institut Curie

PEP-Therapy

Press release

PEP-Therapy and Institut Curie granted approval from ANSM to start first-in-human clinical trial of PEP-010 for the treatment of advanced solid tumors

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Paris (France), 16th March 2021 – PEP-Therapy, a biotechnology company developing cell penetrating peptides as targeted therapies in oncology, and Institut Curie, France's leading cancer center, today announce that they have been granted approval from the French National Agency for Medicines and Health Products (ANSM) to proceed with the first-in-human clinical trial of PEP-Therapy's lead drug candidate, PEP-010.

PEP-010 is a first-in-class therapeutic peptide 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 a number of pre-clinical models and a good safety profile.

The clinical trial, named 'CleverPeptide', is an open-label, non-controlled, multicenter, dose escalation, Phase I clinical trial with an expansion Phase. This Phase Ia/b study has been designed to evaluate the safety, tolerability, pharmacokinetics and preliminary antitumor activity of intravenous PEP-010, administered as a single agent and in combination with paclitaxel in patients with recurrent and/or metastatic solid tumors, and in particular in Triple Negative Breast Cancer (TNBC) and Ovarian Cancer (OC).

This study is sponsored by Institut Curie and led by Pr. Christophe Le Tourneau, Medical Oncologist at Institut Curie and Head of Department of Drug Development and Innovation (D3i), and Principal Investigator of the trial.

Antoine Prestat, CEO and co-founder of PEP-Therapy said: "*We are pleased to have been granted approval by ANSM to start this first-in-human clinical trial of PEP-010. This is a major milestone for PEP-Therapy and our partners, amongst which Institut Curie and Sorbonne University where our technology originated from. PEP-010 aims to fight cancers with poor prognosis for which there are only few or no therapeutic alternatives. We look forward to starting this trial in the coming weeks and to generating results that we hope will confirm the promising results seen in preclinical studies*."

"*This exciting step has been achieved through a strong collaboration between PEP-Therapy and Institut Curie since its inception, demonstrating the ability to develop innovative therapeutics emerging from French institutional research. I am very pleased to involve the D3i - Department of Drug Development and Innovation - in this clinical trial*", says **Pr Christophe Le Tourneau**.

The study will be conducted in three clinical centers in France: Institut Curie, Gustave Roussy and the François Baclesse Center.

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About PEP-Therapy

PEP-Therapy is a French 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.

Founded in January 2014, PEP-Therapy builds on research from Sorbonne University and Institut Curie. Since its inception, PEP-Therapy has raised €3,7 million from Quadrivium 1 Seed Fund, managed by Seventure Partners, and from Dr Bernard Majoie, former Chairman and CEO of Laboratoires Fournier, Founding Chairman of Fournier-Majoie Foundation for Innovation (FFMI).
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, visit: www.curie.fr

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