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Alnara Pharmaceuticals' Liprotamase Demonstrates Long-Term Safety & Maintenance of Nutritional Status in Patients with CF; Results of Landmark Phase 3 Safety Study Reported

Largest, Longest Nutritional Status Study for PERT Product Supporting Growth Highlighted at North American Cystic Fibrosis Conference

Cambridge, Mass., October 19, 2009 – Alnara Pharmaceuticals, a pharmaceutical company developing novel, non-systemic orally delivered protein therapeutics for the treatment of metabolic diseases, today announced results from an international, Phase 3 open-label, long-term safety study demonstrating the safety and nutritional benefits of liprotamase, a novel pancreatic enzyme replacement therapy (PERT) for patients with cystic fibrosis (CF). The nutritional parameters measured during the study showed nutritional maintenance relative to the U.S. population, which is a major finding for this historically challenged patient group.

This is the first time a long-term prospective study has been completed that shows that nutritional status is maintained in CF patients with respect to nutritional measures such as height, weight and vitamin levels over 12 months relative to the healthy U.S. population. The 12-month study is the largest and longest prospective nutritional and safety study ever completed for a PERT. This trial completes the liprotamase new drug application (NDA) clinical development program which has included approximately 600 subjects in various efficacy and safety studies.

Liprotamase is a novel, oral, non-porcine PERT designed to treat maldigestion, malabsorption and malnutrition as a result of exocrine pancreatic insufficiency associated with CF, chronic pancreatitis (CP), pancreatic cancer, pancreatectomy and other pancreatic conditions. Approximately 90 percent of CF patients receive PERT to improve nutritional status and bowel-related symptoms related to pancreatic insufficiency. Overall health in people living with pancreatic insufficiency is directly related to their nutritional status. For those living with CF, nutritional status is important in terms of respiratory health and has been directly tied to better lung function and survival.

These results were presented at the 23rd Annual North American Cystic Fibrosis Conference in Minneapolis, Minnesota by Drucy Borowitz, M.D., principal investigator and professor of clinical pediatrics at State University of New York at Buffalo.

“There is a clear need for new and improved treatments that address the serious issues related to pancreatic insufficiency and these positive and clinically relevant results demonstrate that liprotamase has the potential to make a meaningful difference in the management of patients with cystic fibrosis,” said Alexey Margolin, Ph.D., president and CEO of Alnara

Pharmaceuticals. “We are delighted with the data from this study and appreciate the support we have received from the Cystic Fibrosis Foundation Therapeutics, Inc., the CF community and everyone who worked to complete the liprotamase clinical program. This marks another important milestone for Alnara and we are now focused on filing a new drug application with the FDA for liprotamase as soon as possible, as well as preparing to launch this important therapy.”

Study Design

This landmark, open-label Phase 3 safety study evaluated 214 patients, of which 145 CF patients, ages 7 and above, completed 12 months of treatment with liprotamase based on key nutritional parameters, including weight, height, Body Mass Index (BMI), and fat soluble vitamin absorption, which are important measures of PERT performance. This was an international study with 45 centers in seven countries (34 centers in the U.S. and 11 centers outside the U.S.). Patients were allowed to roll over from the previously completed short-term efficacy trial or enter without previous exposure. Patients began the study taking one small size capsule of liprotamase per meal or snack (five per day) and were allowed to increase their intake up to two capsules per meal and one capsule per snack.

Study Results

Investigators found that 99 percent of CF patients ages 7 to 20 who received liprotamase for 12 months maintained or gained weight, while 96 percent of all CF patients who received liprotamase for 12 months maintained or gained weight. Patients who completed 12 months of treatment with liprotamase demonstrated that they maintained their nutritional status as assessed through a variety of nutritional parameters including BMI over the course of treatment relative to the U.S. population. FEV1, which is a measure of pulmonary function that correlates with nutritional status and survival in people living with CF was maintained. No difference in maintenance of nutritional status was seen between patients in the U.S. or outside the U.S. or between those on or off acid suppression. Liprotamase was well tolerated and the incidence of adverse events and serious adverse events followed expected patterns for CF patients.

"We are very encouraged by these results, which demonstrate the long-term safety and relevant clinical benefits of liprotamase for patients with cystic fibrosis," said Dr. Borowitz. "Pancreatic insufficiency can lead to malnutrition, poor weight gain, and impaired growth and micronutrient status in patients with cystic fibrosis. This study underscores the importance of nutritional measures in the day-to-day clinical setting to assess the performance of PERTS."

