



FDA Approves Gloucester Pharmaceuticals' ISTODAX[®] for Patients with Cutaneous T-cell Lymphoma

--Overall response rates exceeded primary endpoint in ISTODAX studies; sustained duration of response reported--

CAMBRIDGE, MA – November 5, 2009 – Gloucester Pharmaceuticals announced today that the U.S. Food and Drug Administration (FDA) approved ISTODAX[®] (romidepsin) for the treatment of cutaneous T-cell lymphoma (CTCL) in patients who have received at least one prior systemic therapy. The approval of ISTODAX was based on objective disease response defined as the proportion of patients with confirmed complete response or partial response. The New Drug Application (NDA) included efficacy data from two studies encompassing 167 patients. ISTODAX is a member of a new class of cancer drugs known as histone deacetylase (HDAC) inhibitors and is expected to be commercially available in January 2010.

“CTCL is a devastating cancer in which many patients suffer from disfiguring tumors, horribly itchy and infected skin and, in advanced stages, lesions in other organs,” said Youn Kim, MD, an investigator in studies of ISTODAX and Professor, Department of Dermatology and Director, Multidisciplinary Cutaneous Lymphoma Program, Stanford Cancer Center, Stanford, CA. “Current systemic therapies have proved inadequate and patients with CTCL desperately need treatment options that can offer sustained relief from their disease so they can live fuller lives. ISTODAX meets a significant unmet need and provides hope for patients with CTCL, their families and their physicians.”

Paul A. Bunn, Jr., MD, James Dudley Chair in Cancer Research, Professor and Director, University of Colorado Cancer Center and past-President of the American Society of Clinical Oncology said, “ISTODAX offers physicians an important new treatment choice that can provide clinically meaningful, and, most importantly, sustainable responses for some patients with CTCL who have failed prior systemic therapy. Additionally, the approval of a second HDAC inhibitor in cancer is very exciting and speaks to the potential for this class of compounds.”

“The approval of ISTODAX is the result of an extraordinary commitment by our clinical investigators and the patients and their families who volunteered to participate in the ISTODAX clinical trials,” said Jean Nichols, PhD, President and Chief Operating Officer of Gloucester Pharmaceuticals. “Gloucester would also like to recognize the National Cancer Institute which played an invaluable role in the development of ISTODAX.”

Alan Colowick, MD, Chief Executive Officer of Gloucester Pharmaceuticals said, “The approval of ISTODAX is a tremendous accomplishment for Gloucester Pharmaceuticals and for the patients we serve. This milestone is also an important step in the continued clinical development path for ISTODAX in oncology. We look forward to presenting data from our registration study of ISTODAX in peripheral T-cell lymphoma in 2010 and continuing further investigation in additional hematologic indications and solid tumors.”

About CTCL

CTCL is a type of non-Hodgkin's lymphoma, which is a cancer of the immune system. CTCL is caused by a mutation of T cells, unlike most non-Hodgkin's lymphomas which are generally of B-cell origin. The malignant T cells involve the skin, causing plaques, patches, erythroderma and/or tumors and can involve other organs, including the blood, lymph nodes and viscera.

Clinical Trials Overview

The ISTODAX approval was based upon two prospective multicenter, single-arm clinical studies in patients with CTCL. 167 patients with CTCL were accessed for efficacy in the United States, Europe and Australia. Study 1, sponsored by Gloucester, included 96 patients with confirmed CTCL after failure of at least 1 prior systemic therapy. Study 2, sponsored by the National Cancer Institute, included 71 patients with a primary diagnosis of CTCL who received at least 2 prior skin directed therapies or one or more systemic therapies. Patients were treated with ISTODAX at a starting dose of 14 mg/m² infused over 4 hours on days 1, 8, and 15 every 28 days.

In both studies, patients could be treated until disease progression at the discretion of the investigator and local regulators. Objective disease response was evaluated according to a composite endpoint that included assessments of skin involvement, lymph node and visceral involvement, and abnormal circulating T-cells (“Sézary cells”).

The primary efficacy endpoint for both studies was overall objective disease response rate (ORR) based on the investigator assessments and defined as the proportion of patients with confirmed complete response (CR) or partial response (PR). CR was defined as no evidence of disease and PR as ≥50% improvement in disease. Secondary endpoints in both studies included duration of response and time to response.

