Orbus Therapeutics Granted Orphan Drug Designation by European Medicines Agency for Late-Stage Brain Cancer Drug

-- Orphan Drug Designation and Breakthrough Therapy Designation Previously Granted by U.S. Food and Drug Administration --

-- Company Plans to Initiate a Phase 3 Clinical Trial of Eflornithine in Patients with Recurrent Anaplastic Astrocytoma --

PALO ALTO, Calif., June 17, 2016 – Orbus Therapeutics Inc., a private, clinical-stage biopharmaceutical company focused on the development and commercialization of therapies that treat rare diseases, today reported that the Committee for Medicinal Products for Human Use (CHMP) at the European Medicines Agency (EMA) has granted Orphan Medicinal Product status to eflornithine, a novel cytostatic agent, for the treatment of glioma. The Company is developing eflornithine to treat patients with anaplastic astrocytoma, a subtype of anaplastic glioma, a rare form of brain cancer.

In addition to the EMA Orphan Medicinal Product designation, the U.S. Food and Drug Administration (FDA) previously granted Orphan Drug Designation and Breakthrough Therapy Designation for eflornithine for the treatment of patients with anaplastic glioma.

In controlled, randomized and single arm clinical studies, eflornithine has shown an increase in overall survival of patients with newly diagnosed or recurrent anaplastic astrocytoma. The Company plans to initiate a Phase 3 clinical trial with the objective of evaluating the safety and efficacy of eflornithine in patients with recurrent anaplastic astrocytoma.

“We are very pleased that the European Medicines Agency has provided orphan designation for eflornithine for the treatment of patients with malignant glioma. Given the current lack of effective medications for this disease, there exists a tremendous unmet medical need in treating life-threatening brain cancers,” said Bob Myers, Co-Founder and Chief Executive Officer of Orbus Therapeutics. “Eflornithine now has orphan designation in Europe and the United States, along with breakthrough therapy designation in the United States. Given these important regulatory designations and our previously announced Series A financing, we are looking forward to initiating our Phase 3 clinical trial this year.”
About Orphan-Drug and Breakthrough Therapy Designation
The European Commission grants orphan drug status for medicinal products intended to treat diseases or conditions that affect fewer than five in 10,000 people in the European Union (EU). The designation provides certain benefits and incentives in the EU, including protocol assistance, fee reductions, and ten years of market exclusivity upon regulatory approval.

The FDA grants Orphan-Drug Designation to novel drugs that treat a rare disease or condition affecting fewer than 200,000 patients in the United States. The designation provides the drug developer with a seven year period of marketing exclusivity upon regulatory approval for the designated indication, as well as with tax credits for clinical research costs, the ability to apply for annual grant funding, clinical research trial design assistance and the waiver of prescription drug user fees.

A drug may receive Breakthrough Therapy Designation from the FDA if it is intended to treat a serious or life-threatening disease, and preliminary clinical evidence suggests that it provides a substantial improvement over existing therapies.

About Anaplastic Glioma
Several brain tumor types are grouped together under the name glioma which originates in the glial cells that surround and support neurons in the brain. In the United States, approximately 3,600 new cases of anaplastic glioma, one of two categories of malignant glioma, are diagnosed each year with a median survival of approximately three years despite treatment with surgery, radiation and chemotherapy. The prevalence of anaplastic glioma in the United States is estimated to be approximately 20,000 people.

Anaplastic astrocytoma is the largest subset of anaplastic glioma, and represents approximately 75 percent of AG patients. There are approximately 2,500 new anaplastic astrocytoma cases diagnosed in the United States each year.

About Orbus Therapeutics
Orbus Therapeutics Inc., a private, clinical-stage biopharmaceutical company is dedicated to developing products that treat rare diseases for which there are few, if any, effective therapies.

The Company’s product candidate in clinical development is eflornithine. Eflornithine is a novel cytostatic agent, which the Company is developing to treat patients with recurrent anaplastic astrocytoma, a rare form of central nervous system cancer. Eflornithine irreversibly inhibits ornithine decarboxylase (ODC), a key enzyme in mammalian polyamine biosynthesis that is up-regulated in certain types of cancer. For more information, please visit the Company's website at http://www.orbustherapeutics.com
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