

Trial record 1 of 1 for: NCT02953301

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Resminostat for Maintenance Treatment of Patients With Advanced Stage Mycosis Fungoides (MF) or Sézary Syndrome (SS) (RESMAIN)

This study is currently recruiting participants. (see [Contacts and Locations](#))

Verified December 2016 by 4SC AG

Sponsor:
4SC AG

Information provided by (Responsible Party):
4SC AG

ClinicalTrials.gov Identifier:
NCT02953301

First received: October 26, 2016
Last updated: December 20, 2016
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[History of Changes](#)

[Full Text View](#)

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[No Study Results Posted](#)

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Purpose

The purpose of this study is to determine whether resminostat will be able to delay or prevent worsening of disease in patients with advanced stage mycosis fungoides or Sézary Syndrome that have recently achieved disease control with previous systemic therapy.

Condition	Intervention	Phase
Mycosis Fungoides Sezary Syndrome Lymphoma, T-Cell, Cutaneous	Drug: resminostat Drug: Placebo	Phase 2

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Investigator, Outcomes Assessor)
Primary Purpose: Treatment

Official Title: 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

Resource links provided by NLM:

[Genetics Home Reference](#) related topics: [Sézary syndrome](#) [mycosis fungoides](#)

[MedlinePlus](#) related topics: [Fungal Infections](#)

[Genetic and Rare Diseases Information Center](#) resources: [Lymphosarcoma](#) [Mycosis Fungoides](#) [Sezary Syndrome](#)
[Cutaneous T-cell Lymphoma](#)

[U.S. FDA Resources](#)

Further study details as provided by 4SC AG:

Primary Outcome Measures:

- PFS (Progression-free survival) [Time Frame: From date of randomization until the date of first documented progression or date of death from any cause, whichever came first, up to approximately 32 months] [Designated as safety issue: No]

The primary objective is to determine if maintenance treatment with resminostat increases progression free survival (PFS) compared to placebo in patients with advanced stage (Stage IIB-IVB) MF or SS that have achieved disease control (complete response [CR], partial response [PR] or stable disease [SD]) with previous systemic therapy.

Secondary Outcome Measures:

- TTSW (Time to symptom worsening): pruritus [Time Frame: From date of randomisation to first date that criteria for symptom (pruritus) worsening have been met, up to approximately 32 months. Symptom worsening is defined as an increase of a minimum of 3 points on the visual analogue itching scale] [Designated as safety issue: No]
To determine if maintenance treatment with resminostat increases time to symptom (pruritus) worsening (TTSW) compared to placebo.

Other Outcome Measures:

- TTP (Time to progression) [Time Frame: From date of randomization until the date of first documented progression, up to approximately 32 months] [Designated as safety issue: No]
Compare time to progression (TTP) in patients when treated with resminostat vs placebo
- TTNT (Time to next treatment) [Time Frame: From date of randomisation to first date that new treatment is received, up to approximately 44 months.] [Designated as safety issue: No]
Compare time to next treatment (TTNT) in patients when treated with resminostat vs placebo
- PFS2, PFS3 (Progression-free survival 2, 3) [Time Frame: From date of start of subsequent treatment to date of progression or death due to any cause in the absence of documented PD whilst receiving second and third line therapy, respectively, up to approximately 44 months] [Designated as safety issue: No]
Assess the effect of maintenance treatment with resminostat by means of PFS of subsequent treatments (PFS2, PFS3)
- ORR (Overall response rate) [Time Frame: Percent of patients within each treatment Arm that achieve confirmed CR or PR relative to the number of patients belonging to the analysis population of interest, up to approximately 32 months.] [Designated as safety issue: No]
Compare overall response rate (ORR, including CR, PR) in patients when treated with resminostat vs placebo
- DOR (Duration of response) [Time Frame: From date confirmed CR or PR (whichever is first) until the criteria for PD have been met, up to approximately 32 months.] [Designated as safety issue: No]
Compare duration of response (DOR) in patients when treated with resminostat vs placebo
- OS (Overall survival) [Time Frame: From the day of randomisation to death from any cause, up to approximately 44 months.] [Designated as safety issue: No]
Compare overall survival (OS) in patients when treated with resminostat vs placebo
- Incidence of treatment-related AEs and SAEs (Safety and tolerability) [Time Frame: Weekly for 3 cycles, then bi-weekly during treatment phase, up to approximately 9 months] [Designated as safety issue: Yes]
Assess the safety and tolerability of resminostat
- HrQoL (Health related quality of life) [Time Frame: Every 28 days, up to approximately 32 months] [Designated as safety issue: No]
Compare changes in health related quality of life (HrQoL) parameters in patients when treated with resminostat vs placebo
- Maximum Plasma Concentration [Cmax] [Time Frame: At Cycle 3, Day 1 at 0.75h, 2h and 4 h after intake of trial medication / at Cycle 3, Day 5 to be done pre-dose and at 2h and 7h after intake of trial medication] [Designated as safety issue: No]
Assess the maximum plasma concentration [Cmax] of resminostat
- Area Under the Curve [AUC] [Time Frame: At Cycle 3, Day 1 at 0.75h, 2h and 4 h after intake of trial medication / at Cycle 3, Day 5 to be done pre-dose and at 2h and 7h after intake of trial medication] [Designated as safety issue: No]
Assess the Area Under the Curve [AUC] of resminostat

