



News Release

For Immediate Release

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Eurand Granted FDA Approval for ZENPEP™
First and Only FDA-Approved Pancreatic Enzyme Product
Clinically Tested in Patients under 12 Years Old

PHILADELPHIA, Pa. – Aug. 28, 2009 – Eurand N.V. (NASDAQ: EURX), a specialty pharmaceutical company, today announced U.S. Food and Drug Administration (FDA) approval of its New Drug Application (NDA) for ZENPEP™ (pancrelipase) Delayed-Release Capsules for the treatment of exocrine pancreatic insufficiency (EPI) in patients with cystic fibrosis (CF) or other conditions.

ZENPEP is the only FDA-approved pancreatic enzyme product (PEP) that has been evaluated in clinical studies in adults and children – including children from one to 12 years old – and will offer four dosage strengths to meet the varied needs of infants, toddlers, adolescents and adults with EPI.

“The availability of clinical evidence in a pediatric population is particularly important for EPI patients with CF and their caregivers, as early improvements in BMI (Body Mass Index) significantly affect long-term survivability,” said Jamie Wooldridge, M.D., Assistant Professor, Department of Pediatrics, Division of Pulmonary Medicine at Cincinnati Children’s Hospital Medical Center, Cincinnati, Ohio, and a principal investigator in the ZENPEP pediatric trial. ZENPEP capsules were formulated to allow the contents to be sprinkled on food where necessary, which is a key attribute to support the developmental needs of very young children as well as older patients.

EPI is the inability to properly digest food due to a lack of digestive enzymes made by the pancreas. Loss of digestive enzymes leads to maldigestion and malabsorption of nutrients. This is a common disorder for those suffering from cystic fibrosis and other conditions compromising the exocrine function of the pancreas, such as pancreatic cancer, gastrointestinal surgery and chronic pancreatitis. EPI results in malnutrition and, especially in CF patients, impaired growth in children, compromised immune response and shortened life expectancy. ZENPEP replaces these missing enzymes and improves digestion and absorption. In addition, ZENPEP’s stability and precise range of dosage strengths will allow health care professionals to dose a patient’s treatment regimen for optimal symptom control and potentially reduce their pill burden.

ZENPEP was developed specifically to meet the FDA's guidelines on PEPs. Historically, PEPs have not been regulated and approved by the FDA. In 2004, due to inconsistent quality that affected the safety and efficacy of PEPs, the FDA determined it was necessary to better control these products. All manufacturers of EPI drug products were required to file NDAs and receive marketing approvals by April 2010.

"For years, patients with EPI taking unapproved PEPs have lived with far too much variability in the control of their gastrointestinal symptoms as a result of product instability and dosing inconsistency," said Gearóid Faherty, Chairman and Chief Executive Officer. "The approval of ZENPEP is a major milestone for patients suffering from EPI and for Eurand. In preparation for our U.S. launch we have built and continue to expand a first-rate commercial organization to help ZENPEP reach its full market potential." According to IMS Health, the market for PEPs was an estimated \$1.13 billion worldwide in 2008.

The U.S. commercial launch of ZENPEP is planned for the fourth quarter of 2009. Eurand will market ZENPEP for the approved indication through its own sales force to the different physician groups that treat EPI within each of the target CF and non-CF patient populations.

"Eurand is committed to a successful launch of ZENPEP and intends to deploy a sales force of sufficient size and scope to address these distinct market segments. To accelerate adoption, we will also have an extensive sampling and patient support program for a period of time following the launch," Faherty said.

"The Cystic Fibrosis Foundation encouraged the FDA to mandate the NDA process for pancreatic enzymes in order to ensure that all of these products are of the highest quality," said Robert J. Beall, Ph.D., President and Chief Executive Officer of the Cystic Fibrosis Foundation, a leading patient advocacy group. "Pancreatic enzymes approved through this process will help ensure that CF patients receive products that are documented to be safe and effective. The approved formulations will allow for more precise dosing, which will help ensure patients receive the proper nutrients to support growth and development and may reduce their treatment burden. We are pleased that people with CF will have the option of using Eurand's newly approved pancreatic enzyme, ZENPEP, and are grateful to all those who participated in the clinical trials that made this approval possible."

