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Jaguar Health seeks pharma partner for plant-based cancer supportive care drug, CEO says

by Deborah Balshem

Jaguar Health [NASDAQ:JAGX] is actively seeking co-promotion partners in the US as its flagship plant-based prescription medicine Mytesi nears potential US approval for a second indication in oncology, said CEO Lisa Conte.

The San Francisco-based commercial stage pharmaceutical company – which is focused on treating gastrointestinal distress using prescription medicines sustainably derived from rainforest plants – expects top-line results within weeks for its Phase 3 pivotal trial of crofelemer for preventative treatment of chemotherapy-related diarrhea, the number one side effect for cancer patients, according to Conte.

Since Jaguar already markets crofelemer under the brand name Mytesi for symptomatic relief of non-infectious diarrhea in adults with HIV/AIDS on antiretroviral therapy, the company is highly optimistic that the Food and Drug Administration (FDA) will grant a supplemental new drug indication for chemotherapy-induced overactive bowel support for adults, pending positive results from Phase 3, she noted. With approval, commercial sales are anticipated to start by mid-2024, Conte said.

A logical co-promotion partner would be a large pharmaceutical company in the supportive oncology care space, according to Conte. An ideal agreement would provide Jaguar with an upfront fee for access to results, with the two companies both contributing to the cost of commercialization and sharing in the profits, she said.

An industry banker said examples of potential partners in the cancer-supportive care space include Switzerland-based Helsinn, Thousand Oaks, California-based Amgen [NASDAQ:AMGN] and SanDiego, California-based Heron Therapeutics [NASDAQ:HRTX].

Mytesi has a novel mechanism of action that modulates chloride secretion in the gastrointestinal tract, reducing excessive chloride and accompanying water flow and relieving watery diarrhea. The HIV/AIDS supportive care market is relatively small but significantly larger for cancer-supportive cancer, Conte noted.

She pointed to the chemo-induced nausea/vomiting support care market as an analogous sector, which is estimated at USD 4bn globally. “There are roughly 1.1 million cancer patients receiving treatment in the US alone, with every single patient a potential candidate,” the CEO added.

The current standard of care for chemotherapy-related diarrhea is to take cancer patients off treatment or give them a sub-therapeutic dose, Conte said.

Non-US licensing partners sought

While Jaguar’s priority right now is to find the right partner in the US, the company is also interested in traditional out-licensing partners for international sales, similar to its March 2022 agreement that grants Quadri Pharmaceuticals exclusive promotional, commercialization and distribution rights for specified human indications of crofelemer in Bahrain, Kuwait, Qatar, Saudi Arabia, the United Arab Emirate and Oman.

Elsewhere in its pipeline, Jaguar has completed Phase 2 trials for irritable bowel syndrome-diarrhea predominant and is supporting an investigator-initiated trial for idiopathic/functional diarrhea. It recently completed a Phase 1 trial for Inflammatory bowel disease and is in pre-clinical studies for inflammatory diarrhea, including COVID-19-associated diarrhea.

In liquid form, Jaguar is in proof-of-concept studies for symptomatic relief of diarrhea from cholera and in Phase 2 trials for the rare diseases of short bowel syndrome with intestinal failure (SBS-IF) and congenital diarrheal disorders (CDD), with results expected before the end of 2023 and in 2024. Published data could support reimbursed early patient access to crofelemer for SBS-IF or CDD potentially in 2024, Conte noted.

Crofelemer already has been granted Orphan Drug Designation by the FDA and the European Medicines Agency for both microvillus inclusion (MVID) and short bowel syndrome with intestinal failure. MVID, a CDD, is a catastrophic medical situation for pediatric patients for which there are currently no approved drug treatments.

Crofelemer is extracted and purified from the red bark sap of the Croton lechleri tree in the Amazon Rainforest. Mytesi is the only oral FDA-approved drug under botanical guidance.

Animal health

Though Conte said 90% of Jaguar's focus is on human health, it also has an animal health division. Its canine-specific crofelemer formulation, Canalevia-CA1, is conditionally approved for the treatment of chemotherapy-induced diarrhea in dogs and became commercially available in April 2022. According to Conte, more than 50% of household dogs in the US are diagnosed with cancer.

Jaguar Animal Health is also pursuing conditional market approval in the US this year for Canalevia-CA2 for exercise-induced diarrhea in dogs.

Jaguar has 42 employees. Its market cap was approximately USD 6.3m at press time.

For 2Q23, net revenue for Mytesi was approximately USD 2.6m and approximately USD 39,100 for Canalevia-CA1, with an EBITDA loss of USD 7.7m. The company also derives minimal revenue from non-prescription products for calves and foals.

Since November 2022, Jaguar has issued "going concern" warnings in each of its quarterly financial statements, stating it may not have enough cash to fund its operating plan for another year. When asked, Conte pointed to the company's imminent pivotal phase 3 trial results, which if positive, "indicate a strategic focus for a commercial co-promotional partnership for the cancer therapy-related diarrhea indication, including non-dilutive funding."

Jaguar works with patent attorney Margaret Brivanlou at Ballard Spahr and Donald Reinke and Michael Lee at Reed Smith.

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