Development of a new leishmaniasis drug wins EU funding

TT4CL (Targeted treatment for cutaneous leishmaniasis) is a new Horizon 2020-funded project which aims to reduce the burden of a Neglected Infectious (NID) and its social and economic impacts. Horizon 2020, the European Union's (EU) research and innovation programme, helps to bridge the gap between preclinical and clinical development and thus helps to advance promising new drug candidates along the development pipeline. The TT4CL consortium, which brings together partners from academia and industry in Europe and disease-endemic countries, has been awarded EUR3.75 million to develop an oral treatment, D121, against one of the most neglected tropical diseases, cutaneous leishmaniasis.

Leishmaniasis is a disease caused by *Leishmania* parasites, and is spread by the bite of certain types of sand flies. The skin form, cutaneous leishmaniasis, causes tropical ulcers, or lesions, which can last for months or even years and leaving severe stigmatising scarring. The many forms of the disease affect millions of people, mostly the world's most vulnerable populations. More recently leishmaniasis is becoming a concern for Europe too, driven by factors such as climate change, population migration and globalisation.

The EU funding is for clinical development research, CMC research, GMP manufacturing, preparation of regulatory approvals and of exploitation of an exciting treatment prospect that Oblita Therapeutics has successfully tested in animal models and lab studies and developed, with the support of Avivia, into an oral drug formulation.

The initial studies on the new treatment have indicated that it is more potent and better tolerated than existing treatments. Cutaneous lesions can be quite widespread on the body and an oral treatment would be more appropriate than a topical one. Existing therapies suffer from a variety short-comings such as toxic side-effects, extended dosing regimens and cost. Professor Sanjeev Krishna, a world authority on parasitological diseases, said "Early indications are that this new drug could have a huge impact on cutaneous leishmaniasis, a truly neglected tropical disease, but further essential studies are required before it can reach those most in need."

The H2020 funding is via a new pilot scheme which involves pre-determined lump sum payments when technical deliverables are met, rather than the usual cost-reporting process keeping pace with the research effort. The new financing structure frees up the scientists to do the work as it is far more flexible.

The initial scientific studies under TT4CL will be carried out on samples collected from humans in Iran, and in animal models at the London School of Hygiene & Tropical Medicine. Following drug manufacture, the final phase will be to verify the pharmacokinetics and safety of the drug on healthy volunteers. If the drug successfully passes each of the stages of its development, the end result would be that the drug product is ready for testing its efficacy in patients.

Professor Krishna said: “The European Union’s commitment to improve the health of the most needy is exemplified by their support for our consortium, which also shows how important it is to continue to work collaboratively within the EU. In times of fears about Brexit and its impact on research, this is really good news!”

About D121

D121 is an investigational oral drug in development for cutaneous leishmaniasis. Oblita Therapeutics holds the exclusive worldwide rights for D121. D121 has received US and EU orphan drug designation.

About TT4CL

TT4CL is a consortium bringing industrial and academic partners together: St George’s, University of London, UK; the London School of Hygiene and Tropical Medicine, UK; a clinical trials unit at the University of Tuebingen, Germany; a partner of a cutaneous leishmaniasis endemic country, Tehran University of Medical Sciences, Iran; Avivia, a company in the Netherlands specialized in CMC development under tropical conditions; Oblita Therapeutics, a Belgian company, responsible for the development, registration and exploitation of the new drug.

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