Genzyme Receives European Approval of Renvela for Patients with Chronic Kidney Disease

Release Date:
Friday, June 12, 2009 9:00 am EDT

Terms:

Dateline City:
CAMBRIDGE, Mass.

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Genzyme Corporation (Nasdaq: GENZ) today announced that the European Commission has approved Renvela® (sevelamer carbonate) for the control of serum phosphorus in patients with chronic kidney disease (CKD). The approval includes patients not on dialysis with serum phosphorus levels ≥ 1.78 mmol/L (5.5 mg/dL), and covers both the tablet and powder formulations.

"With this marketing authorization, Renvela is the first phosphate binder for patients not on dialysis approved through the centralized procedure in Europe," said Dan Regan, Senior Vice President and General Manager of Genzyme’s renal business. “This is an important step toward improved patient care, and we are pleased that CKD patients in Europe will now have access to this proven therapy.”

Renvela is a next-generation version of Renagel® (sevelamer hydrochloride), a calcium-free, metal-free, non-absorbed phosphate binder, and has the added benefit of a carbonate buffer. In a clinical study comparing Renvela to Renagel, both drugs controlled serum phosphorus equally to within the recommended KDOQI range.

“Hyperphosphatemia is a significant risk factor for cardiovascular disease in patients with CKD, and frequently starts before patients reach dialysis,” said Markus Ketteler, Professor of Medicine and Clinical Nephrologist, Klinikum Coburg, Academic Teaching Hospital of the University of Würzburg, Germany. “Renvela is an important addition to the therapeutic options available to nephrologists, and gives them the opportunity to treat hyperphosphatemia earlier.”

Elevated serum phosphorus levels are common in patients with CKD because phosphorus is not easily filtered by the diseased kidneys and as a result builds up in the body. This build up is associated with calcification of tissues, and therefore controlling serum phosphorous is an important element in the care of patients with CKD.

Genzyme has been working with regulatory officials worldwide to secure additional approvals for Renvela. The company this quarter launched Renvela in India for CKD patients on dialysis. This week, Genzyme also received approval for the treatment in Brazil, the second-largest market for sevelamer outside of the United States. The Brazil approval is for the treatment of CKD patients on dialysis; the company also plans to seek approval in that country for the product’s use in hyperphosphatemic CKD patients who are not on dialysis.

In the United States, Genzyme launched Renvela tablets for patients with CKD on dialysis in March 2008, and the company anticipates FDA approval of the powder formulation for this indication during the second half of this year.

Genzyme has also been in discussions with the FDA regarding the treatment of hyperphosphatemic CKD patients not on dialysis. Genzyme now anticipates that its discussions with the agency will continue beyond midyear, and given the nature of this process, the company cannot provide an anticipated timeframe for the agency’s decision on this indication. Genzyme’s 2009 guidance will not be affected.

About Renvela and Renagel

Renvela (sevelamer carbonate) and Renagel (sevelamer hydrochloride) are currently the only phosphate binders available that do not contain either calcium or a metal. Sevelamer, the active moiety in both Renagel and Renvela, has an established safety profile and is not systemically absorbed. It is used by approximately 450,000 patients worldwide.

Sevelamer is contraindicated in patients with hypophosphatemia or bowel obstruction. Caution should be exercised in patients with dysphagia, swallowing disorders, severe gastrointestinal (GI) motility
disorders including severe constipation or major GI tract surgery. Common adverse events reported with sevelamer include vomiting, nausea, diarrhea, dyspepsia, abdominal pain, and constipation. Other events reported include pruritus, rash, fecal impaction, and intestinal obstruction. Drug-drug interactions may occur with some medications and should be taken into consideration when instructing patients how to take sevelamer. Patients should be informed to take sevelamer with meals and to adhere to their prescribed diets.

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.

With many established products and services helping patients in approximately 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.

This press release contains forward-looking statements regarding Genzyme’s business plans and strategies including, without limitation, statements about: the potential benefits of Renvela; anticipated FDA approval of Renvela powder and the use of Renvela in CKD patients not on dialysis; and the timing of FDA action and its effect on financial guidance. These statements are subject to risks and uncertainties that could cause actual results to differ materially from those forecasted. These risks and uncertainties include, among others: the actual efficacy and safety of Renvela; the timing of discussions with the FDA regarding the approval of an additional formulation of, and indication for, Renvela; whether the FDA approves the powder formulation of Renvela; whether the FDA approves the use of Renvela in CKD patients not on dialysis and the timing of those decisions; and the risks and uncertainties described in Genzyme’s SEC reports filed under the Securities Exchange Act of 1934, including the factors discussed under the caption “Risk Factors” in Genzyme’s Quarterly Report on Form 10-Q for the period ended March 31, 2009. Genzyme cautions 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 Genzyme undertakes no obligation to update or revise the statements.

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