



Jaguar Health Announces Publication of Onco'Zine Article Underscoring the Importance of Controlling Diarrhea in Cancer Patients

June 13, 2022

Diarrhea is also a prevalent side effect in dogs undergoing cancer treatment; managing diarrhea can be important to maintain successful cancer treatment in both humans and dogs

SAN FRANCISCO, CA / ACCESSWIRE / June 13, 2022 / Jaguar Health, Inc. (NASDAQ:JAGX) today announced that an article by Dr. Kathleen Kiernan Harnden titled [Alleviating Targeted Therapy Side Effects: Essential for Patient QOL and Best Outcomes](#) was published June 8, 2022 in Onco'Zine.

Highlights from the article:

- As many as 50% to 100% of cancer patients experience diarrhea, depending on their treatment regimen.
- Diarrhea can severely impact quality of life, including the ability to function well at work, care for children, travel, participate in outdoor activities and achieve good quality sleep.
- Even mild diarrhea over days and weeks can lead to weight loss, clinical deterioration, and mental stress. At its worse, it is a debilitating and potentially life-threatening toxicity that can cause dehydration, electrolyte imbalances, renal insufficiency, malnutrition and extreme dehydration, all of which can lead to cardiovascular compromise and death.
- As the use of targeted therapies increases, so too does the need to better control side effects like diarrhea.
- Regardless of the individual circumstances while on treatment, it is imperative to control difficult side effects so patients can remain on treatment and have the best chance of fighting their cancer.
- Limited options are available for controlling diarrhea. Antidiarrheal use is challenging because patients typically use them after experiencing one or more diarrhea episodes. The available medications also cause constipation.

"Management of cancer treatment-related side effects such as diarrhea is critical in patients - whether the patient is a human or a dog," said Lisa Conte, Jaguar's President, CEO and Founder. "Studies have found the incidence of chemotherapy-induced diarrhea (CID) to be one of the three most prevalent side effects in dogs undergoing cancer treatment, and managing side effects such as CID can be important to maintain successful cancer treatment. The results of a Gallup survey of dog owners, conducted as part of the recently launched [Jaguar Health Canine Cancer: Take C.H.A.R.G.E.](#) (Canine Health And ReGistry Exchange) initiative, make it clear that the side effect of diarrhea is a significant concern among owners of dogs diagnosed with cancer. Of respondents who indicated that they decided not to treat their dog's cancer, [38 percent indicated that their decision was due to concern about treatment side effects.](#)"

Jaguar's 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.

The company's Canalevia[®]-CA1 prescription drug product for the treatment of chemotherapy-induced diarrhea (CID) in dogs [received conditional approval from the FDA on December 21, 2021](#) and is now available from multiple leading veterinary distributors in the U.S.

Onco'Zine, a publication of The International Oncology Network, was created to inform, educate, and support physicians and healthcare professionals treating cancer patients. Kathleen Kiernan Harnden, MD MBA, is the Director of the Breast Medical Oncology Program at Inova Schar Cancer Institute in Fairfax, Virginia.

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 Canalevia[®]-CA1

Canalevia-CA1 (crofelemer delayed-release tablets) is the first and only prescription product that is FDA conditionally approved to treat chemotherapy-induced diarrhea (CID) in dogs. Canalevia-CA1 is an oral formulation of crofelemer, an active pharmaceutical ingredient isolated and purified from the *Croton lechleri* tree. Canalevia-CA1 is conditionally approved by the FDA under application number 141-552. Conditional approval allows for commercialization of the product while Jaguar continues to collect the substantial evidence of effectiveness required for a full approval. Jaguar has received Minor Use in a Major Species (MUMS) designation from the FDA for Canalevia-CA1 to treat CID in dogs. FDA has established a "small number" threshold for minor use in each of the seven major species covered by the MUMS act. The small number threshold is currently 70,000 for dogs, representing the largest number of dogs that can be affected by a disease or condition over the course of a year and still have the use qualify as a minor use.

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.**

Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." 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
Jaguar-JAGX

SOURCE: Jaguar Health, Inc.

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