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For Immediate Release

FDA APPROVES ASTELLAS' VAPRISOL[®] FOR THE TREATMENT OF EUVOLEMIC HYPONATREMIA

First arginine vasopressin (AVP) antagonist approved for the management of potentially life-threatening sodium/water imbalance

DEERFIELD, Illinois, December 30 — Astellas Pharma US, Inc. today announced that the U.S. Food and Drug Administration (FDA) has approved VAPRISOL[®] (investigational name: YM087, generic name: conivaptan hydrochloride injection), an arginine vasopressin (AVP) antagonist for the intravenous treatment of euvolemic hyponatremia in hospitalized patients. VAPRISOL, discovered and developed by Astellas, is the first drug specifically indicated for the treatment of euvolemic hyponatremia, a potentially life-threatening condition that occurs when the body's blood sodium level falls significantly below normal. The FDA also issued an approvable letter for VAPRISOL as a treatment for hypervolemic hyponatremia. Astellas plans on working closely with the FDA to obtain an approval for VAPRISOL's use in patients with hypervolemic hyponatremia.

Hyponatremia is estimated to affect up to 4 percent of hospitalized patients in the United States each year.¹ While many patients with hyponatremia have no symptoms, severe cases are medical emergencies that can result in swelling of the brain, respiratory arrest and death. Euvolemic hyponatremia, which occurs

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when total body water increases with little increase in sodium, is most often associated with conditions such as cancer and hypothyroidism and the use of certain drugs (such as some antidepressants).²

“VAPRISOL will provide physicians with an important new treatment option for a serious condition” said Makoto Nishimura, Ph.D., president and chief executive officer of Astellas Pharma US, Inc. “The approval of VAPRISOL further illustrates Astellas’ commitment to developing innovative pharmaceutical products that improve healthcare.”

In a randomized, double-blind, placebo-controlled study, intravenous administration of VAPRISOL 40 mg/day for four days corrected the balance of sodium and water in hospitalized patients with mild to moderate euvolemic hyponatremia. Significant improvements in serum sodium levels were observed within the first day of treatment with VAPRISOL. The most common adverse events associated with VAPRISOL were infusion site reactions, most of which were mild and did not lead to discontinuation of the drug.

“Currently available treatment options for hyponatremia, such as fluid restriction, diuretics and saline solution are inconsistent in their effects,” said Joseph Verbalis, M.D., Chair, Department of Medicine, Georgetown University Medical Center. “VAPRISOL will allow us to effectively correct the sodium-water balance in patients with euvolemic hyponatremia, and will help us to better manage this common and potentially very serious condition.”

About Hyponatremia

Hyponatremia often results from elevated levels of the hormone arginine vasopressin (AVP), which regulates water and salt balance in the body. It is the most common electrolyte disorder in clinical medicine and one of the most difficult to treat. Syndrome of inappropriate antidiuretic hormone (SIADH), advanced kidney failure, hypothyroidism, cancer and chronic high blood pressure are common causes of hyponatremia. Dilutional hyponatremia, which includes euvolemic and hypervolemic hyponatremia, is the most common form of the condition, and occurs when retained water dilutes serum sodium content.

About VAPRISOL

Discovered and developed by Astellas Pharma Inc. headquartered in Tokyo, Japan, VAPRISOL is a novel drug that blocks the activity of AVP, resulting in increased urine output without loss of valuable electrolytes

such as sodium and potassium. This effect, known as “aquaresis,” helps to correct serum sodium levels in patients with hyponatremia due to increased body water (dilutional hyponatremia). VAPRISOL is the first AVP antagonist that safely and effectively promotes aquaresis for improved management of salt and water imbalance in patients with euvolemic hyponatremia.

VAPRISOL therapy will begin with a loading dose of 20 mg IV administration followed by 20 mg administered as a continuous infusion over 24 hours. Following the initial day of treatment, VAPRISOL is to be administered for an additional 1 to 3 days as a continuous infusion of 20 mg/day. If serum sodium does not rise at the desired rate, VAPRISOL may be titrated upward to a daily dose of 40 mg, again administered in a continuous infusion.

VAPRISOL is indicated for the treatment of euvolemic hyponatremia (e.g., the syndrome of inappropriate secretion of antidiuretic hormone, or in the setting of hypothyroidism, adrenal insufficiency, pulmonary disorders, etc.) in hospitalized patients. VAPRISOL is contraindicated in patients who have hypovolemic hyponatremia and in those who have hypersensitivity to any of its components. The co-administration of VAPRISOL with potent CYP3A4 inhibitors, such as ketoconazole, itraconazole, clarithromycin, ritonavir, and indinavir, is contraindicated. The common adverse reactions reported with VAPRISOL administration include infusion site reactions, hypokalemia, headache, thirst and vomiting. The majority of the reactions were mild and did not lead to discontinuation of the drug. The use of VAPRISOL in patients with hepatic impairment (including ascites, cirrhosis or portal hypertension) has not been systematically evaluated. VAPRISOL is not indicated for the treatment of patients with congestive heart failure.

About Astellas

Astellas Pharma US, Inc., a US subsidiary of Tokyo-based Astellas Pharma Inc., is a research-based pharmaceutical company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. Established on April 1, 2005, Astellas Pharma Inc. was formed through a merger that combined the outstanding research, development and marketing capabilities of Fujisawa Pharmaceutical Co., Ltd. and Yamanouchi Pharmaceutical Co., Ltd. Astellas ranks among the top 20 pharmaceutical companies in the world and will continue to grow as a competitive

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company in the world pharmaceutical market. For more information on Astellas Pharma US, Inc., go to www.astellas.com/us.

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