RESMAIN

Key Information

A multicentre, double blind, randomised, placebo-controlled, Phase II trial to evaluate Resminostat for maintenance treatment of patients with advanced stage (Stage IIB-IVB) mycosis fungoides (MF) or Sézary Syndrome (SS) that have achieved disease control with systemic therapy – the RESMAIN study

ClinicalTrials.gov Identifier	NCT02953301
Primary Endpoint	Progression-free Survival (PFS)
Key Secondary Endpoint	Time to Symptom Worsening (Pruritus)
Planned Last Patient In	December 2021
Number of patients	190

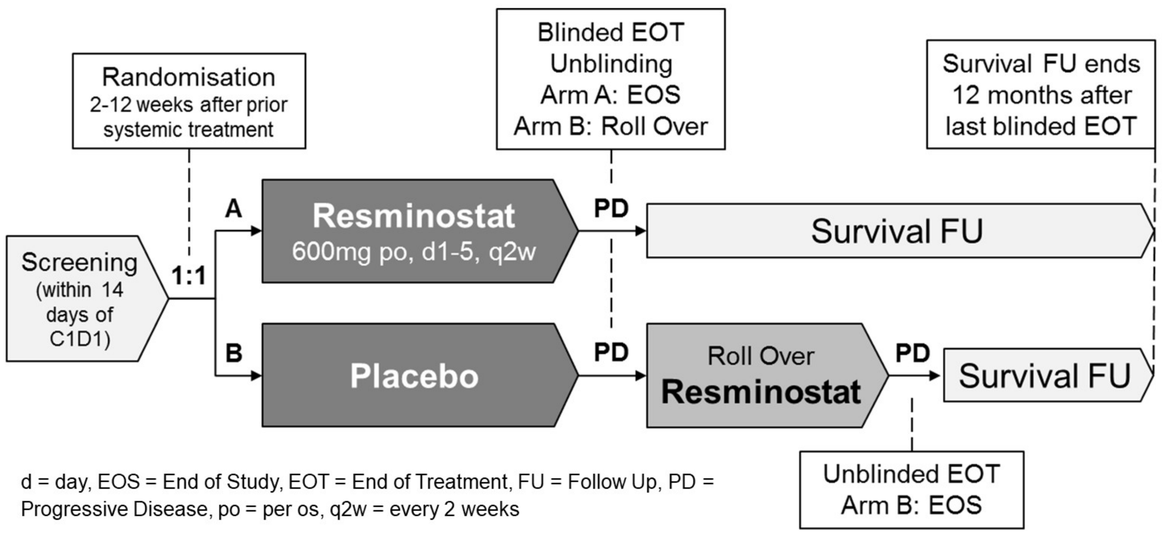
Main Inclusion Criteria

- Patients with histologically confirmed Mycosis fungoides (Stage IIB-IVB) or Sézary Syndrome in an ongoing CR, PR or SD after at least one prior systemic therapy according to local standards (including but not limited to α-interferon, bexarotene, extracorporeal photopheresis, chemotherapy) or total skin electron beam irradiation
  - The most recent systemic therapy must have been completed as planned or stopped due to unacceptable toxicity 2-12 weeks prior to randomisation, i.e. patients should not be withdrawn from a treatment from which they derive benefit
- Eastern Cooperative Oncology Group (ECOG) status score 0-2
- Adequate haematological, hepatic and renal function

Main Exclusion Criteria

- Patients with progressive disease (PD)
- Baseline corrected QT (QTc) interval > 500 milliseconds (NOTE: QTcF is relevant)
- Concurrent use of any other specific anti-tumour therapy including psoralen photo chemotherapy (PUVA), chemotherapy, immunotherapy, hormonal therapy, radiation therapy, or experimental medications

Study Design



d = day, EOS = End of Study, EOT = End of Treatment, FU = Follow Up, PD = Progressive Disease, po = per os, q2w = every 2 weeks

Global Principal Investigator

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