA's announcement, FDA approved changes to the packaging for tablet and capsule forms of the brand-name over-the-counter (OTC) anti-diarrheal medicines Imodium A-D, Imodium Multi-Symptom Relief, and Be Health Loperamide HCl Capsules. These changes limit each carton to no more than 48 mg of loperamide and require the tablets and capsules to be packaged in individual doses.

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.

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 development of possible follow-on indications for crofelemer. 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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