PRESS RELEASE

Hy2Care® receives FDA Breakthrough Device Designation for its CartRevive™ hydrogel implant

Geleen, October 19, 2023
Hy2Care® proudly announces FDA Breakthrough Device Designation for its revolutionary CartRevive™ hydrogel implant. This milestone underlines the FDA's acknowledgment of the CartRevive™ hydrogel implant's potential in the field of cartilage repair.

Employing state-of-the-art hydrogel technology, the CartRevive™ hydrogel implant offers a unique approach to cartilage regeneration. The hydrogel is based on joint-tissue-matching natural polymers and acts as a scaffold. This facilitates patients' own cells to naturally restore optimal cartilage tissue, striving to reduce repeat surgeries.

"With many patients facing limited solutions for effective cartilage repair, Hy2Care's CartRevive™ hydrogel implant is the game-changer in a long-standing clinical challenge." According to Leo Smit, CEO Hy2Care®. "Our technology directly addresses a significant market void, providing an innovative approach that enables natural healing. The FDA's Breakthrough Device Designation not only recognizes the potential of our implant but underscores the pressing need for advanced treatments with improved surgical outcomes in the area of cartilage repair."

The Breakthrough Device Designation supports a more efficient development and review process, accelerating access for patients to this transformative therapy. With its current ACTIVE study in the Netherlands and US clinical trial in preparation, Hy2Care® is committed to delivering the promise of the CartRevive™ hydrogel implant to patients worldwide.

About Hy2Care®
Hy2Care® is a 'spin-off company' of the Tech Med Centre of the University of Twente (NL) and was founded in 2014. The original founders, prof. dr. Marcel Karperien and dr. Sanne Both, continue to be active in the company. Prof. dr. Marcel Karperien and his team of the Developmental BioEngineering group at the University of Twente developed the unique and proprietary technology of Hy2Care®. Hy2Care's launching product, the CartRevive™ hydrogel implant for cartilage repair in the knee, is currently clinically investigated in the Netherlands for European market approval. A US clinical trial is in preparation.
Hy2Care® continues to use facilities in Enschede (NL) at the site of the University of Twente, and has its own laboratory and offices at the Brightlands Chemelot Campus in Geleen (NL).

About Hy2Care's CartRevive™ hydrogel implant
Hy2Care's innovative platform centers on the CartRevive™ hydrogel implant's in-situ formation. Upon application to a cartilage defect, two naturally-derived polymers, Dextran and Hyaluronic acid conjugates, gel within 30-40 seconds, providing a resorbable scaffold that degrades over time. The gel's adherence to adjacent, intact cartilage intends to halt further damage, enabling natural tissue repair as cells infiltrate the scaffold and initiate hyaline cartilage deposition.

Note for the press: for more information please contact Wendy Mertens (Hy2Care®)
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