



Fidia Introduces Hymovis[®], a Next-Generation Hyaluronan, at the AAOS Annual Meeting in Orlando

Hymovis[®], which is being launched in the U.S, is a highly viscoelastic hydrogel (HYADD^{®4}) engineered using a proprietary process that increases lubrication and shock absorption properties

PARSIPPANY, N.J., February 25, 2016 – Fidia Farmaceutici S.p.A., a world leader in the research, development and manufacturing of hyaluronic acid (HA)-based products, and its wholly owned subsidiary, Fidia Pharma USA Inc., will introduce Hymovis[®] (high molecular weight viscoelastic hyaluronan) at the Annual Meeting of the American Academy of Orthopaedic Surgeons (AAOS) in Orlando, March 1-5, 2016.

Hymovis[®] is a next-generation of HA-based intra-articular (IA) therapy 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. The product has a shorter treatment cycle of only two intra-articular injections as compared to many other IA HA viscosupplement regimens to provide pain relief for the patient.

Scientists from Fidia Farmaceutici S.p.A. and the research group led by Dr. Lawrence Bonassar, Professor in the Meinig School of Biomedical Engineering at Cornell University worked together to verify the optimal lubricating characteristics of the HA derivative. Hymovis[®] was bioengineered using a proprietary process that results in a natural hyaluronan similar to the hyaluronan found in the synovial fluid present in human joints. The formulation allows the 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. “In our research, we definitively showed that Hymovis[®] had a lower friction coefficient and, therefore, better viscous lubricating properties than either saline or another viscous HA, across varying conditions that mimic joint load and movement,” states Dr. Bonassar.

Worldwide, hyaluronic acid-based intra-articular injections are used in the treatment of knee pain due to OA of the knee and have been recognized for the treatment of osteoarthritis of the knee.

The Food and Drug Administration’s (FDA) Center for Devices and Radiological Health gave premarket approval (PMA) for Hymovis[®] on August 28, 2015 and Hymovis[®] will be commercially available in March 2016.

“Hymovis[®] represents an important new treatment option for orthopedic surgeon/sports medicine physicians and their patients; particularly those who are active, high-demand patients with OA knee pain,” states Dr. Clarence L. Shields, orthopedic surgeon with the Kerlan-Jobe Orthopaedic Clinic in Los Angeles, CA.

“The launch of Hymovis[®] signals the continued growth and success of Fidia Pharma USA Inc. and builds on our success with our flagship product Hyalgan[®]. With both of these products in our portfolio, we are uniquely positioned to provide the solutions for the broad range of patients with pain in osteoarthritis (OA) of the knee,” states Aldo Donati, President of Fidia Pharma USA Inc.

For more information, please visit Fidia Pharma USA Inc. at the AAOS Annual Meeting at **Booth 2003**.

About Fidia Pharma USA Inc.

Fidia Pharma USA Inc is a wholly-owned subsidiary of Italian pharmaceutical manufacturer Fidia Farmaceutici S.p.A., an established leader in the hyaluronic acid market segment.

Fidia Pharma USA Inc. is focused on expanding Fidia's position in the U.S. and Canadian market, while upholding the company's mission to provide consumers with innovative products that offer quality, safety and performance. Fidia Pharma USA Inc. is headquartered in Parsippany, NJ.

For more information, please visit www.fidiapharma.us.

About Fidia Farmaceutici S.p.A.

Fidia Farmaceutici S.p.A. is an Italian pharmaceutical company founded in 1946. It is a leader in research and marketing hyaluronic acid-based products, with several applications in the biomedical field, such as rheumatology, orthopaedics, surgery, wound care, tissue repair and dermo-aesthetics. Fidia Farmaceutici is part of the P&R Holding group. The company is located in Italy, with R&D facilities in Abano Terme (Padua) and Noto (Sicily). Fidia has more than 700 employees, and its revenue exceeds €250 million euros. Fidia Farmaceutici S.p.A.'s products are marketed in more than 100 countries, through wholly owned subsidiaries and a comprehensive network of international partnerships and distributors. Thanks to its investment in research, it has created a legacy of products with more than 600 patents to its name. For more information, please visit www.fidiapharma.com.

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Indication

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 (e.g., acetaminophen).

Important Safety Information

Hymovis[®] is contraindicated in patients with known hypersensitivity (allergy) to hyaluronate preparations or gram positive bacterial proteins. Do not administer Hymovis[®] to patients with infections or skin diseases in the area of the injection site or joint.

The safety and effectiveness of the use of Hymovis[®] has not been tested in pregnant women, nursing mothers or children. The safety and effectiveness of the use of Hymovis[®] in joints other than the knee, or for use concomitantly with other intra-articular (IA) injections has not been established. The effectiveness of repeat treatment cycles of Hymovis[®] has not been established. Arthralgia, transient pain or swelling may occur after the IA injection. The incidence of arthralgia in the clinical study for Hymovis[®] was equivalent to the control group. No serious adverse reactions or pseudoseptic reactions were reported. Transient increases in inflammation following any IA hyaluronan injection have been reported in some patients with inflammatory joint conditions.

Rx Only

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