



New Analysis of Data in Over 21,000 People Living with HIV Shows Diarrhea Continues to be an Issue and Has Not Declined Significantly Over Time

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Results Reported at the 22nd International AIDS 2018 Conference in Amsterdam, Netherlands

SAN FRANCISCO, CA / ACCESSWIRE / July 24, 2018 / Napo Pharmaceuticals, Inc. (Napo), a human health company developing and commercializing novel gastrointestinal prescription products from plants used traditionally in rainforest areas, and a wholly-owned subsidiary of Jaguar Health, Inc. (NASDAQ: JAGX) (Jaguar), announced today the results of an analysis conducted to examine whether the rate of HIV-associated diarrhea has changed over time. The analysis of data, sourced from the National Institutes of Health (NIH) clinicaltrials.gov database, revealed that 18% of HIV patients experience diarrhea and the rates have not declined significantly over time. The analysis includes data from 38 U.S. clinical trials from 2008-2016 in more than 21,000 patients. The results were reported at the International AIDS 2018 Conference (AIDS 2018) on Tuesday, July 24 in Amsterdam, Netherlands. The poster will be available on the AIDS 2018 website on July 24, 2018 at this [link](#).

With the introduction of newer antiretroviral (ARV) drug therapy, there has been a reduction in the incidence of ARV-induced diarrhea. However, a significant portion of this patient population still suffers from diarrhea caused by HIV enteropathy. In the recent post-combination antiretroviral therapy (cART) era, there has been little available data on the prevalence of diarrhea in the HIV population due to any cause.

The authors examined data from 38 HIV clinical trials conducted between 2008 and 2016 with a combined total of over 21,000 patients. The analysis included data from pivotal efficacy intervention trials conducted in the U.S., including multinational trials, and both comparative and switch studies were evaluated. The incidence of diarrhea reported in each trial was examined for both the interventional treatment and any comparators. Key results of this analysis showed:

- 38 trials met the inclusion criteria with 21,066 trial subjects receiving cART, 11,821 subjects received interventional therapy and 9,245 received a comparator regimen;
- 21 of these trials enrolled naïve (never had treatment) subjects; 11 enrolled treatment experienced subjects who were undetectable in a 'switch' strategy, and 5 enrolled subjects as treatment experienced failing their current regimen; 1 study had two arms--one naïve and one experienced (switch);
- The weighted average of reported diarrhea incidence in those who received interventional regimens vs. those who received comparator regimens was 17.50% and 17.88%, respectively;
- The weighted average of reported diarrhea incidence was significantly higher for naïve subjects vs. experienced subjects: 19.72% vs. 13.74%, respectively ($P<0.001$)

These findings are consistent with a 2014 survey that revealed that approximately 20% of subjects reported diarrhea/loose stools at the time of their visit to their HIV healthcare provider.

"There is a perception that diarrhea is no longer a problem in HIV. However, our analysis proved that even in the modern cART era, in patients who are virally suppressed, there is still a significant proportion of patients that experience diarrhea," commented David Asmuth, MD, Professor, Division of Infectious Diseases, Department of Internal Medicine, UC Davis Medical Center and lead author of the study. "The newer cART regimens may not be contributing to diarrhea. However, it is a myth that they have 'cured' diarrhea. The rates of diarrhea reported in the FDA-approved package inserts may contribute to this myth, as they often reflect only diarrhea that is attributed to the drug, and they may not capture pre-existing diarrhea or diarrhea attributed to HIV enteropathy. We saw this when comparing the overall diarrhea rates reported in the trials to those in the package inserts. The bottom line is that, while the newer ARVs have certainly helped decrease rates of diarrhea, diarrhea stemming from HIV enteropathy continues to be a significant problem--one that ARVs cannot fix."

"We must continue to educate healthcare professionals, people living with HIV and patient advocates about the important and neglected comorbidity of diarrhea in people living with HIV--and about available treatment options," said Lisa Conte, Jaguar's president and CEO.

The poster for this data presentation is available [here](#).

About Napo Pharmaceuticals, Inc.

San Francisco-based Napo Pharmaceuticals, Inc. (Napo), focuses on developing and commercializing proprietary human gastrointestinal pharmaceuticals for the global marketplace from plants used traditionally in rainforest areas. Napo is a wholly-owned subsidiary of Jaguar Health, Inc.,

a commercial stage pharmaceuticals company focused on developing novel, sustainably derived gastrointestinal products for both human prescription use and animals on a global basis.

For more information about Jaguar, please visit jaguar.health. For more information about Napo, visit napopharma.com.

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