



FDA Advisory Committee Recommends Gloucester Pharmaceuticals' Romidepsin for Approval for Cutaneous T-cell Lymphoma

Cambridge, MA – September 2, 2009 -- Gloucester Pharmaceuticals announced today that the Oncologic Drug Advisory Committee (ODAC) appointed by the U.S. Food and Drug Administration (FDA) voted 10 in favor with one abstention to recommend approval of romidepsin to treat patients with cutaneous T-cell lymphoma (CTCL). CTCL is a type of non-Hodgkin's lymphoma, which is a cancer of the immune system. A New Drug Application (NDA) for romidepsin in CTCL is under review with the FDA and a Prescription Drug User Fee Act (PDUFA) date of November 12, 2009 has been set.

"We are pleased that the advisory committee has voted so strongly to recommend approval of romidepsin," said Alan Colowick, M.D., M.P.H, Chief Executive Officer of Gloucester. "Over the past year, Gloucester has presented the final pivotal data for romidepsin in cutaneous T-cell lymphoma and compiled and submitted the NDA for this promising drug candidate while also advancing a second pivotal program in peripheral T-cell lymphoma and recently completing a significant Series D financing. Today's ODAC decision adds to a highly productive year and we now look forward to the FDA's continued review of the NDA. If approved, we believe romidepsin may offer substantial hope and fill a significant treatment void for patients with cutaneous T-cell lymphoma."

In the Phase 2B, international, multicenter registration study of romidepsin in patients with CTCL (n=96, intent-to-treat), patients refractory to prior therapy who received romidepsin had an overall response rate of 34% (33/96) [95% confidence interval (CI): 25, 45]. This exceeded the primary endpoint of the study which required the lower bound of the 95% CI be above 15%. Complete and partial responses were observed at all stages of disease. The median duration of response was 14.9 months. Importantly, despite the exclusion of steroid and antihistamine use, most (63%) patients with moderate to severe pruritus at baseline experienced significant pruritus relief, a key indicator of clinical benefit. The most common adverse effects in clinical trials of romidepsin include fatigue, gastrointestinal disturbances and generally mild to moderate hematologic toxicity.

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. Romidepsin has received Orphan Drug Designation from the FDA for the treatment of non-Hodgkin's T-cell lymphomas, including CTCL.

About Romidepsin

Romidepsin's cyclic peptide structure is novel among members of a new class of cancer drugs known as histone deacetylase (HDAC) inhibitors. HDAC inhibition has been shown to increase acetylation of histones and other proteins. The downstream effects of HDAC inhibition include growth inhibition, apoptosis, inhibition of angiogenesis and differentiation. Nonclinical studies suggest that romidepsin is a pan-HDAC inhibitor and is a potent inhibitor of Class I, Class II and Class IV HDACs.

About Gloucester Pharmaceuticals

Gloucester Pharmaceuticals acquires clinical-stage oncology drug candidates and advances them through regulatory approval and commercialization. The Company's first candidate, romidepsin, a novel histone deacetylase (HDAC) inhibitor, is in late-stage development for T-cell lymphomas and has shown activity across a range of hematologic malignancies. A New Drug Application for romidepsin in cutaneous T-cell lymphoma (CTCL) is under review with the Food and Drug Administration (FDA) and a Prescription Drug User Fee Act (PDUFA) date of



November 12, 2009 has been set. The Company is currently enrolling patients in a registration trial for peripheral T-cell lymphoma (PTCL) and is evaluating romidepsin in multiple additional indications including multiple myeloma. For more information, please visit www.gloucesterpharma.com.

Contacts:

MacDougall Biomedical Communications
Sarah Cavanaugh/Cory Tromblee
Tel: (781) 235-3060