



Santarus Receives FDA Approval for ZEGERID Powder for Oral Suspension 40mg

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First and Only Proton Pump Inhibitor Approved For Reduction of Risk of Upper GI Bleeding in Critically Ill Patients

Santarus, Inc. (Nasdaq:SNTS), a specialty pharmaceutical company focused on therapies for gastrointestinal (GI) diseases and disorders, today announced that the U.S. Food and Drug Administration (FDA) has approved the company's new drug application (NDA) for ZEGERID(TM) (omeprazole) Powder for Oral Suspension 40mg, for the reduction of risk of upper GI bleeding in critically ill patients and the short-term treatment (four to eight weeks) of active benign gastric ulcers. ZEGERID is the first and only immediate-release oral proton pump inhibitor (PPI) and is the only PPI approved for the indicated use in critically ill patients. Santarus plans to commercially launch ZEGERID Powder for Oral Suspension 40mg in the first quarter of 2005. This represents the second product approval for Santarus, following the launch of ZEGERID Powder for Oral Suspension 20mg in October 2004.

"With the approval of ZEGERID 40mg, we are now able to offer physicians and patients a higher dosage that provides immediate release and strong and sustained acid control, with gastric pH above 4.0 for 18.6 hours per day with repeated once-daily dosing," said Gerald T. Proehl, president and chief executive officer of Santarus. "We believe ZEGERID 40mg presents an attractive opportunity for Santarus in the over \$12 billion U.S. prescription PPI market, given that the vast majority of prescriptions for currently marketed PPIs are filled at the highest dose strength available."

The company and its co-promotion partner, Otsuka America Pharmaceutical, Inc., are preparing their combined approximately 400 person field sales force to promote ZEGERID 40mg to target physicians. In connection with ZEGERID's approval for reduction of risk of upper GI bleeding in critically ill patients, Santarus is also evaluating strategies to expand the promotion of ZEGERID to the hospital market, including to the teaching and other influential institutions that serve this patient population, in order to create greater awareness of the ZEGERID brand over time.

About ZEGERID

ZEGERID Powder for Oral Suspension, now approved in both 20mg and 40mg dose strengths, is an immediate-release formulation of omeprazole that reaches peak plasma levels within approximately 30 minutes and provides strong acid control throughout the day. In addition to providing acid control during the day, repeated once-daily dosing of ZEGERID 40mg prior to bedtime was found to provide effective control of nighttime gastric acidity (median gastric pH of 4.1 for nighttime hours and 4.7 for a 24-hour period).

ZEGERID's proprietary formulation utilizes an antacid to protect the omeprazole from acid degradation in the stomach, allowing the omeprazole to be quickly absorbed into the blood stream. All other marketed oral PPIs are delayed-release formulations that utilize an enteric coating to protect the PPI from acid degradation, delaying absorption and initial acid suppression.

The approval of ZEGERID 40mg for the reduction of risk of upper GI bleeding in critically ill patients and the short-term treatment of gastric ulcers adds to the broad range of indications for which ZEGERID, in its other dosage strength, is approved. ZEGERID 20mg was approved earlier this year for short-term treatment of active duodenal ulcer, for heartburn and other symptoms associated with gastroesophageal reflux disease (GERD), for the short-term treatment (four to eight weeks) of erosive esophagitis which has been diagnosed by endoscopy and for maintenance of healing of erosive esophagitis.

Upper GI Bleeding in Critically Ill Patients - Reducing the Risk

"ZEGERID 40mg is the only PPI approved for the reduction of risk of upper GI bleeding in critically ill patients," said Bonnie Hepburn, M.D., senior vice president, drug development and chief medical officer of Santarus. "When evaluating ZEGERID 40mg for this indication, we were particularly pleased to see such a significant reduction in gastric acidity in this patient population, beginning with the first dose and continuing throughout the day."

