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Novartis to develop new oral drug for visceral leishmaniasis

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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 DNDi to reimagine treatment options for people with leishmaniasis around the world."

Broader partnerships

The collaboration between DNDi and Novartis is aligned with a broader program with Wellcome 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 DNDi.