Press release

Hy2Care® Reaches milestone in finalizing second phase of clinical study

Geleen, 17 October, 2024
Hy2Care® announces completion of the second phase of its clinical trial, with the treatment of the 46th patient using the CartRevive® hydrogel implant. In early 2023, the Medical Ethical Review Committee of UMC Utrecht granted approval to continue the clinical study with an additional group of 36 patients, following a successful first safety group of 10 patients that started in 2022. This second phase of the trial is being conducted in collaboration with Dutch hospitals UMC Utrecht, Elisabeth-TweeSteden Ziekenhuis (ETZ), Maastricht UMC+, and Martini Hospital Groningen. The CartRevive® hydrogel implant is designed to enable optimal cartilage repair in the knee, addressing a significant unmet clinical need due to the high prevalence of cartilage repair surgeries worldwide.

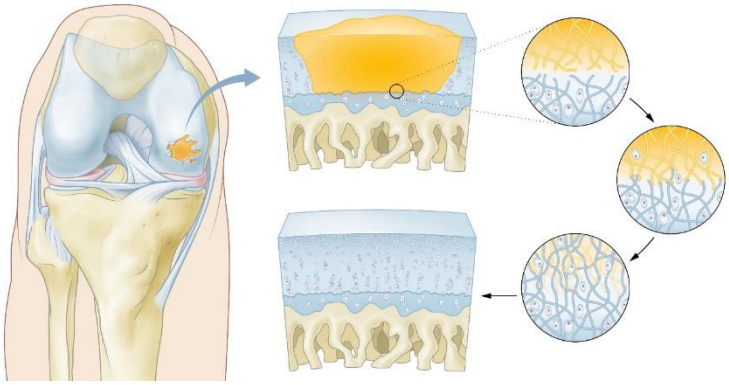
Dr. Roel Custers, principal investigator at UMC Utrecht: "We are enthusiastic about the new CartRevive® hydrogel implant. It is highly user-friendly and easy to implant in patients during standard cartilage repair surgery. The initial findings of the First-in-Human (safety) cohort have shown promising preliminary results with clear clinical relevance, and we look forward to collecting the full results of the trial."

Leo Smit, CEO of Hy2Care®, shares his excitement: "Treating our 46th patient is a major achievement in our mission to bring the Hy2Care® CartRevive® hydrogel implant to patients worldwide. The first real experiences with applying this new therapy strengthen our conviction that we are on the right track of delivering a new solution that improves patient outcomes and will have a positive influence in the daily lives of many people."

Next Steps: US clinical trial and EU market entry
The next step is expanding into the US market, where Hy2Care® is preparing to submit an Investigational Device Exemption (IDE) by the end of 2024. The IDE will pave the way for the US clinical trial, with the first patient treatment expected in early 2026. This milestone aligns with Hy2Care's European goals, as CE marking is anticipated also by early 2026. Upon receiving CE approval, Hy2Care® will begin commercialization and initiate reimbursement trials in various European countries.

About Hy2Care®
Hy2Care® is a spin-off company from the TechMed Centre at the University of Twente (NL), founded in 2014. Of the original founders, Prof. Dr. Marcel Karperien and Dr. Sanne Both remain active in the company. Prof. Dr. Karperien and his team from the Developmental BioEngineering group at the University of Twente developed Hy2Care's unique and proprietary technology. Hy2Care's launching product, the CartRevive® hydrogel implant for cartilage repair in the knee, has just completed the second phase of its clinical investigation, with 36 patients in the Netherlands, aimed at European market approval. The clinical results of the first safety group of 10 patients, completed in early 2023, were very promising, providing further confidence as preparations for the US clinical trial progress.

Patient part of the clinical trial treated with Hy2Care's CartRevive® hydrogel at Maastricht UMC+ by Dr. Pieter J. Emans.



During the surgery, the surgeon fills the cartilage defect with the 2 natural polymers. Within a minute, these polymers solidify into a perfectly fitting gel-plug that firmly adheres to the surrounding cartilage. Over time the gel disappears, and new cartilage has been formed.

For more information, contact Wendy Mertens: wendy.mertens@hy2care.com