The ORRs in these two trials were similar (34% and 35% in Study 1 and Study 2, respectively) and CR rates were the same (6%). The median response duration was 15 months (range of 1 to 20+ months) in Study 1 and 11 months (range of 1 to 66+ months) in Study 2. Median time to first response was 2 months (range 1 to 6) in both studies. Median time to CR was 6 months in Study 1 and 4 months in Study 2 (range 2 to 9). The most common adverse reactions in Study 1 were nausea, fatigue, infections, vomiting and anorexia and in Study 2 were nausea, fatigue, anemia, thrombocytopenia, ECG T-wave changes, neutropenia and lymphopenia. See below for important safety information.

In Study 1, the median number of prior skin-directed therapies was 2 and the median number of prior systemic therapies was 2. In Study 2, the median number of prior skin-directed therapies was 1 and the median number of prior systemic therapies was 2. In Study 1, 71% of the patients had Stage IIB or greater disease and 87% of the patients in Study 2 had Stage IIB or greater disease.

Important Safety Information

ISTODAX is indicated for treatment of cutaneous T-cell lymphoma (CTCL) in patients who have received at least one prior systemic therapy.

Warnings and Precautions

Due to the risk of QT prolongation, potassium and magnesium should be within the normal range before administration of ISTODAX.

Treatment with ISTODAX can cause thrombocytopenia, leukopenia (neutropenia and lymphopenia), and anemia; therefore, these hematological parameters should be monitored during treatment with ISTODAX, and the dose should be modified, as necessary.

Several treatment-emergent morphological changes in ECGs including T-wave and ST-segment changes have been reported in clinical studies. The clinical significance of these changes is unknown. In patients with congenital long QT syndrome, patients with a history of significant cardiovascular disease, and patients taking anti-arrhythmic medicines or medicinal products that lead to significant QT prolongation, appropriate cardiovascular monitoring precautions, such as the monitoring of electrolytes and ECGs should be considered.

Based on its mechanism of action, ISTODAX may cause fetal harm. Woman should avoid becoming pregnant while being treated with ISTODAX and pregnant women should be advised of the potential harm to the fetus.

ISTODAX binds to estrogen receptors. Women of childbearing potential should be advised that ISTODAX may reduce the effectiveness of estrogen-containing contraceptives.

Adverse Reactions

Safety data was available and evaluated in 185 patients with CTCL in two clinical trials. Adverse reactions are presented separately for each study due to methodological differences between the studies. The most common reported adverse reactions in Study 1 were nausea (56%), fatigue (53%), infections (46%), vomiting (34%), and anorexia (23%) and in Study 2 were nausea (86%), fatigue (77%), anemia (72%), thrombocytopenia (65%), ECG T-wave changes (63%), neutropenia (57%), and lymphopenia (57%). Most of the adverse reactions were reported to be mild or moderate in severity. Most deaths in the studies were due to disease progression. Discontinuation due to an adverse event occurred in 21% of patients in Study 1 and 11% in Study 2. Serious adverse reactions reported in > 2% of patients in Study 1 were infection, sepsis, and pyrexia. In Study 2, serious adverse reactions in > 2% of patients were infection, supraventricular arrhythmia, neutropenia, fatigue, edema, central line infection, ventricular arrhythmia, nausea, pyrexia, leukopenia, and thrombocytopenia.

Drug Interactions

Prothrombin time (PT) and International Normalized Ratio (INR) should be carefully monitored in patients concurrently administered ISTODAX and Coumadin derivatives.

Co-administration of strong CYP3A4 inhibitors may increase concentrations of ISTODAX and should be avoided.

Co-administration of potent CYP3A4 inducers may decrease concentrations of ISTODAX and should be avoided.

Caution should be exercised if ISTODAX is administered with drugs that inhibit P-glycoprotein.

Use in Specific Patient Populations

Patients with moderate and severe hepatic impairment or end-stage renal disease should be treated with caution.

For additional important safety information, please see full prescribing information for ISTODAX at www.ISTODAX.com or call 1-866-223-7145.

About Gloucester Pharmaceuticals

Gloucester Pharmaceuticals acquires clinical-stage oncology drug candidates and advances them through regulatory approval and commercialization. The Company's first candidate, ISTODAX[®] (romidepsin), a novel histone deacetylase (HDAC) inhibitor, is FDA approved for the treatment of cutaneous T-cell lymphoma (CTCL) in patients who have received at least one prior systemic therapy. Gloucester is currently conducting a registration trial in peripheral T-cell lymphoma (PTCL) and anticipates data from this study in 2010. In addition, the Company is continuing further investigation of ISTODAX in other hematologic indications and solid tumors. For more information, please visit www.gloucesterpharma.com.

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