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.

**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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TTP = time to progression; TTNT = time to next treatment; ORR = overall response rate; OS = overall survival; PK = pharmacokinetics; HrQoL = health related quality of life.