



PRESS RELEASE

Step Pharma Progresses into Oncology Clinical Trials with STP938, the World's Most Advanced CTPS1 Inhibitor

- Clearance of IND and CTA applications in the US and UK for STP938 for the treatment of T cell and B cell lymphomas
- First-in-class targeted therapy with potential applications in multiple cancer indications
- Novel mechanism of action with high selectivity has the potential to yield an oral treatment with minimal side effects

St. Genis-Pouilly, France, 28 July 2022 - Step Pharma, a world leader in CTPS1 inhibition for the targeted treatment of cancer, announces today that its lead asset STP938 has cleared both an Investigational New Drug (IND) application by the Food and Drug Administration (FDA), and a clinical trial application (CTA) by the UK's Medicines and Healthcare products Regulatory Agency (MHRA), enabling Step Pharma to progress STP938, its first-in-class, selective CTPS1 inhibitor into the clinic in the US and UK.

STP938 has now entered an open label, first-in-human, Phase 1/2 study to evaluate the safety, tolerability, pharmacokinetics, and preliminary efficacy of STP938 in adult subjects with relapsed/refractory B cell and T cell lymphomas. Further details of the study can be found on clinicaltrials.gov under the identifier [NCT05463263](https://clinicaltrials.gov/ct2/show/study/NCT05463263). Patients with such cancers currently face high relapse rates from existing treatments.

Step Pharma is pioneering a novel class of oral drugs that specifically inhibits nucleotide synthesis and the enzyme cytidine triphosphate synthase 1 (CTPS1) in particular, 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 ground-breaking approach should enable the highly selective treatment of both blood cancers and solid tumours.

Andrew Parker, Chief Executive Officer of Step Pharma, said: "Our unique approach to cancer treatment has the potential to yield a novel targeted cancer therapy that can form the backbone of both blood and solid tumour cancer treatment regimens. We are delighted to have moved STP938 into the clinic for hard-to-treat lymphomas with the ultimate goal of improving the lives of millions of cancer patients."

Brian Schwartz, Chief Medical Officer of Step Pharma, commented: "The clinical trial approvals by both the US FDA and UK MHRA are a significant milestone for Step Pharma and our highly differentiated lead candidate STP938, as we become a clinical-stage company and move at speed to bring this first-in-class treatment to cancer patients with high unmet medical needs."

Step Pharma will initially investigate STP938 in blood cancers, with a focus on T cell lymphomas, where there has been no improvement in five-year survival rates for over 20 years. However, as studies have shown that all cancer cells require CTPS1 for DNA synthesis, STP938 could be a key component of a multitude of cancer treatment regimens.

-Ends-



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 cancer treatments for both blood cancers and solid tumours.

The Company's lead product STP938 has received both IND and CTA clearance to proceed into first in human trials in the US and UK for the treatment of T cell and B cell lymphomas. Clinical trials in lymphoma commenced in the second half of 2022. STP938 has the potential to be the backbone of a multitude of cancer therapies as well as a potent monotherapy for hard-to-treat blood cancers.

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.

For more information please contact:

Step Pharma

Andrew Parker, Chief Executive Officer
contact@step-ph.com

Consilium Strategic Communications

Amber Fennell, Namrata Taak, Stella Lempidaki
Tel: +44 (0) 20 3709 5700
steppharma@consilium-comms.com