



## **Napo Pharmaceuticals Surveys of Neurologists, Patients, and Caregivers Regarding Amyotrophic Lateral Sclerosis (ALS) Treatment Indicate Real World Burden of Diarrhea and Potential Treatment Interruption**

August 16, 2023

***Jaguar Health family company Napo Pharmaceuticals focuses on essential supportive care and management of neglected toxicities in multiple complicated disease states***

**SAN FRANCISCO, CA / ACCESSWIRE / August 16, 2023 / [Napo Pharmaceuticals, Inc.](#)** (Napo), a [Jaguar Health, Inc.](#) (NASDAQ:JAGX) family company, today announced that the results of a Napo-sponsored survey of 15 US neurologists who treat patients with amyotrophic lateral sclerosis (ALS), and the results of a corresponding Napo-sponsored survey of 15 US individuals who are either ALS patients or caregivers of an ALS patient, indicate that the burden of diarrhea associated with a commonly used treatment ("the ALS drug") for this rare progressive neurodegenerative disease may be higher than previously understood. Napo focuses on essential supportive care and management of neglected toxicities in multiple complicated disease states.

### **Highlights of the survey of neurologists:**

- 87% reported the severity of diarrhea associated with the ALS drug as moderate to severe.
- Over half reported stopping a patient's use of the ALS drug due to diarrhea.
- 13% reported that ALS patients in their care had been hospitalized or required other medical interventions due to diarrhea while taking the ALS drug.
- 79% reported the impact of diarrhea on the quality of life of patients on the ALS drug as moderate to severe.
- 40% reported that patients in their care had skipped doses of the ALS drug due to diarrhea.

### **Highlights of the survey of ALS patients & caregivers:**

- 93% of participants rated the severity of the diarrhea as moderate or higher. 27% rated it severe.
- Similarly, 93% rated the impact on quality of life as moderate or greater. 40% rated the impact severe.
- Almost half reported stopping the ALS drug due to diarrhea.
- 40% reported requiring hospitalization or some other medical intervention due to diarrhea.
- 67% of participants said diarrhea was experienced throughout the time on the ALS drug, with 20% reporting that symptoms increased over time.
- Slightly less than half took any medications to manage their diarrhea.

"The results of both surveys indicate that chronic diarrhea may be a substantial compliance issue of patients receiving the ALS drug, and that the severity of the diarrhea - and its impact on patient quality of life, dignity, and the ability of patients to remain on the drug - may be higher than previously understood," said Lisa Conte, Jaguar's president and CEO. "The data from the Napo-sponsored survey of individuals who are either ALS patients or caregivers of an ALS patient underscores the importance of real-world patient reported outcomes (PRO) data and the importance of managing side effects for critical diseases such as ALS or cancer. PRO is the primary endpoint of Napo's Phase 3 [OnTarget](#) clinical trial of crofelemer for preventative treatment of diarrhea in adult cancer patients receiving targeted therapy with or without cytotoxic chemotherapy, for which top line results are expected to be available in late October of this year."

"Crofelemer is a non-opioid, plant-derived molecule which is not absorbed systemically. It is a gastrointestinal chloride channel modulator. In alignment with our company focus on rare diseases, which includes clinical programs in short bowel syndrome and microvillus inclusion disease, we believe it is important to evaluate the potential of crofelemer's novel mechanism of action to improve the quality of life of patients treated with the ALS drug and help prevent discontinuations and dose reductions of their disease modifying medications due to diarrhea," Conte continued.

ALS, also known as Lou Gehrig's Disease, is a rare neurological disease that affects motor neurons - those nerve cells in the brain and spinal cord that control voluntary muscle movement. Voluntary muscles are those we choose to move to produce movements like chewing, walking, and talking. The disease is progressive, meaning the symptoms get worse over time. ALS has no cure and there is no effective treatment to reverse its progression.

There are currently an estimated 30,000 ALS patients in US, and by 2040 ALS incidence is predicted to increase worldwide by 70%, according to The ALS Association.

## About Crofelemer

Crofelemer is a novel, oral plant-based prescription medicine purified from the red bark sap, also referred to as "dragon's blood," of the *Croton lechleri* tree in the Amazon Rainforest. Napo has established a sustainable harvesting program, under fair trade practices, for crofelemer to ensure a high degree of quality, ecological integrity, and support for Indigenous communities.

## About the Jaguar Health Family of Companies

Jaguar Health, Inc. (Jaguar) is a commercial stage pharmaceuticals company focused on developing novel proprietary prescription medicines sustainably derived from plants from rainforest areas for people and animals with GI distress, specifically overactive bowel, which includes symptoms such as chronic debilitating diarrhea, GI urgency, and GI incontinence. Jaguar family company Napo Pharmaceuticals focuses on developing and commercializing human prescription pharmaceuticals. Napo Pharmaceuticals' crofelemer drug product candidate is the subject of the [OnTarget](#) study, an ongoing pivotal Phase 3 clinical trial for preventative treatment of chemotherapy-induced overactive bowel (CIOB) in adults with cancer on targeted therapy. Jaguar family company Napo Therapeutics is an Italian corporation Jaguar established in Milan, Italy in 2021 focused on expanding crofelemer access in Europe and specifically for rare diseases. Jaguar Animal Health is a Jaguar tradename. Magdalena Biosciences, a joint venture formed by Jaguar and Filament Health Corp., is focused on developing novel prescription medicines derived from plants for mental health indications.

For more information about Jaguar Health, please visit <https://jaguar.health>. For more information about Napo Pharmaceuticals, visit [www.napopharma.com](http://www.napopharma.com). For more information about Napo Therapeutics, visit [napotherapeutics.com](http://napotherapeutics.com). For more information about Magdalena Biosciences, visit [magdalenabiosciences.com](http://magdalenabiosciences.com).

## Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." These include statements regarding the expectation that chronic diarrhea may be a substantial compliance issue of patients receiving the ALS drug, and that the severity of the diarrhea - and its impact on patient quality of life, dignity, and the ability of patients to remain on the drug - may be higher than previously understood, the expectation that top line data from the OnTarget trial will be available in late October of this year, and statements about the possibility that crofelemer's novel mechanism of action may have potential to improve the quality of life of patients treated with the ALS drug and help prevent discontinuations and dose reductions due to diarrhea. 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:

[hello@jaguar.health](mailto:hello@jaguar.health)  
Jaguar-JAGX

**SOURCE:** Jaguar Health, Inc.

[accesswire.com](http://accesswire.com)  
<https://www.accesswire.com/774413/Napo-Pharmaceuticals-Surveys-of-Neurologists-Patients-and-Caregivers-Regarding-Amyotrophic-Lateral-Sclerosis-ALS-Treatment-Indicate-Real-World-Burden-of-Diarrhea-and-Potential-Treatment-Interruption>