

Global phase 3 trial of zoliflodacin

September 30 2019



Credit: CC0 Public Domain

The Global Antibiotic Research and Development Partnership (GARDP), a not for profit organisation developing new treatments for drug resistant infections, and Entasis Therapeutics (NASDAQ: ETTX), a clinical-stage biopharmaceutical company focused on the discovery and development of novel antibacterial products, today jointly announced the initiation of a global phase 3 pivotal trial of zoliflodacin. Zoliflodacin is

a novel, first-in-class oral antibiotic being developed for the treatment of uncomplicated gonorrhoea. Following positive phase 2 results previously published in the *New England Journal of Medicine (NEJM)*, Entasis and GARDP have partnered to complete late stage development, with GARDP fully-funding and sponsoring the global phase 3 trial.

Gonorrhoea is a common sexually transmitted infection (STI) affecting both men and women, particularly between 15 and 24 years old. Globally the infection rate of gonorrhoea is increasing, with 87 million new cases estimated each year. Uncomplicated gonorrhoea infections carry high morbidity, enhance transmission of other sexually transmitted diseases and are highly stigmatized. Gonorrhoea is caused by the bacterium *Neisseria gonorrhoeae*, which has progressively developed resistance to globally recommended treatments and has been identified by the World Health Organization as among a family of 'priority pathogens' posing the greatest threat to global health.

Teodora Wi, WHO Medical Officer for STIs, said: "Gonorrhoea rates are increasing, resulting in substantial morbidity and a huge psychosocial and economic cost worldwide. At the same time, we are observing increasing resistance to the last line-options for treatment in *Neisseria gonorrhoeae*. That is why there is an urgent need for new treatments and why the World Health Organization is supporting GARDP."

"The initiation of the phase 3 trial of zoliflodacin is an important milestone and brings hope for people affected by this disease. Our partnership with Entasis is critical for preventing the dire scenario of untreatable gonorrhoea and controlling this infection," said Dr. Manica Balasegaram, Executive Director of GARDP. "The global nature of the trial, across four continents, represents our commitment to ensuring this treatment is available to anyone who needs it, wherever they live."

The trial is expected to enrol approximately 1,000 adults with urogenital

gonorrhoea from clinical trial sites in the United States, Netherlands, Thailand and South Africa. Patients included in the trial will be randomized (2:1) to receive either zoliflodacin or a combination of ceftriaxone and azithromycin and will be assessed one week later for persistence of the infection. Data from the phase 3 clinical trial is anticipated in 2021.

"The phase 3 trial of zoliflodacin marks the last major clinical trial for our gonorrhoea program. Entasis' partnership with GARDP reflects our commitment to enable global access of this potential novel oral treatment for a disease that is quickly becoming resistant to all currently available antibiotics," said Manos Perros, Ph.D., President and Chief Executive Officer of Entasis Therapeutics. "We both believe a solution lies with an oral treatment option, which not only overcomes existing resistance but also offers significant benefits compared to the current standard of care of one or more intramuscular injections. We look forward to continuing our relationship with GARDP as we progress this global phase 3 trial."

Under the partnership agreement, GARDP is responsible for the phase 3 trial and pharmaceutical development activities for zoliflodacin to support regulatory approval and market access and availability. GARDP has commercial rights to zoliflodacin in up to 168 low- and select [middle-income countries](#), while Entasis retains commercial rights in the rest of the world. The phase 3 trial initiation marks an important milestone for this novel industry and non-profit partnership in jointly developing a novel antibiotic and building a strategic plan for successful market access within the countries that have high rates of [gonorrhoea](#) and for patients who need it most.

More information: Stephanie N. Taylor et al. Single-Dose Zoliflodacin (ETX0914) for Treatment of Urogenital Gonorrhoea, *New England Journal of Medicine* (2018). [DOI: 10.1056/NEJMoa1706988](https://doi.org/10.1056/NEJMoa1706988)

Provided by Global Antibiotic Research & Development Partnership

Citation: Global phase 3 trial of zoliflodacin (2019, September 30) retrieved 27 April 2024 from <https://medicalxpress.com/news/2019-09-global-phase-trial-zoliflodacin.html>

This document is subject to copyright. Apart from any fair dealing for the purpose of private study or research, no part may be reproduced without the written permission. The content is provided for information purposes only.