

Press release

PEP-Therapy and Institut Curie announce first patients dosed in Phase I clinical trial of PEP-010 for the treatment of advanced solid tumors

Paris (France), 5th October 2021 – PEP-Therapy, a clinical-stage biotechnology company developing cell penetrating peptides as targeted therapies in oncology, and Institut Curie, France's leading cancer center, today announce that the first patients have been dosed in a Phase Ia/b multicenter clinical trial evaluating PEP-Therapy's lead candidate, PEP-010. In this first-in-human trial, PEP-010 is being administered in patients with advanced solid tumors.

PEP-010 is the first of a new class of therapeutic peptides based on PEP-Therapy's innovative Cell Penetrating and Interfering Peptides (CP&IP) technology. These innovative molecules penetrate cells and specifically block relevant intracellular protein-protein interactions, leading to the inhibition of key pathological mechanisms, without altering physiological mechanisms. PEP-010 is a pro-apoptotic agent which has demonstrated anti-tumor efficacy in several pre-clinical models and a good safety profile.

The trial has been initiated at Institut Curie and is led by Professor Christophe Le Tourneau, Medical Oncologist at Institut Curie and Head of the Department of Drug Development and Innovation (D3i), and Principal Investigator of the trial. The main objectives of this Phase Ia/b trial are to evaluate the safety, tolerability, pharmacokinetics and preliminary antitumor activity of intravenous PEP-010, administered as a single agent and in combination with paclitaxel, a taxoid chemotherapeutic agent, in patients with recurrent and/or metastatic solid tumors, and in particular in Triple-Negative Breast Cancer (TNBC) and Ovarian Cancer (OC).

"We are very pleased that the first patients have been dosed with PEP-010 at Institut Curie. Despite the progress made in recent years in the field of oncology, we still need innovative therapeutic approaches. The D3i has a dedicated unit for early phase clinical trials and can rely on multidisciplinary and motivated teams to conduct this clinical trial and evaluate how PEP-010 could benefit patients with advanced solid tumors. We expect this trial to deliver important initial clinical data for the development of PEP-010 and I look forward to seeing the preliminary results." said **Pr. Christophe Le Tourneau**.

Antoine Prestat, CEO and co-founder of PEP-Therapy added: *"The initiation of this study represents another significant milestone for PEP-Therapy, following the successful Series A fundraising announced earlier this year. PEP-010 is the first clinical program to emerge from our innovative Cell Penetrating and Interfering Peptides technology. We are expecting to generate potential promising clinical data, particularly in two indications with poor prognosis and limited therapeutic alternatives: metastatic Triple-Negative Breast Cancer and platinum resistant Ovarian Cancer. We look forward to announcing the preliminary safety and tolerability data in 2022."*

The clinical trial, named 'CleverPeptide' ([NCT_04733027](https://clinicaltrials.gov/ct2/show/study/NCT04733027)), is an open-label, non-controlled, multicenter, dose escalation trial (Phase Ia) with an expansion phase (Phase Ib). It is estimated that a total of 56 adult patients will be recruited gradually, with increasing dose levels of PEP-010 in monotherapy, then in combination with paclitaxel, with a goal of establishing a Maximum Tolerated Dose (MTD). Two expansion cohorts at this MTD will follow to confirm safety data and evaluate preliminary efficacy.

The study will also be conducted at two other clinical oncology centers, Gustave Roussy and the François Baclesse Center, where patients will receive the next dose levels.

Ends

About PEP-Therapy

PEP-Therapy is a French clinical-stage biotechnology company developing first-in-class peptides as targeted therapies in oncology, based on the Company's innovative **C**ell **P**enetrating and **I**nterfering **P**eptides (CP&IP) technology. These innovative molecules penetrate cells and specifically block relevant intracellular protein-protein interactions, leading to the inhibition of key pathological mechanisms without altering physiological mechanisms.

PEP-Therapy, which was founded in 2014 and builds on research from Sorbonne University and Institut Curie, is backed by international investors: Anaxago, i&i Prague, Italian Angels for Growth (IAG), Doorway, Magna Capital Partners (MCP), Business Angels des Grandes Ecoles (BADGE), Seventure Partners (Quadrivium 1 Seed Fund), and Dr. Bernard Majoie (former Chairman and CEO of Laboratoires Fournier, Founding Chairman of Fournier-Majoie Foundation for Innovation).

For more information, please visit www.pep-therapy.com

About Institut Curie

Institut Curie, France's leading cancer center, combines an internationally-renowned research center with a cutting-edge hospital group that treats all types of cancer, including the rarest. Founded in 1909 by Marie Curie, Institut Curie employs 3,600 researchers, physicians, and health professionals across three sites (Paris, Saint-Cloud, and Orsay), working on its three missions: treatment, research, and teaching. A private foundation with public utility status, Institut Curie is authorized to receive donations and legacies, and thanks to the support of its donors, is able to make discoveries more quickly, improving treatments and quality of life for patients.

For more information, please visit: www.curie.fr

Contacts

PEP-Therapy

Antoine Prestat, CEO & co-founder

hello.pep@pep-therapy.com

+33 1 81 70 76 82

MEDISTRAVA Consulting

Sylvie Berrebi, David Dible

PEP-Therapy@medistrava.com

+44 (0)7714 306525

Institut Curie

Elsa Champion, Press Relations Officer

elsa.champion@curie.fr

+ 33 7 64 43 09 28