

Optimal cartilage repair in the knee one step closer through new clinical study

- Hy2Care hydrogel technology designed to prevent osteoarthritis -

Geleen, 17 February 2022 - Hy2Care today announced that it will initiate a First-in-Human study with its injectable hydrogel to repair cartilage damage in the knee. The Medical Ethical Review Committee has granted approval to start the *ACTIVE* clinical study at UMC Utrecht, the Netherlands. The technology has been developed to provide optimal cartilage repair in the knee. The company anticipates this will prevent the onset of osteoarthritis. This addresses a large unmet clinical need based on the high prevalence of cartilage repair surgeries worldwide.

Hydrogel promotes natural recovery of patient's own cartilage

Existing cartilage repair techniques often stimulate scar tissue formation rather than cartilage, which causes mostly short-term pain relief. This leads to high recurrence rates and increased onset of osteoarthritis. Prof. dr. Marcel Karperien with his group at the University of Twente (Netherlands) invented the hydrogel technology and co-founded Hy2Care. The gel is based on natural components, which are quickly bound into a gel after injection. The gel will degrade over time and is expected to be replaced by naturally formed new cartilage tissue.

Promising solution for many patients

Hy2Care aims to reach many patients with this new technology. Millions of people worldwide receive cartilage repair surgery each year for example after a sports injury. In many of these cases, the pain and disability return after a few years, leading to an increased chance of development towards osteoarthritis. "Our hydrogel enables the body to heal itself. Therefore, we expect to replace current surgeries with our new hydrogel treatment and ultimately make a positive change in the lives of millions of people", says Leo Smit, CEO of Hy2Care.

The Dutch Arthritis Society recognizes a large potential in this groundbreaking solution and actively works with Hy2Care to bring the solution to patients. Corné Baatenburg de Jong, deputy director of the Dutch Arthritis Society: "Osteoarthritis is already the most common rheumatic disease in the Netherlands. If we do not find a solution that prevents or cures osteoarthritis, it will become the leading national disease by 2040. Hy2Care's technique is unique because it aims to prevent the disease. We therefore anticipate that this solution can help us in the fight against osteoarthritis."

Clinical study in UMC Utrecht, the Netherlands

Dr. Roel Custers, orthopedic surgeon at the University Medical Center Utrecht (UMCU) will lead the study as Principal Investigator. Dr. Roel Custers is an expert in knee treatments with more than a decade of experience, especially in cartilage repair. "The quality of the formed tissue after a cartilage repair intervention is an important factor for the long-term success. This new technique aims to stimulate the creation of natural cartilage by the patient's own cells and is easily performed", says dr. Roel Custers.

About Hy2Care

Hy2Care® is a 'spin-off company' of the Tech Med Centre of the University of Twente, the Netherlands and was founded in 2014. The original founders, prof. dr. Marcel Karperien and dr. Sanne Both, continue to be active in the company.

The unique technology of Hy2Care was developed by prof. dr. Marcel Karperien and his team of the Developmental BioEngineering group at the University of Twente. This injectable hydrogel technology is protected through several patents. Hy2Care's launching product, the injectable hydrogel for cartilage repair in the knee, will now be clinically investigated. Treatment of other joints and new applications of the hydrogel technology are in early-stage R&D phase.

In 2019 Hy2Care received a €3.7M Series-A investment. It's current Chief Executive Officer Leo Smit joined, and an additional team expansion was initiated, bringing in also Sanna Severins as Chief Operations Officer and co-director of the company. The goal of the Series-A Investment is to finance the scale up of the technology and initiate clinical trials. Also, a separate product and venture for veterinary applications is under development.

The company continues to use laboratory 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.

About the *ACTIVE* clinical Investigation

The name of the study, *ACTIVE*, stands for Advanced Cartilage Treatment with Injectable hydrogel Validation of the Effect. To be eligible to participate in this study patients must meet certain criteria, amongst which medical history, an age between 18 – 50 years, and cartilage trauma with a size of 0.5 – 2cm².

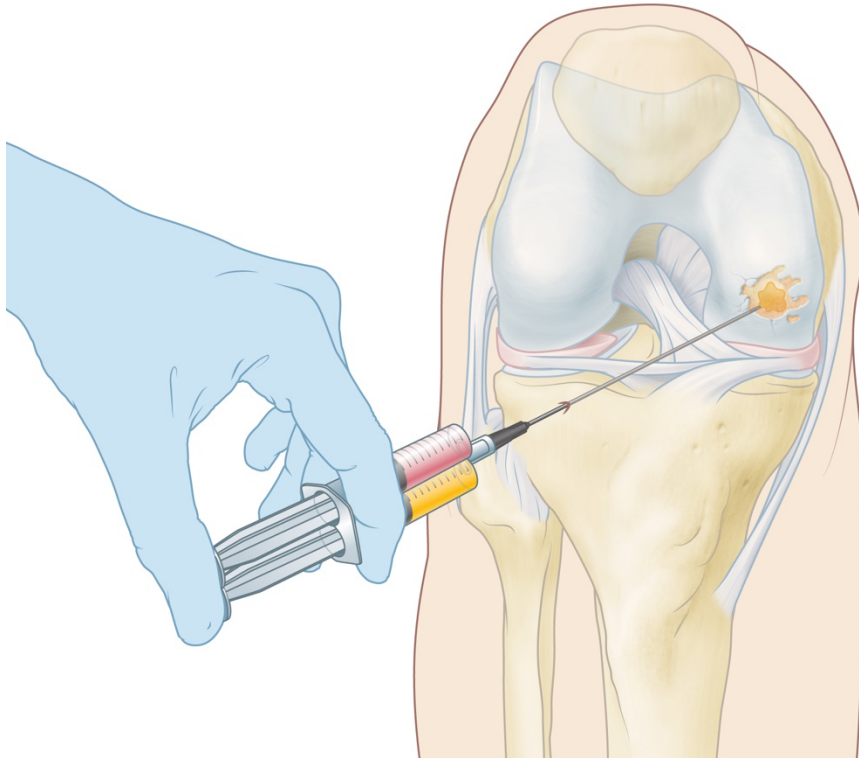
In the surgery, the surgeon will apply the hydrogel to the cartilage defect, which will firmly attach to the surrounding cartilage and bone in less than a minute. After implantation, patients will be periodically checked and examined during the course of 1 year.

At this moment a phase 1 study starts including 10 patients to evaluate safety. When successfully completed, an additional group of patients will be treated towards the end of this year, assessing the actual performance of the injectable hydrogel.

Patients interested in participating in the *ACTIVE* study can find more information via <http://www.umcutrecht.nl/activestudie>

Note for the press: for more information please contact:

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CEO at Hy2Care

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