# Step Pharma announces first patient dosed in a phase 1 trial of dencatistat for patients with solid tumours

- *Entry into solid tumours builds upon the ongoing phase 1/2 trial for patients with T or B cell lymphoma.*
- *Dose escalation in solid tumours will be followed by a phase 1b safety expansion cohort in CTPS2 null ovarian cancer, planned to start in Q1 2025.*
- *Start of the trial in solid tumours follows IND clearance in US and CTA approval in UK.*

**Saint-Genis-Pouilly, France, 3 September 2024 –** Step Pharma ("the Company"), the global leader in CTPS1 inhibition for targeted cancer treatment, today announced that the first patient has been dosed at Next Oncology, San Antonio, TX USA, with its lead asset dencatistat (STP938) in a clinical trial for patients with solid tumours.

This open label trial is evaluating the safety, tolerability and pharmacokinetics of dencatistat, a first-in-class, highly selective, orally bioavailable CTPS1 inhibitor. The trial consists of two parts: a phase 1a dose escalation recruiting patients with solid tumours, followed by a phase 1b expansion cohort specifically for patients with CTPS2 null ovarian cancer, planned to start in Q1 2025.

Approximately 325,000 women worldwide are diagnosed with ovarian cancer each year. 15-20% of ovarian cancers harbour a deletion of the gene encoding CTPS2. Selecting patients whose tumours have deleted CTPS2 represents a precision oncology approach that is expected to maximise the therapeutic potential of dencatistat. The trial is recruiting patients with advanced cancer who have no other treatment options available.

**Andrew Parker, Chief Executive Officer of Step Pharma, commented**: "The start of our first clinical trial of dencatistat for solid tumours marks a significant milestone in our 'pipeline in a product' strategy. Dencatistat, our first-in-class CTPS1 inhibitor, is now expanding from blood cancers to solid tumours, demonstrating its versatility. With a substantial number of ovarian cancer patients potentially harbouring CTPS2 deletions, and similar deletions observed in other cancer types, we are excited about the potential of dencatistat as a tumour-agnostic targeted treatment."

Furthermore, the Company announces that the Clinical Trial Application for the phase 1 trial of dencatistat in patients with solid tumours has been approved by the UK Medicines and Healthcare products Regulatory Agency (MHRA). This approval, along with the previously cleared Investigational New Drug (IND) application to the US Food and Drug Administration (FDA), announced in June 2024, enables the Company to progress dencatistat into clinical trials in both the UK and the US.

The start of this solid tumour trial follows the ongoing phase 1/2 trial of dencatistat for adult patients with relapsed/refractory T or B cell lymphoma, which commenced in October 2022.

Step Pharma is pioneering a novel class of oral drugs that specifically inhibit nucleotide synthesis and the enzyme 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.

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 (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 October 2022 for the treatment of T cell and B cell lymphoma and in September 2024 for the treatment of solid tumours.

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.

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

Media Relations
ICR Consilium
Amber Fennell, Namrata Taak, Davide Salvi
Tel. +44 (0) 20 3709 5700
steppharma@icrhealthcare.com