CTCL is characterized by the presence of a clonal T-cell population in the skin and/or blood, lymph nodes or visceral organs. Patients with early disease can be treated effectively with topical treatments. However, a key challenge is to achieve durable remissions in patients with advanced disease, who require systemic treatment. In malignant T cells of CTCL, epigenetic alterations are known to play a key role in pathogenesis. Resminostat is an orally available HDAC inhibitor, which induces changes in gene expression resulting in growth inhibition, modified cell differentiation and enhanced tumor immunogenicity.

The purpose of the RESMAIN study is to investigate resminostat as maintenance treatment for patients with advanced stage mycosis fungoides (MF) or Sézary syndrome (SS) that have achieved disease control with systemic therapy.

**RESMAIN - Study Design**

**Eligibility and Study Logistics**

**Key Inclusion Criteria:**
- Patients (≥ 18 years) with histologically confirmed MF (Stage IIB-IVB) or SS in an ongoing complete response (CR), partial response (PR) or stable disease (SD) after at least one prior systemic therapy according to local standards, including but not limited to interferon-α, bexarotene, extracorporeal photopheresis (ECP), chemotherapy or total skin electron beam (TSEB) therapy
- The most recent systemic therapy must have been completed as planned or stopped due to unacceptable toxicity 2-12 weeks prior to randomization
- ECOG performance score 0-2
- Adequate hematological, hepatic and renal function

**Key Exclusion Criteria:**
- Patients with progressive disease (PD)
- Baseline QTc interval > 500 ms
- Concurrent use of any other specific anti-tumor therapy

**Study Logistics:**
- Enrollment: 150 patients
- Trial centers: 54 centers in 11 countries (EU), 5 centers in JP
- Planned trial period: FPI: Dec 2016
- LPO: Dec 2020

**Objectives**

**Primary objective:**
- Determine whether maintenance treatment with resminostat increases progression free survival (PFS) compared to placebo.

**Key secondary objective:**
- Determine whether resminostat delays the time to symptom worsening (TTSW) of pruritus compared to placebo.

Further objectives include TTP, TTNT, ORR, OS, PK, Safety and HRQoL and comprehensive biomarker evaluation.

To our knowledge, this is the first randomized study that investigates an HDAC inhibitor as maintenance therapy in advanced-stage CTCL.

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