Actelion launches VALCHLOR (mechlorethamine) gel 0.016% in the US

- First and only FDA-approved topical formulation of mechlorethamine available for patients with stage IA and IB mycosis fungoides-type cutaneous T-cell lymphoma who have received prior skin-directed therapy

- Actelion establishes a patient assistance and support program

SOUTHWARK, CA – 18 November 2013 – Actelion (SIX: ATLN) announced today that VALCHLOR™ (mechlorethamine), the first and only FDA-approved topical formulation of mechlorethamine, is now available for patients in the United States (US). VALCHLOR, a gel which is applied topically once a day, is an alkylating drug indicated to treat patients with stage IA and IB mycosis fungoides-type cutaneous T-cell lymphoma (MF-CTCL) who have received prior skin-directed therapy. VALCHLOR is an orphan drug that was acquired by Actelion US Holding Company, a subsidiary of Actelion Ltd., on September 18, 2013 as part of a merger with Ceptaris Therapeutics, Inc. VALCHLOR is distributed in the US by Accredo Specialty Pharmacy.

"The availability of VALCHLOR is exciting news for patients and the treatment community. Physicians now have the option to treat appropriate MF-CTCL patients with the first formulation of topical mechlorethamine that is FDA-approved based on rigorous clinical evidence to support its use," said Youn H. Kim, M.D., Joanne and Peter Haas Jr. professor for cutaneous lymphoma research, professor of dermatology, and director, Multidisciplinary Cutaneous Lymphoma Clinic, Stanford University School of Medicine.

"The use of topical mechlorethamine has been documented over several decades," said Stuart Lessin, M.D. former director of dermatology at the Fox Chase Cancer Center, president of the Board of Directors of the Cutaneous Lymphoma Foundation and lead investigator in the VALCHLOR pivotal trial. "With the launch of VALCHLOR, physicians can prescribe with confidence knowing that an FDA-approved formulation is now available, along with support and financial-assistance programs for eligible patients to help facilitate education and access."

Mycosis fungoides is the most common type of cutaneous T-cell lymphoma, a rare form of non-Hodgkin's lymphoma. In the US, approximately 20,000 patients are currently diagnosed with stage IA-IB MF-CTCL, qualifying it as a rare or orphan disease.

"We look forward to partnering with dermatology and oncology specialists to bring this treatment to appropriate patients with MF-CTCL," said Bill Fairey, president of Actelion Pharmaceuticals US Inc. “Actelion has deep expertise in rare, orphan diseases which we are utilizing to help ensure VALCHLOR is accessible to patients who may benefit from this important therapy."
COMMITMENT TO ACCESS AND PATIENT SUPPORT
Actelion has established VALCHLOR Support™, an assistance program to help eligible patients successfully start and remain on VALCHLOR therapy. The program, administered by Accredo Specialty Pharmacy (www.accredo.com), includes reimbursement and financial support for eligible patients, as well as disease and product information.

“MF-CTCL can have a significant impact on the appearance and daily lives of patients affected by the disease,” said Susan Thornton, chief executive officer of the Cutaneous Lymphoma Foundation. “We are thrilled to have a new treatment option in VALCHLOR, supported by an assistance program for eligible patients to help ensure access.”

For more information on the VALCHLOR Support program, patients can call 1-855-4-VALCHLOR (1-855-482-5245) between 9:00am – 11:00pm Eastern Time, or visit www.valchlor.com.

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ABOUT VALCHLOR
VALCHLOR (mechlorethamine) gel 0.016% is an alkylating drug indicated for the topical treatment of stage IA and IB mycosis fungoides-type cutaneous T-cell lymphoma (MF-CTCL) in patients who have received prior skin-directed therapy. VALCHLOR is a gel which is applied topically once a day. Mechlorethamine, commonly known as nitrogen mustard, is a chemotherapeutic agent previously approved for intravenous treatment of mycosis fungoides, the most common type of cutaneous T-Cell lymphoma. Mechlorethamine is one of the suggested skin-directed treatment regimens for early-stage MF-CTCL according to the latest National Comprehensive Cancer Network® (NCCN®) Clinical Practice Guidelines in Oncology (NCCN Guidelines®)\(^1\). VALCHLOR is the first and only FDA-approved topical formulation of mechlorethamine.

For more information and full prescribing information visit www.valchlor.com

IMPORTANT SAFETY INFORMATION FOR VALCHLOR
Caregivers must wear disposable nitrile gloves during application and avoid direct skin contact. VALCHLOR is for topical dermatologic use only. VALCHLOR is a cytotoxic drug. Avoid direct skin contact with VALCHLOR in individuals other than the patients due to risk of dermatitis, mucosal injury and secondary cancers. The use of VALCHLOR is contraindicated in patients with a history of severe or systemic hypersensitivity to mechlorethamine or inactive ingredients.

Contact with mucous membranes, especially those of the eyes, must be avoided. Exposure of the eyes to mechlorethamine may cause pain, burns, inflammation, photophobia, blurred vision and in some cases severe and long-lasting injury to the eye. Patients should be monitored for non-melanoma skin cancers during and after treatment with VALCHLOR. The most common adverse reaction to VALCHLOR is dermatitis, which in some cases may be severe and require dosing changes or discontinuation. Elderly patients may be more susceptible to dermatitis. Women should avoid becoming pregnant or nursing while using VALCHLOR due to potential hazard to the fetus. VALCHLOR is an alcohol-based gel. Avoid fire, flame and smoking until the gel has dried.

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 malignant T-cells. The malignant T-cells in the body initially migrate to the skin, causing...

- US launch of Valchlor™ -
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.

**ACTELION LTD**

Actelion Ltd is a biopharmaceutical company with its corporate headquarters in Allschwil/Basel, Switzerland. Actelion's first drug Tracleer® (bosentan), an orally available dual endothelin receptor antagonist, has been approved as a therapy for pulmonary arterial hypertension. Actelion markets Tracleer through its own subsidiaries in key markets worldwide, including the United States (based in South San Francisco), the European Union, Japan, Canada, Australia and Switzerland. Actelion, founded in late 1997, is a leading player in innovative science related to the endothelium - the single layer of cells separating every blood vessel from the blood stream. Actelion's over 2,300 employees focus on the discovery, development and marketing of innovative drugs for significant unmet medical needs. Actelion shares are traded on the SIX Swiss Exchange (ticker symbol: ATLN) as part of the Swiss blue-chip index SMI (Swiss Market Index SMI®).

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**References:**

1Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Non-Hodgkin's Lymphomas V.2.2013. © National Comprehensive Cancer Network, Inc 2013. All rights reserved. Accessed [November 14, 2013]. To view the most recent and complete version of the guideline, go online to www.nccn.org. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, NCCN GUIDELINES®, and all other NCCN Content are trademarks owned by the National Comprehensive Cancer Network, Inc.

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