Press release

PEP-Therapy reports positive results from GLP-toxicity study of PEP-010 drug candidate

A major step towards clinical trials

Paris (France), May 16, 2019 - PEP-Therapy, a biotechnology company developing peptides as targeted therapies for oncology, announces that its first-in-class drug candidate, PEP-010, successfully completed Good Laboratory Practice (GLP) toxicity study, moving towards its first-in-human clinical trial.

PEP-010 was studied in rodent and non-rodent species, in a 4-week toxicity study. The administration schedule was chosen to cover all possible schedules that could be implemented during clinical trial. The study was performed by a world leading CRO specialized in safety and toxicology studies and in accordance with the OECD principles of Good Laboratory Practice as accepted by regulatory authorities.

PEP-010 was well tolerated in rodent and non-rodent species. The study confirmed the absence of systemic toxicity and neuro-behavioural effects, and cardiovascular functions were unaffected by the treatment at all the dose levels. Based on these results, the no-observed-adverse-effect level (NOAEL) was defined and the starting dose for the coming phase I clinical trial calculated.

« *The PEP-Therapy team is very pleased with the outcome of this study, which represents a key milestone for the company. The results are very encouraging, PEP-010 is safe and well tolerated at doses significantly higher than those intended to be studied in patients* » said Antoine Prestat, CEO and co-founder of PEP-Therapy. « *We have now gathered all required preclinical data paving the way for the clinical study* ».

Based on these positive results, the Phase I clinical batch and the regulatory documents are in preparation for the submission of a Clinical Trial Application in 2019. PEP-Therapy has entered into a collaborative partnership for Phase I clinical trials with Institut Curie and Gustave Roussy, two leading European cancer centres. The synopsis of the clinical study protocol has been drawn-up for advanced solid tumours. Pr Christophe Le Tourneau (Head of the Department of Drug Development and Innovation (D3i) at Institut Curie) will be the Principal Investigator. « *We have been working with PEP-Therapy since the beginning of the project, starting with preclinical work. We are now eager to start the first-in-human clinical trial with a compound that successfully completed GLP-toxicity studies. The Institut Curie is proud to sponsor this clinical trial with such an innovative drug* ».

About PEP-Therapy

PEP-Therapy is a medical biotechnology company developing peptides as targeted therapies for oncology.

PEP-Therapy has developed a Cell Penetrating and Interfering Peptide technology (CP&IP) for the development of its therapeutic products. These innovative molecules penetrate cells and then specifically block relevant intracellular protein-protein interactions, thus inhibiting key pathological mechanisms.

Founded in January 2014, PEP-Therapy is building on research from Sorbonne University (formerly Pierre and Marie Curie University, UPMC) and Institut Curie. Since its inception, PEP-Therapy has raised 2,5 M€

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 details: www.pep-therapy.com

About PEP-010
PEP-010 is PEP-Therapy's first CP&IP-based product and a first-in-class targeted approach to cancer therapy. PEP-010 specifically blocks the intracellular protein-protein interaction between Caspase-9 and protein phosphatase 2A (PP2A), two major effectors of the apoptosis pathway (programmed cell death).
PEP-010 has completed preclinical proof-of-concept demonstrating significant anti-tumour activity in patient-derived xenograft (PDX) models. Repeated GLP-toxicity studies showed a good tolerance of the product. Phase I clinical regulatory documents are in preparation for submission of a Clinical Trial Application shortly.

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