FDA Approves Genzyme’s Synvisc-One for Osteoarthritis of the Knee

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Genzyme Corporation (Nasdaq: GENZ) today announced that the U.S. Food and Drug Administration (FDA) has granted marketing approval for Synvisc-One™ (hylan G-F 20), a product intended for the relief of pain associated with osteoarthritis (OA) of the knee. Synvisc-One is the only single-injection viscosupplement approved for the treatment of OA knee pain in the United States. This therapy has the potential to redefine the market for viscosupplementation products by extending the benefits of this therapeutic approach to a broader set of patients and reducing the total cost and burden of multiple injections.

"In just one visit to the doctor's office, patients suffering from osteoarthritis may experience clinically significant pain relief for up to six months and for some patients this pain relief could potentially translate into a delay in the need for a total knee replacement," said Jack M. Bert, M.D., president of the Arthroscopy Association of North America and adjunct clinical professor at the University of Minnesota School of Medicine. "This single injection regimen will provide greater physician and patient convenience."

Synvisc-One is administered through a single intra-articular injection. It is an alternative treatment regimen to Genzyme's Synvisc® (hylan G-F 20), a three-injection viscosupplement approved in the United States in 1997 and in use worldwide for more than 16 years. Synvisc-One contains the same material and total treatment volume as Synvisc but provides the 6 mL of hylan G-F 20 in a single injection. Viscosupplementation is a procedure in which hyaluronic acid or a derivative such as hylan G-F 20 is injected into the knee joint to replace synovial fluid that typically becomes degraded in patients with osteoarthritis. In synovial fluid, hyaluronic acid relieves pain and improves the knee joint's natural shock absorbing abilities.

"Synvisc-One is an important therapy for OA of the knee because it delivers long-term pain relief through a single injection without the systemic side effects that can be caused by steroids and anti-inflammatory medication," said Ann Merrifield, professor at the University of Minnesota School of Medicine. "This single injection regimen will provide greater physician and patient convenience." Synvisc-One is also approved in the European Union and a number of Asian and Latin American countries. Nearly 10,000 patients have been treated with Synvisc-One since it was first approved last year. Genzyme will begin making Synvisc-One available immediately. For full prescribing information please visit www.synvisc.com.

Important Therapy Provides Six Months Pain Relief with Single Injection

About Synvisc-One

Synvisc-One™ (hylan G-F 20) 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 and simple analgesics, e.g., acetaminophen.

Synvisc-One is contraindicated in patients with known hypersensitivity to hyaluronan products or patients with infections in or around the target knee. Use caution when injecting Synvisc-One in patients allergic to avian proteins, feathers, or egg products; who have evidence of venous or lymphatic stasis in the leg to be treated; or who have severe inflammation in the knee to be treated.

The most commonly reported related local adverse events were transient, mild-to-moderate arthralgia, arthritis, arthropathy, injection site pain and joint effusion. No serious adverse events have been reported in knees injected with Synvisc-One. Repeat treatment did not affect the safety profile. In the pivotal clinical trial, there was one related systemic event of syncope. The most common systemic side effects irrespective of relationship to Synvisc-One were headache, back pain, nasopharyngitis and influenza. Systemic adverse event profiles were similar between patients in the Synvisc-One and Saline Control groups. Side effects such as rash have been reported rarely in association with Synvisc.

Patients should be advised to avoid strenuous or prolonged weight-bearing activities for approximately 48 hours after treatment. Aspiration of any effusion prior to injection is highly recommended. Strict adherence to aseptic technique must be followed to avoid joint infection. The safety and effectiveness of Synvisc-One have not been established in children or in pregnant or lactating women. It is unknown whether Synvisc-One is excreted in human milk.

About Genzyme

One of the world's leading biotechnology companies, Genzyme is dedicated to making a major positive impact on the lives of people with serious diseases. Since 1981, the company has grown from a small start-up to a diversified enterprise with more than 11,000 employees in locations spanning the globe and 2008 revenues of $4.6 billion. In 2007, Genzyme was chosen to
receive the National Medal of Technology, the highest honor awarded by the President of the United States for technological innovation.

With many established products and services helping patients in nearly 100 countries, Genzyme is a leader in the effort to develop and apply the most advanced technologies in the life sciences. The company's products and services are focused on rare inherited disorders, kidney disease, orthopaedics, cancer, transplant and immune disease, and diagnostic testing. Genzyme's commitment to innovation continues today with a substantial development program focused on these fields, as well as cardiovascular disease, neurodegenerative diseases, and other areas of unmet medical need.

Genzyme's press releases and other company information are available at www.genzyme.com and by calling Genzyme's investor information line at 1-800-905-4369 within the United States or 1-678-999-4572 outside the United States.

This press release contains forward-looking statements, including Genzyme's assessment of Synvisc-One's market potential and its expectation that the product will be a significant growth driver for the business. These statements are subject to risks and uncertainties that could cause actual results to differ materially from those projected. These risks and uncertainties include, among others, the extent to which the government and private insurers recognize the benefits of Synvisc-One and implement or maintain reimbursement policies that reflect these benefits, whether doctors recognize the benefits of Synvisc-One and adopt it as a preferred treatment option and the risks and uncertainties described in reports filed by Genzyme with the U.S. Securities and Exchange Commission, including without limitation the factors discussed under the caption "Risk Factors" in Genzyme's Quarterly Report on Form 10-Q for the quarter ended September 30, 2008. We caution investors not to place undue reliance on the forward-looking statements contained in this press release. These statements speak only as of the date of this press release, and we undertake no obligation to update or revise the statements.

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