

MEDIA UPDATE • MEDIA UPDATE • MEDIA UPDATE**Novartis and DNDi to collaborate on the development of a new oral drug to treat visceral leishmaniasis**

- *LXE408 is a first-in-class compound, discovered at Novartis with financial support from the Wellcome Trust*
- *Novartis is responsible for completing Phase I clinical trials and has committed to maximizing access in endemic countries, once approved*
- *DNDi will lead Phase II and III clinical development, starting in India with additional trials planned in East Africa*
- *Leishmaniasis, which is transmitted by the sand fly, affects over one billion people; visceral leishmaniasis, the most serious form of the disease, affects an estimated 50 000 to 90 000 people per year*

Basel, February 25, 2020 – Novartis and the Drugs for Neglected Diseases *initiative* (DNDi), a not-for-profit research and development (R&D) organization, have signed a collaboration and licence agreement to jointly develop LXE408, as a potential new oral treatment for visceral leishmaniasis, one of the world's leading parasitic killers.

LXE408 is a first-in-class compound, discovered at Novartis with financial support from the Wellcome Trust. Within the scope of the agreement, Novartis is responsible for completing Phase I clinical trials. In addition, it will drive pharmaceutical development and regulatory submissions. Upon approval, Novartis has committed to distributing the drug on an affordable basis worldwide with a focus on maximizing access in endemic countries.

DNDi will lead Phase II and Phase III clinical development, with the first Phase II study scheduled to start in early 2021 in India. Additional trials are planned to take place in East Africa, which has the highest burden of visceral leishmaniasis.

“Existing treatments for visceral leishmaniasis are simply not good enough. They are too long, increasingly ineffective, and can be toxic, painful, and costly,” said Dr Bernard Pécoul, Executive Director of DNDi. “Our hope is to radically transform this by developing new oral drugs that are affordable, safe, effective, easy to take, and can also be adapted to meet the treatment needs of patients in different countries.”

Over one billion people worldwide are at risk of leishmaniasis, which is transmitted by the bite of a sand fly. Visceral leishmaniasis, also known as kala-azar, is the most serious form of leishmaniasis, causing fever, weight loss, spleen and liver enlargement, and if left untreated, death. There are an estimated 50 000 to 90 000 new cases per year. Treating the disease is

complex as it is dependent on the species of infecting parasite and the country, as treatment responses differ from region to region.

“Novartis has a long-term commitment to neglected tropical diseases that spans several decades. Diseases caused by kinetoplastid parasites, such as leishmaniasis, are one of our strategic research priorities and, together with our partners, we have developed a promising portfolio of drug candidates,” said Dr Lutz Hegemann, Chief Operating Officer for Global Health at Novartis. “We are excited to collaborate with DND*i* to reimagine treatment options for people with leishmaniasis around the world.”

Broader partnerships

The collaboration between DND*i* and Novartis is aligned with a broader program with the Wellcome Trust and other partners to develop new combinations of entirely new, all-orally acting chemical entities, to treat visceral leishmaniasis and cutaneous leishmaniasis, another form of the disease.

The program brings together a strong consortium of R&D partners, including the University of Dundee, GSK, Pfizer, TB Alliance, and Takeda Pharmaceutical Company Limited. These partners have built a portfolio of lead series, pre-clinical and clinical drug candidates, originating from different chemical classes with different mechanisms of action against *leishmania* parasites.

“We are delighted to be partnering with Novartis from drug development to delivering a promising new oral treatment for visceral leishmaniasis. Together, we can contribute to sustaining elimination efforts in India and altering the treatment landscape in East Africa,” said Dr Fabiana Alves, Head of Visceral Leishmaniasis Clinical Program at DND*i*.

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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 750 million people globally and we are finding innovative ways to expand access to our latest treatments. About 109,000 people of more than 145 nationalities work at Novartis around the world. Find out more at www.novartis.com

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About DND*i*

A not-for-profit research and development organization, DND*i* works to develop new treatments for people living with neglected diseases, notably Chagas disease, sleeping sickness (human African trypanosomiasis), leishmaniasis, filarial infections, mycetoma, pediatric HIV, and hepatitis C. Since its inception in 2003, DND*i* has delivered eight new treatments, including new drug combinations for kala-azar, two fixed-dose antimalarials, and DND*i*'s first successfully developed new chemical entity, fexinidazole, approved in 2018 for the treatment of both stages of sleeping sickness.

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