Critically ill ventilated patients are at high risk for developing erosions and upper GI bleeding that occur when the gastric mucosa, already compromised by stress, is continuously exposed to significant amounts of acid. Many hospitals treat these patients prophylactically to reduce acid and the risk of upper GI bleeding. Patients who develop upper GI bleeding may require blood transfusions or in some cases may require surgery with a high mortality rate. It is estimated that as many as four million critically ill patients are treated annually in the U.S., with 1.5 million at highest risk for upper GI bleeding due to the use of mechanical ventilators.

To support approval of the upper GI bleeding indication, Santarus evaluated ZEGERID 40mg in a double-blind, multicenter, randomized clinical trial. In the trial 178 critically ill patients were treated with ZEGERID 40mg via nasogastric or orogastric tube, and only 4% of the patients experienced clinically significant upper GI bleeding. Trial results also demonstrated that ZEGERID provided significant reduction of gastric acid, with a median daily gastric pH above 4.0 in at least 95% of the patients over the course of the 14-day trial, beginning with the first dose (99% of patients 1-2.5 hours postdose and 92% of patients 6 hours postdose).

Important Safety Information

ZEGERID Powder for Oral Suspension 20mg is indicated for short-term treatment of active duodenal ulcer, for heartburn and other symptoms associated with gastroesophageal reflux disease (GERD), for the short-term treatment (four to eight weeks) of erosive esophagitis which has been diagnosed by endoscopy, and for maintenance of healing of erosive esophagitis. ZEGERID Powder for Oral Suspension 40mg is indicated for the reduction of risk of upper GI bleeding in critically ill patients and the short-term treatment (four to eight weeks) of active benign gastric ulcers. ZEGERID is contraindicated in patients with known hypersensitivity to any components of the formulation.

The most frequently reported adverse events with ZEGERID are headache, diarrhea and abdominal pain. Symptomatic response to therapy does not preclude the presence of gastric malignancy. Atrophic gastritis has been noted occasionally in gastric corpus biopsies from patients treated long term with omeprazole.

ZEGERID contains 460mg sodium per dose in the form of sodium bicarbonate, which should be taken into consideration for patients on a sodium-restricted diet. Sodium bicarbonate is contraindicated in patients with metabolic alkalosis and hypocalcemia.

About Santarus

Santarus, Inc. is a specialty pharmaceutical company focused on acquiring, developing and commercializing proprietary products for the prevention and treatment of gastrointestinal diseases and disorders. The company's current products are immediate-release formulations of omeprazole, a widely prescribed PPI. The company launched its first product, ZEGERID Powder for Oral Suspension 20mg in October 2004 and received FDA approval to market ZEGERID Powder for Oral Suspension 40mg in December 2004. The company also is developing capsule and chewable tablet formulations of ZEGERID. More information about Santarus is available on the company's Web site at www.santarus.com.

Santarus cautions you that statements included in this press release that are not a description of historical facts are forward-looking statements. These forward-looking statements include statements regarding the timing of the commercial launch of ZEGERID Powder for Oral Suspension 40mg and the potential market acceptance of this product.

The inclusion of forward-looking statements should not be regarded as a representation by Santarus that any of its plans will be achieved. Actual results may differ materially from those set forth in this release due to the risks and uncertainties inherent in Santarus' business, including, without limitation: Santarus' ability to successfully launch ZEGERID Powder for Oral Suspension 40mg and to establish market acceptance and demand for ZEGERID Powder for Oral Suspension 20mg and 40mg; difficulties or delays in development, testing, manufacturing and marketing of, and obtaining regulatory approval for, Santarus' other products under development; unexpected adverse side effects or inadequate therapeutic efficacy of ZEGERID Powder for Oral Suspension or Santarus' other products under development that could delay or prevent product development or commercialization, or that could result in recalls or product liability claims; competition from other pharmaceutical or biotechnology companies; Santarus' ability to obtain additional financing as needed to support its operations; and other risks detailed in Santarus' prior press releases as well as in public periodic filings with the Securities and Exchange Commission.

You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement and Santarus undertakes no obligation to revise or update this news release to reflect events or circumstances after the date hereof. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

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