ZENPEP was shown to be safe and effective for the treatment of EPI in two Phase III multicenter clinical trials – one in older children, adolescents and adults, and one in young children (ages 1 through 6). Both studies established efficacy and safety of ZENPEP in CF patients with EPI. In the placebo-controlled, randomized, double-blind pivotal study in older children and adult patients, ages 7-23 years, the primary efficacy endpoint was mean Coefficient of Fat Absorption (CFA), the gold standard for assessing the severity of EPI. CFA was statistically higher with ZENPEP treatment (88.3%) than placebo (62.8%)($p < 0.001$).

In the open-label, single-arm study in young patients, patients maintained symptom control when switched from their usual PEP regimen to ZENPEP at similar doses. The safety and efficacy in pediatric patients evaluated in this study were similar to adult patients.

ZENPEP was not associated with any serious drug-related adverse events in any of the clinical trials. The most common adverse events were gastrointestinal

complaints, which were similar in type and frequency across all age ranges in the two studies. The most commonly reported adverse events occurring in at least two patients ($\geq 6\%$ of patients) included: abdominal pain, flatulence, headache, cough, decreased weight, early satiety, and contusion. The type and incidence of adverse events were similar in children and adults.

ZENPEP is the sixth Eurand-developed product to be approved by the FDA since 2001 and the second this year following the May 8th approval of LAMICTAL[®] ODT[™].

About Exocrine Pancreatic Insufficiency (EPI)

Exocrine Pancreatic Insufficiency (EPI) is the inability to properly digest food due to a lack of digestive enzymes made by the pancreas. EPI can result from a number of diseases, including cystic fibrosis, pancreatic cancer, gastrointestinal surgery, and chronic pancreatitis. The FDA estimates that more than 200,000 Americans suffer from EPI. If left untreated, EPI causes malnutrition and, especially in CF patients, impaired growth in children, compromised immune response and shortened life expectancy. EPI is treated by porcine-derived pancreatic enzyme products, which have been marketed in the U.S. without FDA approval for more than 70 years.

About ZENPEP[™] (pancrelipase) Delayed-Release Capsules

ZENPEP is an innovatively formulated pancreatic enzyme product for the treatment of exocrine pancreatic insufficiency. The product was developed in response to the 2004 FDA initial guidance on pancreatic enzyme products, which outlined the need to reduce the variability in enzyme levels, address stability issues associated with unapproved enzyme therapies and regulate them under NDAs. ZENPEP is a highly stable formulation of a porcine pancreatic extract that is biologically similar to the endogenous human pancreatic secretions necessary for proper human digestion.

Every dose of ZENPEP provides patients and physicians with a consistent amount of the main pancreatic enzymes lipase, protease and amylase due to its highly stable formulation. These features allow health care professionals to fine tune treatment regimens to achieve optimal symptom control with improved dosing precision. Safety and efficacy of ZENPEP in EPI were demonstrated in two multicenter Phase III clinical trials in adult and pediatric patients of all ages, down to one year old. Good nutrition is considered to be critically important to growth characteristics in children with cystic fibrosis, resulting in improvement in lung function and overall quality of life for these patients.

Important Information

ZENPEP has been approved with a Risk Evaluation and Mitigation Strategy (REMS) to ensure that the benefits of the drug outweigh its risks. As part of the REMS, a Medication Guide with important dosing and safety information about ZENPEP will be handed out with each new prescription and refill.

The REMS and Medication Guide address the risk associated with the use of ZENPEP, including fibrosing colonopathy, a rare, serious adverse reaction that has been reported following treatment with high-dose use of pancreatic enzyme replacement therapy in the treatment of cystic fibrosis patients usually over a prolonged time period. The total daily dose of ZENPEP should not exceed 10,000 lipase units/kg of body weight per day, and caution should be used with doses exceeding 2,500 lipase units/kg of body weight per meal. Also, there is a theoretical risk of transmission of

viral disease, since ZENPEP, as other porcine-derived pancreatic enzymes, is sourced from pancreatic tissue from swine used for food consumption. No cases of transmission of an infectious illness associated with the use of porcine pancreatic extracts have been reported.

