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Novartis receives FDA approval for Egaten® for the treatment of fascioliasis, a neglected tropical disease

- *Egaten is the only drug approved in the US for the treatment of people with fascioliasis and is currently the only treatment recommended by the WHO*
- *Fascioliasis, commonly known as liver fluke infestation, is estimated to infect 2.4 million people globally¹*
- *Novartis has been donating Egaten to the WHO since 2005, helping to treat around 2 million patients in more than 30 countries*
- *FDA approval reinforces the company's commitment to reduce the burden of neglected tropical diseases including fascioliasis, leprosy and malaria*

Basel, Switzerland, February 13, 2019 – Novartis announced today that the US Food and Drug Administration (FDA) has approved Egaten® (triclabendazole) for the treatment of fascioliasis in patients six years of age and older. This makes Egaten the only FDA-approved drug for people with this disease and is expected to facilitate broader access to this important drug not only in the US, but also in affected countries worldwide.

“Novartis has a long-standing commitment to addressing global health challenges and supporting disease elimination efforts, in diseases such as leprosy, malaria and fascioliasis,” said Vas Narasimhan, CEO of Novartis. “Today’s FDA approval of Egaten is another important milestone that we believe will help further expand access to this one-day treatment, taking us a step closer toward disease elimination.”

Fascioliasis, commonly known as liver fluke infestation, is a neglected tropical disease that infects 2.4 million people worldwide¹, with an additional 180 million at risk of infection². It is caused by two species of parasitic flatworms that can infect humans following ingestion of larvae in contaminated water or food.

Egaten is currently the only medicine for fascioliasis recommended by the WHO and is on the WHO Model List of Essential Medicines. It is supplied by WHO during epidemic outbreaks and for periodic use in endemic countries. FDA approval of Egaten is expected to facilitate drug licensing and import to these countries, helping ensure sufficient and prompt availability of the drug when needed. Fascioliasis is recognized by the FDA as a neglected tropical disease, triggering the award of a Priority Review Voucher based upon this approval.

Novartis has been donating Egaten to the WHO since 2005, helping to treat around 2 million fascioliasis patients in more than 30 countries. In 2018, we renewed our agreement with the WHO to extend the drug donation until 2022, expected to reach 300 000 patients per year.

“This FDA decision is welcome news for millions who suffer or are at risk of fascioliasis and removes a major hurdle in expanding treatment to countries where it is most needed,” said Dr Mwelecela Malecela, Director of the Department of Control of Neglected Tropical Diseases at the WHO. “We are thankful to Novartis for their sustained decade-long commitment in tackling yet another disease of poverty.”

The Novartis commitment to neglected tropical diseases

Novartis is a signatory to the London Declaration on Neglected Tropical Diseases, which aims to control, eliminate or eradicate 10 diseases by 2020. The Novartis Institute for Tropical Diseases, founded in 2001, is dedicated to finding new medicines to treat neglected diseases. In addition to malaria, research currently focuses on parasitic diseases such as cryptosporidiosis (diarrheal disease) and three major kinetoplastid diseases: human African trypanosomiasis (sleeping sickness), Chagas disease and leishmaniasis. Building on our experience in neglected diseases, Novartis also implements programs to target access to medicine for chronic diseases and, most recently, to address sickle cell disease in Africa, starting in Ghana.

About fascioliasis

Fascioliasis is caused by two species of parasitic flatworms or trematodes that mainly affect the liver (*Fasciola hepatica* or *Fasciola gigantica*). Both species can infect humans following ingestion of larvae in contaminated water or food (mainly raw or undercooked vegetation). The larvae mature into adult worms in the biliary tract. No continent is free from fascioliasis; human cases have been reported from more than 70 countries worldwide¹.

Left untreated, fascioliasis can result in considerable pain and discomfort, leading to poor quality of life and loss of productivity. The acute phase of the disease is manifested with fever, abdominal pain, nausea, diarrhea and eosinophilia. The disease later progresses to a latent phase with less symptoms and ultimately into a chronic or obstructive phase. In children, fascioliasis can be a serious infection with high fever, enlarged tender liver, and anemia.

About Novartis

Novartis is reimagining medicine to improve and extend people's lives. As a leading global medicines company, we use innovative science and digital technologies to create transformative treatments in areas of great medical need. In our quest to find new medicines, we consistently rank among the world's top companies investing in research and development. Novartis products reach more than 800 million people globally and we are finding innovative ways to expand access to our latest treatments. About 130,000 people of more than 145 nationalities work at Novartis around the world. To learn more, visit www.novartis.com.

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References

1. https://www.who.int/neglected_diseases/news/fascioliasis-review-provides-new-perspectives-infection-control/en/
2. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4568335/>

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