Press Release
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CellProthera shares U.S. regulatory progress of ProtheraCytes® cell therapy program

Positive pre-IND meeting with FDA helps position CellProthera for a U.S. and international Phase III trial for ProtheraCytes® in patients following a severe heart attack

Mulhouse, France, August 29, 2024 – **CellProthera**, a regenerative cell therapy developer specialising in ischemic diseases, announced alignment with regulators on a planned pivotal Phase III trial design for its ProtheraCytes® cell therapy following the completion of its pre-Investigational New Drug (IND) meeting with the U.S. Food and Drug Administration (FDA). Building on a successful Phase II trial in the U.K.and France, CellProthera is moving into the final phase of clinical development for ProtheraCytes, with a trial to take place in the U.S. and Europe. The trial will include a larger number of patients, with two years of long-term follow up expected in patients treated after an acute myocardial infarction (AMI), to monitor the ability of ProtheraCytes to prevent subsequent heart diseases.

In the meeting, regulators reviewed pre-clinical and clinical data collected by CellProthera to date, as well as a proposed Phase III clinical trial design based on takeaways from its Phase II EXCELLENT study, which was completed earlier this year. FDA staff agreed with CellProthera's plan for a randomized, concurrent-controlled, open-label trial with standard-of-care post-AMI treatment as the control, measured with a composite endpoint based on findings from the Phase II trial. EXCELLENT demonstrated that ProtheraCytes improved left ventricular (LV) volumes and viability of myocardial segments at 6 months following treatment, strong and promising signals of the therapy's efficacy that will be confirmed through long-term follow-up.

"With positive feedback from FDA regulators, we feel we are in a favorable position to launch a pivotal Phase III trial in the U.S. after successful IND filing that will build on the results we have seen thus far," said Matthieu de Kalbermatten, CellProthera's CEO.

"This will run in parallel with our recently launched PERFECT study, which will provide additional long-term safety and efficacy data by following patients from our Phase II study over an additional ten years."

The prevention of mortality and hospitalization for heart failure in AMI patients remains a major challenge. Despite optimal guideline-directed therapies, the event rate remains high in AMI patients presenting a large necrosis. ProtheraCytes differentiate into endothelial cells and release paracrine factors that support angiogenesis and enhance the proliferation of resident cardiomyocytes, thus attenuating adverse remodeling effects.

CellProthera presented its latest updates in a press conference today in London, which featured investigators from the Phase II EXCELLENT clinical trial team and members of the company's Scientific Advisory Board. A recording of the press conference will be available via the CellProthera website, or can be provided on request.

About CellProthera
CellProthera is a regenerative cell therapy developer specializing in cardiovascular diseases with a leading program in myocardial infarction. CellProthera has developed a unique GMP-compliant cell expansion process as well as a proprietary automation technology for in vitro production of large quantity of purified, CD34+ stem cells. Its lead therapy ProtheraCytes®, is an autologous cell therapy and has been developed for body regeneration and targeted to regenerate various damaged tissues, including cardiac tissue. ProtheraCytes is registered as an Advanced Therapy Medicinal Product – ATMP -by the European Medicines Agency (EMA). CellProthera's proprietary technology platform comprises an automated expansion device called StemXpand® and its disposable kit StemPack®. CellProthera is headquartered in France.