

Drug Application For Chemo-induced Diarrhea In Dogs Moving Forward

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SAN FRANCISCO Jan. 14, 2014 /PRNewswire/ -- An investigational new animal drug application (INADA) number has been received by Napo Pharmaceuticals, Inc. for its lead animal drug candidate, SP-303, which is isolated and purified from *Croton lechleri*, a medicinal plant sustainably harvested from the rain forest. The target indication is chemotherapy-induced diarrhea ("CID") in dogs.

The INADA will be assigned to Jaguar Animal Health, Inc. ("Jaguar") a subsidiary of Napo formed to develop and commercialize proprietary health solutions for the global animal health marketplace, based on an exclusive worldwide license to Napo's drug and natural product pipeline.

Jaguar's Drug Business:

The companies expect to file 5-6 additional INADAs for various products in the gastro-intestinal, infectious disease, and metabolic disease areas, each of which has substantial and relevant animal and human clinical testing completed and available for regulatory filings. The target species include dogs, cats, and horses.

There are <70,000 dogs who suffer from CID, a specialty target opportunity for which the company is seeking MUMS act designation ("Minor Use and Minor Species Animal Health Act"). The MUMS act provides innovative ways to bring products to market for small populations of affected animals and allows the sponsor to make the drug available before collecting all necessary effectiveness data, but after proving the drug is safe in accordance with the full FDA approval standard and showing that there is a reasonable expectation of effectiveness. This provision was modeled on the "Orphan Drug Act" for humans. The company hopes to file a new animal drug application for this indication in 2014.

Other target markets for Jaguar's drug pipeline include diarrhea in the general dog and cat population, for which ~8% of the companion animal populations seek treatment from a veterinarian (138 million dogs, 150 million cats; US/EU); severe acute debilitating diarrhea in adult horses and foals (including Salmonella and C. difficile induced diarrhea); and insulin-resistant diabetes in dogs, cats, and horses.

Jaguar's nutraceutical business:

Jaguar is studying and developing distinct nutraceutical formulations of products derived from *Croton lechleri* for applications in calves, horses, and camels initially, with the expectation of expanding to other food, farm, and high value/race animals in the future. Currently, Jaguar has an ongoing study of a nutraceutical product, SB-300 -- a standardized botanical extract derived from *Croton lechleri* in neonatal dairy calves challenged with E. coli at Cornell University's School of Veterinary Medicine. This study is a follow-on to a proof of concept study of SB-300 conducted earlier this year by Cornell, which tested the nutraceutical in 82 dairy calves in a placebo-controlled study during a Salmonella outbreak. The results of the earlier study were a significant improvement in stool formation scores of calves treated with SB-300. There are ~35 million calves born each year in the US, with about 15-50% incidence of diarrhea, also known as scours in cattle. Affected calves may die within a day if they are not treated promptly. According to "Cattle Today" magazine, scours causes more financial loss to producers than any other disease-related problems. Worldwide, the cattle population is about 8 times that in the US, with scours sometimes wiping out entire herds, threatening livelihood and food security for emerging market populations.

Also ongoing is a study of SB-300 in camels at the Camel Hospital in Dubai.

About Jaguar:

Jaguar Animal Health, Inc. was formed to develop and commercialize naturally derived solutions -- drugs, nutraceuticals, and food supplements-- for the global animal health marketplace. Jaguar has the exclusive worldwide veterinary rights to

Napo's drug and natural product pipeline. Jaguar's strategy is to merge the high margin drug and nutraceutical business model with the high-volume food supplement model, addressing health and food security needs on a global basis.

SOURCE Napo Pharmaceuticals, Inc.