Top News

RSS Feed

MEDIA INQUIRIES
Mike Beyer
Sam Brown Inc.
Phone: 773-463-4211
beyer@sambrown.com

February 27, 2013

Ceptaris Resubmits New Drug Application (NDA) to FDA for Proprietary Gel Formulation of Mechlorethamine Hydrochloride

MALVERN, PA (February 27, 2013) -- Ceptaris Therapeutics Inc., a privately held, specialty pharmaceutical company, announced today that it has resubmitted the New Drug Application (NDA) for its proprietary gel formulation of mechlorethamine hydrochloride (mechlorethamine) to the U.S. Food and Drug Administration (FDA). The FDA issued a Complete Response letter to Ceptaris in May 2012. Ceptaris is seeking U.S. marketing approval for the treatment of early stage (stages I-IIA) mycosis fungoides, the most common type of Cutaneous T-Cell Lymphoma (CTCL).

“We look forward to working closely with the FDA on this submission to move our proprietary mechlorethamine gel through the regulatory review process over the coming months,” said Ceptaris Chairman and CEO Steve Tullman. “We believe our product has the potential to meet an important clinical need for CTCL and it is our goal to make it commercially available to patients who may benefit from it.”

The FDA has also granted Orphan Drug Status to Ceptaris’ mechlorethamine gel. Ceptaris is planning to submit a Marketing Authorization Application (MAA) for the gel in the EU in mid-2013.

About Mycosis Fungoides and Cutaneous T-Cell Lymphoma

Mycosis fungoides is the most common type of Cutaneous T-Cell Lymphoma, a rare form of non-Hodgkin's lymphoma. The cause of mycosis fungoides remains unknown and there is no known cure. Unlike most non-Hodgkin's lymphomas, mycosis fungoides is caused by a mutation of T-cells. The malignant T-cells in the body initially migrate to the skin, causing various lesions to appear. These lesions typically begin as what appears to be a rash and may progress to form plaques and disfiguring tumors. Early stage cases may be confused with other skin conditions until a definitive diagnosis is made based upon skin biopsy. Most cases of mycosis fungoides are early-stage and are diagnosed in patients over the age of 50.

About Mechlorethamine Gel

Mechlorethamine is a chemotherapeutic agent previously approved for intravenous treatment of mycosis fungoides, the most common type of CTCL. Topical mechlorethamine preparations are currently recommended as first line-treatment for early stage CTCL by the National Comprehensive Cancer Network (NCCN); however, there are no FDA-approved topical mechlorethamine products, limiting availability to non-standardized, pharmacy-compounded preparations.

About Ceptaris Therapeutics

Ceptaris Therapeutics Inc. is a privately held, specialty pharmaceutical company that is developing a proprietary gel formulation of mechlorethamine hydrochloride for the treatment of early stage (stages I-IIA) mycosis fungoides, a type of CTCL. If approved, Ceptaris' investigational drug would be the first topical mechlorethamine product available to treat the signs and symptoms of this rare cancer. Please visit http://www.ceptaris.com for more information.

This release includes forward-looking statements concerning the Company including expectations regarding regulatory filings. The statements are based on assumptions about many important factors, including the following, which could cause actual results to differ materially from those in the forward-looking statements: satisfaction of regulatory and other requirements; actions of regulatory bodies and other governmental authorities; changes in laws and regulations; product quality or patient safety issues. The information contained in this press release was accurate at the time of issuance and Ceptaris assumes no responsibility for updating the information to reflect subsequent developments.

###

Media Contact:
Mike Beyer, Sam Brown Inc.
beyer@sambrown.com
773-463-4211