

CellProthera announces peer-reviewed publication of its Phase I/IIb results on safety and feasibility of ProtheraCytes® in patients with severe heart failure post-myocardial infarction

JACC-Heart Failure publication highlights high-quality cell expansion, good tolerability, manageable procedural risk and encouraging early signals of functional effects.

Mulhouse, France, September 10, 2025 – **CellProthera** today announced that its open-label randomized controlled EXCELLENT Phase I/IIb trial results have been published in *JACC: Heart Failure*, delivering the first peer-reviewed data on ProtheraCytes® in patients suffering from a large myocardial infarction (MI).

The study enrolled post-MI patients, with an average left ventricular ejection fraction of just 35%, a week after a severe heart attack with significant myocardial damage. Although the trial was not designed to prove efficacy, there were early trends of improvement in several surrogate markers of myocardial function, a good tolerability and a manageable procedural risk. Treated patients showed a 9% average reduction in left ventricular end-systolic volume index, a reduction by half of severely damaged heart tissue at six months and a seventy percent average drop in NT-proBNP levels at three months.

ProtheraCytes® were well tolerated. No patients experienced adverse drug reactions, and there were no deaths. Over six months, one of the 33 patients treated with ProtheraCytes® (3%) required a heart failure hospitalisation, and three of 16 patients (19%) in the standard-care group, one of whom went on to receive a heart transplant. There were nine procedure-related complications in the active group, but all recovered promptly. Future procedures will be done with improved imaging, planning, and operator training.

"The fact that several cardiac markers improved in the first six months in this population with severe MI encourages us to further investigate it in a larger study with longer follow-up and all the necessary safeguards in place to reduce the risk of procedural complications", said Prof. Jérôme Roncalli.

In these high-risk patients, CellProthera's automated expansion platform reliably produced patient's own expanded CD34+ stem cells at clinical scale. On average, the ProtheraCytes had a purity over 90% and viability of almost 98%. They were delivered fresh to catheter labs in France and the UK within hours for timely administration.

"These results demonstrate that ProtheraCytes® can be manufactured and delivered to some of the most fragile post-MI patients while maintaining exceptional quality," said Matthieu de Kalbermatten, CEO of CellProthera.

The EXCELLENT trial was a prospective, multicentre, open-label, randomised controlled study in France and the UK. Out of the 49 analysed patients, 33 participants were administered ProtheraCytes transendocardially on top of standard-of-care, and 16 participants received standard-of-care alone. It assessed the feasibility and safety of transendocardial injections of expanded autologous CD34+ cells in patients with a recent large MI. Building on these results, CellProthera is preparing larger trials to confirm long-term benefits and further evaluate safety in this high-risk population.

About CellProthera

CellProthera is a regenerative cell therapy developer specializing in ischemic diseases, with a leading program in myocardial infarction. CellProthera has developed a unique GMP-compliant cell manufacturing process as well as proprietary automation technology for *in vitro* production of a large quantity of purified, expanded CD34+ cells. Its lead therapy ProtheraCytes®, is an autologous cell therapy 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 single use kit StemPack®. CellProthera is headquartered in Mulhouse, France.