



Step Pharma announces US FDA clearance for a Phase I clinical trial in solid tumours with dencatistat (STP938)

Saint-Genis-Pouilly, France, 25 June 2024 – Step Pharma, the global leader in CTPS1 inhibition for targeted cancer treatment, today announced that its lead asset dencatistat (STP938), a first-in-class selective CTPS1 inhibitor, has cleared an investigational new drug (IND) application by the US Food and Drug Administration (FDA), enabling Step Pharma to progress dencatistat into a Phase 1 clinical trial for patients with solid tumours, anticipated to start in Q3 2024.

The open label trial will evaluate the safety, tolerability and pharmacokinetics of dencatistat in adults living with advanced solid tumours, with a safety expansion in advanced CTPS2 null ovarian cancer. Selecting patients whose tumours have deleted CTPS2 represents a precision oncology approach that is expected to maximise the therapeutic potential of dencatistat. The trial will recruit patients with advanced cancer who have no other treatment options available.

Step Pharma is pioneering a novel class of oral drugs that specifically inhibit nucleotide synthesis and the enzyme cytidine triphosphate synthase 1 (CTPS1) in particular, which was originally identified as an essential gene for lymphocyte proliferation. By targeting CTPS1, Step Pharma has unlocked the ability to selectively target the *de novo* pyrimidine synthesis pathway in cancer cells. This groundbreaking approach is predicted to enable the highly selective treatment of both blood cancers and solid tumours.

Andrew Parker, Chief Executive Officer of Step Pharma, commented: “The approval by the US FDA to initiate clinical evaluation of dencatistat in solid tumours is a significant milestone for Step Pharma as we continue to advance our lead candidate beyond blood cancers and into solid tumours, bringing us a step closer to a potentially paradigm-shifting treatment for patients. We look forward to starting the study in Q3 2024 and continuing our progress in driving a step change in the way we treat cancer, making a real difference to patients’ lives.”

Further details of the planned Phase 1 trial can be found on clinicaltrials.gov under the identifier NCT06297525.

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About dencatistat

Dencatistat (previously STP938) is a first-in-class, highly selective, orally bioavailable inhibitor of CTP synthase 1 (CTPS1), a key component of the pyrimidine synthesis pathway. CTPS1 inhibition blocks the proliferation of cancer cells and results in cell death. All cancers appear to be addicted to CTPS1 for DNA synthesis. Dencatistat entered clinical development in September 2022 for the treatment of T cell and B cell lymphoma.

Dencatistat has the potential to become the backbone of treatment regimens for a broad range of haematological and solid tumours, as well as being a potent monotherapy for hard-to-treat blood cancers.

About Step Pharma

Step Pharma’s goal is to bring about a step change in how cancer is treated with targeted therapies that kill cancer cells and leave healthy cells unharmed. The Company is the world leader in CTPS1 inhibition, a new approach with the potential to yield highly selective, safe and effective treatments for both blood cancers and solid tumours.



The Company's lead asset, dencatistat, previously received investigational new drug (IND) and clinical trial application (CTA) clearance to proceed into first in human trials in the US, UK and EU for the treatment of T cell and B cell lymphomas, and has now received clearance in the US to commence clinical development for the treatment of solid tumours. Clinical trials in lymphoma commenced in September 2022; the solid tumour clinical trial is expected to commence recruitment Q3 2024.

Step Pharma was founded in 2014 by Kurma Partners, the Imagine Institute and Sygnature Discovery, based on the scientific discoveries of Prof. Alain Fischer and Dr Sylvain Latour. Step Pharma is based in Saint-Genis-Pouilly, France, and is supported by a strong syndicate of investors led by Kurma Partners and including Bpifrance (Fonds Biothérapies Innovantes et Maladies Rares and InnoBio2 Fund), Pontifax, Hadean Ventures, Sunstone Life Science Ventures, Inserm Transfert Initiative, Idinvest, Sygnature Discovery and the Imagine Institute. More information on the company can be found at www.step-ph.com.

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