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CellProthera collaborates with Japanese stem cell experts at Shonan-Kamakura General Hospital (SKGH) on clinical manufacturing for upcoming autologous stem cell trials in ischemic diseases

- Upcoming clinical trials, led by stem cell pioneer Professor Takayuki Asahara, will use CellProthera's StemXpand(R) and StemPack(R) technology to manufacture endothelial progenitor cells (EPCs)
- This collaboration is the first to bring CellProthera's manufacturing systems to Japan, following successful use of the systems in clinical trials in Europe

Mulhouse, France, February 27 2024 – **CellProthera**, a regenerative cell therapy developer specializing in ischemic diseases, announces a collaboration with stem cell leaders at Shonan Kamakura General Hospital (SKGH), Japan, to manufacture autologous endothelial progenitor cells (EPCs) in forthcoming clinical trials. SKGH researchers led by world-renowned stem cell expert Takayuki Asahara, M.D., Ph.D., will deploy CellProthera's clinically validated StemXpand(R) automated manufacturing device and StemPack(R) single-use cell culture kits to produce clinical-grade autologous EPC therapies for patients with ischemic and renal diseases. [1] Prof. Asahara, the first researcher to isolate EPCs from peripheral blood, [2] is Deputy Director of Shonan Research Institute of Innovative Medicine at SKGH.

EPCs are naturally deployed in the body to repair blood flow after it is restricted (as in ischemic stroke). Preclinical and clinical testing have confirmed the potential and safety of these CD34+ regenerative cells in response to ischemic injury. [3][4] They are similar to ProtheraCytes(R), the autologous stem cell-derived therapy that CellProthera tested in Phase I/IIb to prevent heart failure following heart attack. CellProthera uses StemXpand and StemPack technology for the automated manufacture of ProtheraCytes for the trial, [5] expected to read out later this year.

The StemXpand, which has been in use in European trials to grow patients' own cells into a therapeutic dose, will be rigorously tested to meet SKGH's manufacturing specifications and adapted as needed to begin qualification runs for an upcoming clinical trial. After the collaborators confirm consistency and reproducibility both in the manufacturing process and with the previously manufactured product, Prof. Asahara's team will perform validation runs to ready the technology's use for clinical testing.

"We are honoured to work with Prof. Asahara given his ground-breaking experience in the regenerative medicine space, and think he is the ideal partner to demonstrate the utility of our manufacturing technology beyond our own pipeline," says Matthieu de Kalbermatten, CEO, CellProthera. "As a long-time advocate for the use of stem cells for the treatment of ischemic and renal diseases, I am hopeful this collaboration will pave the way for the StemXpand and StemPack to play a pivotal role in the research and development of stem cell treatments across the globe."

"Ischemic diseases remain one of the leading causes of death in Japan, with limited treatment options," comments Prof. Asahara. "We hand-picked CellProthera for collaboration based in part on how StemXpand, a tried and trusted technology, will help us meet the needs of patients with ischemic diseases through our development of targeted stem cell therapies."

About CellProthera

CellProthera is a clinical-stage regenerative cell therapy developer specializing in ischemic diseases. CellProthera has developed a unique GMP-compliant cell expansion process as well as a proprietary automation technology for *in vitro* production of a large quantity of purified CD34+ stem cells.

Its lead therapy, ProtheraCytes(R), is an autologous cell therapy that has been developed for tissue reperfusion and salvage of damaged cardiac tissue. ProtheraCytes(R) is registered as an Advanced Therapy Medicinal Product by the European Medicine Agency (EMA). CellProthera's proprietary technology platform includes StemXpand(R), an automated expansion device, and its single-use StemPack(R) cell culture kits. CellProthera is headquartered in France.

For more information, visit cellprothera.com.

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