

Press release

PEP-Therapy and Institut Curie Announce First Patients Dosed in Phase Ib Clinical Trial Evaluating PEP-010 in Ovarian and Pancreatic Cancers

Paris (France), April 25, 2024 – PEP-Therapy, a clinical-stage biotechnology company developing first-in-class peptides as targeted therapies in oncology, and Institut Curie, France's leading cancer center, today announced the dosing of the first patients in a Phase Ib clinical trial evaluating PEP-Therapy's lead candidate, PEP-010, based on highly encouraging Phase Ia results. This second part of the Phase I study is evaluating PEP-010 in combination with chemotherapy (paclitaxel or gemcitabine), in advanced or metastatic ovarian cancer (OC) and in metastatic pancreatic ductal adenocarcinoma (PDAC), two indications with high unmet medical need.

PEP-010 is a first-in-class bifunctional therapeutic peptide that penetrates cells and specifically disrupts the interaction between Caspase-9 and PP2A, leading to the inhibition of key pathological mechanisms, without altering physiological mechanisms. PEP-010 is a pro-apoptotic agent which has demonstrated a good safety and tolerability profile and first signals of efficacy in the CLEVer-PEptide Phase Ia dose escalation clinical trial.

The two-cohort, open-label, non-controlled, multicenter Phase Ib program will evaluate the safety and tolerability, complete or assess the pharmacokinetics, and evaluate the anti-tumor activity of intravenous PEP-010 when administered in combination with paclitaxel or gemcitabine. The first cohort (expansion cohort) will evaluate the efficacy of PEP-010 at the recommended Phase II dose (RP2D) in combination with paclitaxel in patients with metastatic PDAC. The second cohort (dose escalation) will determine the maximum tolerated dose (MTD) and the RP2D of PEP-010 when administered in combination with gemcitabine in patients with metastatic PDAC or advanced or metastatic OC. Target enrollment is up to 53 patients. Four sites in France are currently recruiting: Institut Curie, Gustave Roussy, Centre François Baclesse and Institut de Cancérologie de l'Ouest.

"We are thrilled to see the first patients dosed in this Phase Ib trial. PEP-010 represents a potentially safer and effective new option for patients with few therapeutic alternatives. I am delighted to work with our clinical team and the different centers to determine if PEP-010, when combined with chemotherapies, can provide therapeutic benefits for patients." said **Pr. Christophe Le Tourneau**, Medical Oncologist at Institut Curie, Head of the Department of Drug Development and Innovation (D3i), and Principal Investigator of the CLEVer-PEptide trial.

Antoine Prestat, CEO and co-founder of PEP-Therapy added: *"We are delighted with the start of our Phase Ib trial, and we are grateful for the support of the participating cancer centers which has enabled this important new milestone for our company. This study reflects our commitment to provide a new treatment that addresses unmet medical needs and improve patient outcomes in combination with the standard-of-care. Reactivating apoptosis of cancer*

cells using peptide technology represents a promising and innovative therapeutic modality. We look forward to confirming the potential of PEP-010 in this Phase Ib trial."

Encouraging [data from the Phase Ia study](#) were presented at the AACR-NCI-EORTC Conference on Molecular Targets and Cancer Therapeutics 2023 confirming the safety of PEP-010 with encouraging preliminary signals of antitumoral activity in 13 patients who experienced partial response or stable disease, including 2 confirmed partial responses in combination with paclitaxel in ovarian and pancreatic cancers, along with a good safety profile in patients with recurrent and/or metastatic solid cancers.

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About PEP-010

PEP-010 is a first-in-class bifunctional peptide that penetrates cells and specifically disrupts the interaction between Caspase-9 and PP2A, two key proteins involved in the apoptotic pathway. PP2A and Caspase-9, when released, restore normal apoptosis in cancer cells. PEP-010 is currently evaluated in a Phase Ia/b clinical trial.

About CLEVer-PEptide trial

CLEVer-PEptide is a Phase Ia/b, open-label, non-controlled, multicenter clinical study ([NCT 04733027](#)). It is a first-in-human dose escalation and expansion study that is expected to enroll up to 87 patients to evaluate the safety, pharmacokinetics and preliminary antitumor activity of intravenous PEP-010, administered as single agent and in combination with paclitaxel or with gemcitabine in patients with recurrent and/or metastatic solid cancer.

In Phase Ia, results obtained on 34 patients showed good safety profile of PEP-010 in monotherapy, the Recommended Phase 2 Dose (RP2D) being the highest dose level tested. In combination with paclitaxel, preliminary antitumor activity (4 confirmed Partial Responses) was observed, including in OC and PDAC patients. The clinical development continues with a Phase Ib focusing on two indications, advanced/metastatic OC and PDAC. A new combination of PEP-010 with a standard-of-care in these two indications, gemcitabine, will also be evaluated.

PEP-010 clinical development is conducted in partnership with two leading European cancer centers, Institut Curie and Gustave Roussy, and also recruiting at Centre François Baclesse and Institut de Cancérologie de l'Ouest. CLEVer-PEptide is led by Professor Christophe Le Tourneau, Medical Oncologist at Institut Curie, Head of the Department of Drug Development and Innovation (D3i), and Principal Investigator of the trial.

About PEP-Therapy

PEP-Therapy is a Paris-based clinical-stage biotechnology company developing first-in-class peptides as targeted therapies in oncology. PEP-010, lead drug candidate, is a pro-apoptotic agent currently evaluated in a Phase Ia/b clinical trial. The company also develops a pipeline of peptide-based products in oncology.

Founded in 2014, PEP-Therapy builds on research from Sorbonne University and Institut Curie, and is backed by international investors: Seventure Partners (Quadrivium 1 Seed Fund), CapHorn, i&i Prague, Italian Angels for Growth (IAG), Doorway, Magna Capital Partners (MCP), Business Angels des Grandes Ecoles (BADGE), and Jérôme Majoie (former Managing Director of Laboratoires Fournier affiliates (USA, UK, Sweden, Japan), CEO of La Fondation Fournier-Majoie).

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, treating all types of cancer, including the rarest. Founded in 1909 by Marie Curie, Institut Curie has 3 sites (Paris, Saint-Cloud and Orsay) with over 3,700 researchers, physicians and health professionals working on its 3 missions: treatment, research and teaching. A private foundation with public utility status, Institut Curie is authorized to accept donations and bequests, and thanks to the support of its donors, is able to accelerate discoveries and improve patient treatment and quality of life. To find out more: www.curie.fr, [Twitter](#), [Facebook](#), [LinkedIn](#), [Instagram](#)

Institut Curie has been a **certified "Carnot Curie Cancer Institute" since 2011**. The Carnot certification is a recognition of excellence awarded to academic research organizations whose quality and involvement in partnership-based research have been demonstrated. Curie Cancer offers industrial partners the opportunity to implement research collaborations utilizing the expertise of Institut Curie's research teams to develop innovative therapeutic solutions for cancer, from therapeutic target to clinical approval. Curie Cancer is a member of the Carnot FINDMED network, a group of thirteen Carnot institutes, to facilitate access to their technological platforms and to their innovations for very small and medium-sized companies in the pharmaceutical industry. Find out more: <http://www.instituts-carnot.eu/fr/institut-carnot/curie-cancer> - <https://findmed.fr>

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