



Fidia Announces Presentation of New Data Evaluating HYMOVIS® Effects on Cartilage Volume and Type II Collagen Turnover at Osteoarthritis Research Society International (OARSI) World Congress Meeting

Poster Title: "Hyaluronan Derivative Hymovis® Increases Cartilage Volume and Type II Collagen Turnover in Osteoarthritis Knee:

Data from MOKHA (MRI, BiOmarkers, Knee, Hymovis®, OsteoArthritis) Study"

Abano Terme, Italy, April 25, 2018 – Fidia Farmaceutici, a world leader in the research, development and manufacturing of hyaluronic acid (HA)-based products and its wholly owned subsidiary, Fidia Pharma USA Inc., announces that new data will be presented at the Osteoarthritis Research Society International (OARSI) World Congress Meeting in Liverpool, U.K., April 26-29.

The pilot study "MOKHA," coordinated by Fidia Farmaceutici, which involved eight sites in France and Belgium, aimed to explore the potential structural modifying effect of HYMOVIS®, an HA viscosupplement, in patients suffering from symptomatic knee osteoarthritis (OA) using a combination of clinical outcomes and objective measurements including biological and MRI-based imaging markers. This open, multicenter, prospective study on 46 patients showed that HYMOVIS® significantly enhanced type II collagen turnover as suggested by the increase of Coll2-1 ($p < 0.001$) and PIIANP ($p < 0.001$) soluble biomarkers and by the decrease over time of the ratios Coll2-1/PIIANP and CTX-II/PIIANP ($p < 0.005$). Cartilage volume and thickness enhancement was observed by MRI in some knee compartments ($p < 0.05$). Furthermore, WORMS effusion (Whole-Organ Magnetic Resonance Imaging Score), an indicator of synovitis, significantly decreased ($p < 0.016$).

In addition, global KOOS (Knee Injury and Osteoarthritis Outcome Score) and subscales significantly increased over time ($p < 0.001$) while pain at rest, walking pain, and patients or investigators global assessment of disease activity decreased ($p < 0.001$). Furthermore, HYMOVIS® showed a favorable safety profile with no serious adverse events related to the product and low incidence of injection-site pain. "Importantly, this study highlights the potential beneficial effect of HYMOVIS® on pain and function. Altogether, this data suggests that HYMOVIS® could have a structural modifying effect in knee OA and provides critical information for the design of a larger clinical trial," said Dr. Pascal Richette, Service de Rhumatologie, Hôpital Lariboisière, Paris, France.

The new data will be presented at the Osteoarthritis Research Society International (OARSI) World Congress Meeting in Liverpool, U.K., April 26-29. *Poster Title: "Hyaluronan Derivative Hymovis® Increases Cartilage Volume and Type II Collagen Turnover in Osteoarthritis Knee: Data from MOKHA (MRI, BiOmarkers, Knee, Hymovis®, OsteoArthritis) Study" – Henrotin Y. et al.*

About HYMOVIS®

HYMOVIS® is a highly viscoelastic non-crosslinked hydrogel bioengineered using a proprietary process that increases lubrication and shock absorption properties. This results in a natural hyaluronan similar to

the hyaluronan found in the synovial fluid present in human joints. The formulation allows this unique molecule to recover its original structure, even after repetitive mechanical stress. Due to reversible hydrophobic interactions, the non-crosslinked HYMOVIS® has increased elasticity, viscosity and residence time in the joint.* Its unique molecular structure results in enhanced biomechanical properties and long-lasting efficacy, all in a convenient two-dose regimen.

*Preclinical studies may not be indicative of human clinical outcomes.

In Europe, HYMOVIS® is indicated for the treatment of pain in osteoarthritic joints and in the conservative treatment of the meniscal lesion of the knee and for the improvement of joint mobility through the enhancement of synovial fluid viscoelasticity.

In the U.S., HYMOVIS® is indicated for the treatment of pain in osteoarthritis (OA) of the knee in patients who have failed to respond adequately to conservative non-pharmacologic therapy or simple analgesics.

HYMOVIS® is contraindicated in patients with known hypersensitivity to hyaluronate preparations or gram-positive bacterial proteins or patients with infections/skin diseases in the area of the injection site/joint. The safety and effectiveness of HYMOVIS® has not been tested in pregnant women, nursing mothers or children. See package insert for full prescribing information including adverse events, warnings, precautions, and side effects at www.hymovis.com.

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About Fidia Farmaceutici

Fidia Farmaceutici is part of Fidia Pharma Group, an Italian multinational company, with R&D, manufacturing and sales capabilities, and an extensive product portfolio mainly based on natural and functionalized hyaluronic acid (over 650 patents), in joint care, wound healing, ophthalmology, aesthetics and regenerative medicine. Manufacturing operations are FDA-inspected and approved, and the company extends its global reach through wholly-owned subsidiaries and partners in 100 countries worldwide. For more information, please visit www.fidiapharma.com.

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