Care should be taken to ensure that ZENPEP is not chewed or retained in the mouth to avoid irritation of oral mucosa and the capsules or beads should be swallowed immediately with adequate amounts of liquid. Caution should be exercised when using ZENPEP in patients with gout, renal impairment, or hyperuricemia; porcine-derived pancreatic enzyme products may increase blood uric acid levels. Caution should be exercised for patients with known allergies to proteins of porcine origin. In rare instances, severe allergic reactions including anaphylaxis, asthma, hives, and pruritus have been reported with other pancreatic enzyme products with different formulations of the same active ingredient, pancrelipase, as that of ZENPEP.

In clinical trials assessing the short-term safety of ZENPEP, the incidence of adverse events (regardless of causality) was similar during double-blind ZENPEP treatment and placebo treatment. The most commonly reported adverse events occurring in at least two patients ($\geq 6\%$ of patients) included: abdominal pain, flatulence, headache, cough, decreased weight, early satiety, and contusion. The type and incidence of adverse events were similar in children and adults.

Please see full Prescribing Information and Medication Guide at www.eurand.com for complete information about safety, warnings and precautions for ZENPEP.

About Cystic Fibrosis

Cystic fibrosis (CF) is a life-threatening genetic disease that affects approximately 30,000 children and adults in the United States and nearly 70,000 people worldwide. It causes life-threatening lung infections and serious digestive complications. CF is caused by a mutation in the CFTR (Cystic Fibrosis Transmembrane conductance Regulator) gene whose lack of proper function leads to the symptoms, complications and premature mortality in people with CF.

About the Cystic Fibrosis Foundation

The Cystic Fibrosis Foundation, the leading organization in the United States devoted to curing and controlling cystic fibrosis, has invested more than \$320 million in drug research with biotech companies since 1998 to develop therapies to fight CF. As a result, the Foundation has built a drug pipeline with more than 30 promising therapies in development. Based in Bethesda, Md., the Foundation has 80 chapters and branch offices, and supports and accredits a nationwide network of 110 CF care centers that provide treatment and vital resources to patients and families. For more information, visit www.cff.org.

About Eurand

Eurand is a specialty pharmaceutical company that develops, manufactures and commercializes enhanced pharmaceutical and biopharmaceutical products based on its proprietary pharmaceutical technologies. Eurand has had six products approved by the FDA since 2001 and has a pipeline of product candidates in development for itself and its collaboration partners. The Company's technology platforms include bioavailability enhancement of poorly soluble drugs, custom release profiles, taste-masking orally disintegrating tablet (ODT) formulations, and drug conjugation.

Eurand is a global company with facilities in the U.S. and Europe. For more information, visit www.eurand.com.

All websites referenced herein are for informational purposes only and shall not be incorporated by reference.

Eurand Forward-Looking Statement

This release, and oral statements made with respect to information contained in this release, constitutes forward-looking statements. Such forward-looking statements include those which express plan, anticipation, intent, contingency, goals, targets or future development and/or otherwise are not statements of historical fact including, but not limited to the future and status of our regulatory filings or commercial plans for ZENPEP or our partnered products, enrollment and future plans for our clinical trials, progress of and reports of results from clinical studies, clinical development plans and product development activities. The words "expects", "potentially", "anticipates", "could", "calls for" and similar expressions also identify forward-looking statements. These statements are based upon management's current expectations and are subject to risks and uncertainties, known and unknown, which could cause actual results and developments to differ materially from those expressed or implied in such statements. Factors that could affect actual results include risks associated with unexpected delays or additional requirements in preparing for commercial launch; the outcome of any discussions with the FDA or other regulatory agencies; and those risks and uncertainties set forth in the Company's Annual Report on Form 20-F and subsequent filings. Forward-looking statements contained in this press release are made as of this date, and we undertake no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Actual events could differ materially from those anticipated in the forward-looking statements.

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