Allegro's Hydrocelin significantly improves knee osteoarthritis pain and function in clinical trial

- Nanotechnology-based injection significantly improved knee pain and function with favorable safety and efficacy sustained over 6 months following a single administration
- Feasibility trial in Belgium completed recruitment ahead of schedule with last patient treated; three-month data from study are expected in second half of 2026

Liege, Belgium – 9 September 2026 (08:30 CET) – Allegro NV, a biomedical company developing a transformative nanotechnology treatment for osteoarthritis, today announced statistically significant improvements in pain and function endpoints over 6-months from an ongoing clinical study with Hydrocelin in 30 patients with knee osteoarthritis.

Hydrocelin is a first-in-class nanotechnology designed to restore the shock-absorbing properties of the joint. Unlike conventional injectable products, which primarily provide lubrication or temporary symptom relief, Hydrocelin has been developed to address the loss of the joint's natural protective mechanics, one of the key causes of osteoarthritis.

"These successful clinical results with Hydrocelin in knee osteoarthritis patients represent an important milestone for Allegro, and give us confidence to progress as quickly as possible towards a future registrational study," said **Lucas Decuypere, Chief Executive Officer of Allegro.** "The rapid onset of pain relief and the fact that the majority of patients remained pain-free through six months are particularly encouraging. Together, these findings support our belief that the key to improving osteoarthritis treatment lies in restoring the biomechanics of the joint."

In the clinical study, patients were measured on the 100-point KOOS (Knee injury and Osteoarthritis Outcome Score) grading, which surveys factors such as pain, daily living, sport and quality of life. Patients receiving a single injection showed a median improvement of 21.7 points after 4 weeks. A difference of 8-10 points is generally accepted as clinically meaningful. Clinical outcomes continued to improve during follow-up, reaching 31.1 points after twelve

weeks and 35.7 points after six months. All improvements were statistically significant compared to baseline measures. Investigators also reported a rapid onset of response, with most patients experiencing meaningful improvement within the first week following treatment. Only one minor adverse event (pain at the injection site) was reported which resolved naturally within 24 hours.

Separately, the last patient was treated in Allegro's European feasibility trial (Clinicaltrials.gov: NCT07516457) with Hydrocelin in 20 patients with osteoarthritis of the knee. The primary endpoint in this open-label study across three centers in Belgium is safety and tolerability at 13 weeks, and patients will be monitored for a total of 12 months, with efficacy evaluated as a secondary endpoint. Topline results from this study, available in second half of 2026, will provide input into the design of a future global registrational study. Faster than expected recruitment of the Belgian study, which took just two months, highlights the clinical investigators' interest in Hydrocelin and the significant unmet need for new treatment options for patients with knee osteoarthritis.

"Osteoarthritis is a widespread and debilitating condition, yet today's non-surgical treatments provide patients with only limited and temporary relief. The development of new technologies that aim to address the disease more fundamentally, as Allegro is doing, is long overdue," said **Dr Pieter-Jan Vandekerckhove**, a specialist knee surgeon at the AZ Sint-Jan Hospital in Bruges, Belgium, and an investigator in the ongoing Belgian trial.

After reviewing the clinical results, **Prof. Dr. Frank Luyten, advisor to Allegro and an internationally recognized expert in joint diseases**, described the initial findings as encouraging. "Tolerability has been very favorable, and the observed effect sizes of clinical relevance are promising in this patient population."

Osteoarthritis affects an estimated 650 million people worldwide and is one of the leading causes of pain, loss of mobility and reduced quality of life. By 2050, the number of affected patients is expected to approach one billion. Effective treatment options other than surgery are limited.

Hydrocelin is a first-in-class injectable nanotechnology device, designed as a minimally-invasive treatment for osteoarthritis. Hydrocelin aims to address a key primary cause of the disease: the loss of the shock-absorbing characteristics of the synovial fluid inside the joint. Hydrocelin contains cross-linked microparticles that act as tiny shock absorbers. Once injected, Hydrocelin disperses within the synovial fluid, where it adapts under load to replicate the mechanics of healthy joint fluid.

Allegro NV is a clinical-stage biomedical company developing transformative technologies for degenerative joint diseases based on its proprietary nanotechnology platform, INTRICATE. The company's lead product candidate, Hydrocelin, is a first-in-class injectable device for osteoarthritis, a novel performance biomaterial designed to restore the natural protective

mechanics of the joint, rather than merely masking symptoms. By altering the trajectory of the disease at its source we aim to redefine the future of osteoarthritis and its care.

For more information please visit www.allegro.bio.

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