

Liège (Belgium),

New state-of-the-art clinical trial aiming for comprehensive insights into an efficient treatment for Osteoarthritis

Wobenzym and **Artialis** are pleased to announce that they have randomized the first Osteoarthritis patients for the Wobe-SMART clinical study.

Nestlé Health Science and Artialis (Belgium), a research organization specialized in the field of musculoskeletal disorders, have jointly developed a post-marketing clinical trial to address patients suffering from Osteoarthritis (OA) of the knee. The Wobe-SMART trial, to be conducted in Belgium, will further elucidate the mechanism of action of Wobenzym® by using state of the art technologies in proteomics and cartilage biomarkers research to reveal pathways and targets modulated by Wobenzym®. This study is also unique in with additional innovative clinical parameters such as the structural evaluation of joint tissues by magnetic resonance imaging (MRI) and the physical mobility of patients using connected devices.

Osteoarthritis (OA) affects more than 250 million of people worldwide¹. OA of the knee is a painful condition and one of the most common causes of physical disability among older adults. It's estimated that globally 9.6% of men and 18.0% of women aged over 60 years have symptomatic osteoarthritis and are hence affected by the burden of this disease².

There are few treatment options that can help to relieve pain and improve mobility, especially for a safe long-term use, therefore there is a high unmet need for an anti-inflammatory treatment that is effective in reducing symptoms, but is also well tolerated and has a superior risk-benefit profile.

Wobenzym® is an oral enzyme combination with Bromelain, Trypsin and includes the flavonoid rutoside. It is approved as a pharmaceutical drug in Germany and many other countries in the EU and CIS/CEE region, supported by clinical evidence. A 2016 published meta-analysis has confirmed that Wobenzym® is as effective as gold standard NSAID Diclofenac in reducing joint pain, increasing joint function and mobility and yet has a favorable safety profile bringing a clear clinical benefit to patients with knee osteoarthritis³. While it is well established that Wobenzym® is safe and has proven efficacy

¹ Vos T, et al. : Years lived with disability (YLDs) for 1160 sequelae of 289 diseases and injuries 1990-2010: a systematic analysis for the Global Burden of Disease Study 2010. *Lancet*. 2012 Dec 15;380(9859):2163-96. doi: 10.1016/S0140-6736(12)61729-2. Erratum in: *Lancet*. 2013 Feb 23;381(9867):628. Almazroa, Mohammad A; Memish, Ziad A . PMID: 23245607; PMCID: PMC6350784.

² World Health Organization. Chronic rheumatic conditions [Available from: <https://www.who.int/chp/topics/rheumatic/en/>, accessed 14th May 2021].

³ Ueberall MA, Mueller-Schwefe GH, Wigand R, Essner U. Efficacy, tolerability, and safety of an oral enzyme combination vs diclofenac in osteoarthritis of the knee: results of an individual patient-level pooled reanalysis of data from six randomized controlled trials. *J Pain Res*. 2016;9:941-961. Published 2016 Nov 4. doi:10.2147/JPR.S108563.

in painful conditions, inflammation and OA, this clinical study is going to provide further insights on its mechanism of action.

About Wobenzym

Wobenzym has an extensive history in Systemic Enzyme Therapy spanning over 50 years. The Wobenzym® product range is offered in Europe, Russia and North America and is globally recognized in the joint health market. Wobenzym products, in addition to their rich clinical history, are well-known within the medical community for numerous benefits in the health of joints, muscles, and tendons. The line has been recently expanded by the Wobecare® brand including products like a CBD cream. Wobenzym prides itself on bringing high quality products to patients and practitioners worldwide. Wobenzym® has the mission of leading the way to provide solutions that maximize the body's ability to protect and restore itself.

Wobenzym website: <https://www.wobenzym.com/>

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About Artialis SA

Founded in 2010 by Professor Henrotin (University of Liège, Belgium), Artialis is a niche Contract Research Organization company highly specialized in the management of preclinical and clinical studies in the field of musculoskeletal disorders. Artialis offers customized solutions to its clients (Biotech / Pharma / Medical device and food nutrition companies) from preclinical to post-marketing clinical trials and propose a large panel of clinical, imaging and biochemical markers useful to support drug development.

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For more information on WOBESMART study

The Wobe-Smart study is a randomized, double-blind, placebo-controlled, two parallel arms, crossover, multicentric trial. This **Study** will investigate the **Mechanism of Action** of an Oral enzyme Wobenzym® with Bromelain, Trypsin and Rutoside treatment versus Placebo in Subjects with osTeoarthritis (Wobe-SMART). The study is expected to enroll 40 patients (20 per group). Patients will be daily treated with the product Wobenzym®, enteric-coated tablets for oral use or Placebo. The study duration per subject is 38 to 40 weeks – enrolment is open for eligible participants. Details can be found under <https://clinicaltrials.gov/> (NCT05038410).