Notably, liprotamase has the potential to significantly reduce the daily pill burden for patients taking PERT treatments. Patients in this Phase 3 study took an average of 5.6 small capsules per day over the 12 month period. Patients on average take approximately 20 capsules per day for the current PERT standard of care. In addition, liprotamase has the potential to be the first PERT that can be taken by the approximately 10,000 CF patients who are unable to use existing capsule formulations due to difficulty swallowing capsules (the current formulation for all PERTs).

“The long-term safety data on liprotamase has been eagerly awaited by the community since it captures a unique data set, and we are very pleased with the progress that has been made in developing this drug by Alnara,” said Robert J. Beall, Ph.D., president and CEO of the Cystic Fibrosis Foundation. “Our collaboration with Alnara on the development of liprotamase plays an

important role in our goal of supporting the development of a non-porcine pancreatic enzyme replacement therapy for patients with cystic fibrosis.”

Liprotamase has successfully completed two well-controlled, efficacy clinical trials and an additional long-term safety and nutritional study, representing the largest CF population studied in prospective clinical trials for a PERT. Liprotamase met the primary endpoint in both the Phase 2 and Phase 3 efficacy trials and demonstrated statistically ($p \leq 0.001$) and clinically significant improvement in fat and protein absorption. Results from these previously reported studies show liprotamase was well tolerated and in addition, improved other important clinical measures such as stool weight and frequency. Liprotamase has also been evaluated in a long-term nutritional tracking and safety study in patients with chronic pancreatitis or pancreatectomy. Alnara received a Therapeutics Development Award for the development of liprotamase from Cystic Fibrosis Foundation Therapeutics, Inc., a nonprofit affiliate of the Cystic Fibrosis Foundation, and plans to file a NDA with the U.S. Food and Drug Administration (FDA) shortly.

About Pancreatic Insufficiency

Pancreatic insufficiency results in maldigestion and malabsorption of nutrients which can cause malnutrition, poor weight gain and impaired growth, even though patients may be eating large quantities of food. Pancreatic insufficiency is associated with conditions like cystic fibrosis (CF), chronic pancreatitis (CP), pancreatic cancer, pancreatectomy, and other diseases of the pancreas.

About Liprotamase & Pancreatic Enzyme Replacement Therapy (PERT)

Liprotamase (formerly known as ALTU-135 and Trizyte) is a novel, oral, non-porcine pancreatic enzyme replacement therapy (PERT) designed to treat maldigestion, malabsorption and malnutrition as a result of exocrine pancreatic insufficiency associated with cystic fibrosis (CF), chronic pancreatitis (CP), pancreatic cancer, pancreatectomy and other pancreatic diseases. Patients with pancreatic insufficiency cannot properly absorb and digest fat, protein, and carbohydrates preventing adequate nutrient absorption. PERT is a life-saving treatment involving the administration of pancreatic enzymes, and liprotamase offers potential advantages over the existing standard of care. In 2008, sales of PERTs were over \$1.1 billion worldwide.

Based on the available data, Alnara believes liprotamase may have the potential to overcome the challenges and issues associated with currently available therapies, by reducing pill burden, providing a formulation for patients unable to swallow capsules and removing the risk for viral contamination thereby providing a first-in-class non-porcine produced PERT.

Unlike liprotamase, currently available PERTs are developed by harvesting enzymes from the pancreas of the pig. Currently available PERT products are enteric-coated, a process that is designed to protect enzymes from being broken down and degraded in the acidic environment of the stomach and released in the small intestine for digestion. However, polymer or enteric coatings may result in the inappropriate release of enzymes preventing optimal digestion. Current products also have a high pill burden that may impact patient compliance and do not have available liquid formulations to treat patients who are unable to swallow capsules.

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. The disease is caused by a mutation in the CFTR gene that manifests in primarily progressive chronic lung and pancreatic disease leading to premature mortality. The Cystic Fibrosis Foundation is the world leader in the fight against cystic fibrosis. For more information, please visit www.cff.org.

About Alnara

Alnara Pharmaceuticals, Inc. is dedicated to developing and commercializing novel protein therapeutics for the treatment of metabolic diseases. The company's innovative approach focuses on designing effective protein therapies that can be orally delivered directly to the gastrointestinal tract without being absorbed into the bloodstream. Alnara's lead product is liprotamase, a novel, non-porcine pancreatic enzyme replacement therapy, which has completed Phase 3 clinical development in collaboration with the Cystic Fibrosis Foundation Therapeutics, Inc. (CFFT). The company is committed to bringing breakthrough new treatments to patients with unmet medical needs. Based in Cambridge, Massachusetts, Alnara is backed by an experienced management team and top-tier venture investors, including Frazier Healthcare Ventures, Third Rock Ventures and Bessemer Venture Partners. For more information, please visit the company's website at www.alnara.com.

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