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FDA Accepts Filing of New Drug Application (NDA) for Yaupon's Proprietary Gel Formulation of Mechlorethamine Hydrochloride

– Yaupon seeking U.S. marketing approval for topical treatment for early stage (stages I-IIA) mycosis fungoides, a common type of Cutaneous T-Cell Lymphoma –

MALVERN, PA (October 04, 2011) – Yaupon Therapeutics, Inc., a privately held specialty pharmaceutical company, announced today that the U.S. Food and Drug Administration (FDA) has accepted for filing the New Drug Application (NDA) for its proprietary gel formulation of mechlorethamine hydrochloride (mechlorethamine). Yaupon is seeking U.S. marketing approval of its mechlorethamine gel for the treatment of early stage (stages I-IIA) mycosis fungoides, the most common type of Cutaneous T-Cell Lymphoma (CTCL).

"We are pleased to have reached this important milestone, and look forward to working with the FDA throughout the review process," said Yaupon Chairman and CEO Steve Tullman.

Mechlorethamine is a chemotherapeutic agent previously approved for intravenous treatment of mycosis fungoides, the most common type of CTCL. Currently, topical mechlorethamine preparations are recommended for treatment of early stage CTCL by the National Comprehensive Cancer Network (NCCN).^{*} However, there are no FDA-approved topical mechlorethamine drugs, limiting availability to non-standardized, pharmacist-compounded preparations. These preparations are typically petroleum jelly-based formulations. Yaupon's formulation is a water-soluble, greaseless topical gel.

The FDA has granted Orphan Drug Status to Yaupon's mechlorethamine gel. The NDA submission includes data from a pivotal, multi-center clinical study of this topical mechlorethamine gel in patients with early stage mycosis fungoides, which met its primary and secondary endpoints. The primary endpoint was an assessment of lesion severity. Adverse events potentially related to Yaupon's formulation include dermatitis (skin irritation, pruritus and erythema) and hyperpigmentation. Dermatitis ranged from mild to moderately severe.

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 Yaupon Therapeutics

Yaupon Therapeutics, a privately held, specialty pharmaceutical company, is developing a proprietary gel formulation of mechlorethamine hydrochloride for the treatment of early stage (stages I-IIA) mycosis fungoides, a type of Cutaneous T-Cell Lymphoma (CTCL). If approved, Yaupon's investigational drug would be the first topical mechlorethamine gel widely available to treat the signs and symptoms of this rare cancer. Please visit the new Yaupon website www.yaupontherapeutics.com for more information.

^{*}www.nccn.org

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