Press release **Stockholm November 3, 2026**

SmartCella signs Extroducer® license agreement with HeartWorks for precise delivery of cell therapies

SmartCella Holding AB ("SmartCella") today announces the signing of a non-exclusive license agreement with HeartWorks, Inc. ("HeartWorks"), a biotechnology company founded to advance and commercialize autologous cell therapies for congenital heart disease. The agreement gives HeartWorks the right to use the Extroducer® platform for the delivery of certain cell therapies, covering both clinical development and commercialization.

The Extroducer® is SmartCella's modality-agnostic endovascular delivery platform designed for localized drug delivery to hard-to-reach organs, tumors, and tissues. Developed at Karolinska Institutet and FDA 510(k)-cleared for use in peripheral (including abdominal) tissues, it enables minimally invasive, catheter-based delivery using arteries and veins as natural access routes for localized injection of therapeutic agents into target tissues.

HeartWorks is a US-based nonprofit biotechnology organization dedicated to advancing regenerative therapies for congenital heart disease (CHD). Founded in 2020, HeartWorks develops personalized heart cell therapies designed to regenerate damaged heart muscle using a patient's own cells. As the sponsor of the world's only active clinical study using autologous iPSC-derived cardiac cells for congenital heart disease, HeartWorks is advancing regenerative therapies toward clinical translation.

Congenital heart disease is the most common birth defect, affecting approximately 1 in every 100 babies born and an estimated 2.4 million people in the US. For patients with complex single-ventricle heart defects such as HLHS, today's surgeries help patients survive but cannot replace or regenerate damaged heart muscle. As many patients develop heart failure later in life, transplantation often becomes the only remaining treatment option. HeartWorks is working to change that by developing regenerative therapies designed to rebuild heart muscle and expand treatment options beyond transplantation.

Dr Tim Nelson, CEO and co-founder of HeartWorks, says: "For patients with the most severe forms of congenital heart disease, the challenge has never been developing promising cell therapies alone, it has been delivering them safely and precisely into the heart. The Extroducer®'s ability to reach the myocardium through the vasculature, without open-heart surgery, is exactly the kind of innovation we need to bring autologous cardiac cell therapies to more patients."

Niklas Prager, CEO at SmartCella, comments: "We are thrilled to team up with HeartWorks, they are a truly purpose-driven organization and determined to find a cure for univentricular congenital heart disease. Knowing that our Extroducer® has a role to play in this vital work, and in the lives it has the potential to change, means a lot to us."

The agreement reflects a long-term partnership that also covers other cardiovascular indications and supports both parties' strategic ambitions. It also follows SmartCella's business model, with revenue generated across multiple streams throughout the partnership, including development and commercial milestones, royalties and product sales. The agreement is on similar general terms to previously announced agreements.

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About SmartCella
SmartCella is a global drug delivery company pioneering innovative delivery solutions for targeted therapies. The main technology, the Extroducer®, is a modality-agnostic endovascular delivery device designed for localized delivery to hard-to-reach organs, tumors, and tissues. The Extroducer® is FDA 510(k)-cleared for use in peripheral (including abdominal) tissues to inject diagnostic and therapeutic solutions into the extravascular space. It is currently in clinical investigation for additional indications. SmartCella commercializes the Extroducer® through licensing agreements with global biotech and pharma companies, enabling broad application across all development phases. The company also offers a proprietary stem cell platform for the delivery of mRNA therapeutics, featuring a proof-of-concept program focused on Osteoarthritis.

Founded in 2014, SmartCella is built on world-class research from Sweden's Karolinska Institutet..

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About HeartWorks Inc.
HeartWorks is a nonprofit biotechnology organization singularly focused on congenital heart disease. By bringing together discovery research, translational science, clinical development, and advanced manufacturing, HeartWorks develops personalized regenerative therapies designed to repair damaged heart muscle using a patient's own cells.

Today, HeartWorks is the sponsor of the world's only active clinical study using autologous iPSC-derived cardiac cells for congenital heart disease and is advancing a pipeline of regenerative therapies designed to transform how congenital heart disease is treated. The organization's vision is simple: transform today's treatments into tomorrow's cures so children and adults born with congenital heart disease can live longer, healthier lives.

Read more www.heartworksinc.org and follow HeartWorks on LinkedIn