Estimated Enrollment: 150
 Study Start Date: November 2016
 Estimated Study Completion Date: February 2020
 Estimated Primary Completion Date: February 2019 (Final data collection date for primary outcome measure)

<u>Arms</u>	<u>Assigned Interventions</u>
Experimental: resminostat 3 x 200 mg tablets p.o., 5 days treatment followed by 9 days rest (cycles until progress or unacceptable toxicity)	Drug: resminostat Other Name: 4SC-201
Placebo Comparator: Placebo 3 tablets p.o. matching verum, 5 days treatment followed by 9 days rest (cycles until progress or unacceptable toxicity)	Drug: Placebo

▶ Eligibility

Ages Eligible for Study: 18 Years and older (Adult, Senior)
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Main Inclusion Criteria:

- Patients 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 α -interferon, bexarotene, total skin electron beam irradiation, chemotherapy) [the most recent systemic therapy must have been completed as planned or stopped due to unacceptable toxicity 2-8 weeks prior to randomisation]
- 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
- Concurrent use of any other specific anti-tumour therapy including psoralen photo chemotherapy (PUVA), chemotherapy, immunotherapy, hormonal therapy, radiation therapy, or experimental medications

▶ Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see [Learn About Clinical Studies](#).

Please refer to this study by its ClinicalTrials.gov identifier: NCT02953301

Contacts

Contact: Susanne Danhauser-Riedl, M.D. +49 89 700763 ext 0 RESMAIN@4sc.com

Locations

Belgium

Cliniques Universitaires Saint-Luc Bruxelles, Belgium	Recruiting
Universitaire Ziekenhuizen Leuven, Belgium	Recruiting

Netherlands

Leids Universitair Medisch Centrum (LUMC) Leiden, Netherlands	Recruiting
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Spain

Hospital Del Mar Barcelona, Spain	Recruiting
Hospital Duran i Reynals Barcelona, Spain	Recruiting
Hospital Universitario 12 de Octubre Madrid, Spain	Recruiting
Hospital General Universitario Valencia, Spain	Recruiting

United Kingdom

University Hospital Birmingham, United Kingdom	Recruiting
Beatson West of Scotland Cancer Centre Glasgow, United Kingdom	Recruiting
St John's Institute Of Dermatology - Guy's & St Thomas' Nhs Foundation Trust London, United Kingdom	Recruiting

Sponsors and Collaborators

4SC AG

Investigators

Principal Investigator: Rudolf Stadler, Prof. Johannes Wesling Klinikum, Minden, Germany

▶ More Information

Responsible Party: 4SC AG
ClinicalTrials.gov Identifier: [NCT02953301](#) [History of Changes](#)
Other Study ID Numbers: 4SC-201-6-2015 2016-000807-99
Study First Received: October 26, 2016
Last Updated: December 20, 2016
Health Authority: Germany: Federal Institute for Drugs and Medical Devices
Italy: The Italian Medicines Agency
Netherlands: Medicines Evaluation Board (MEB)
United Kingdom: Medicines and Healthcare Products Regulatory Agency
France: Agence Nationale de Sécurité du Médicament et des produits de santé
Spain: Agencia Española de Medicamentos y Productos Sanitarios
Austria: Austrian Medicines and Medical Devices Agency
Belgium: Federal Agency for Medicinal Products and Health Products
Poland: National Institute of Medicines
Switzerland: Swissmedic

Individual Participant Data

Plan to Share IPD: No

Keywords provided by 4SC AG:

Cutaneous T-Cell Lymphoma (CTLC)
Maintenance
resminostat
4SC

HDAC
Mycosis Fungoides
Sézary Syndrome

Additional relevant MeSH terms:

Syndrome
Mycoses
Mycosis Fungoides
Sezary Syndrome
Lymphoma, T-Cell
Lymphoma, T-Cell, Cutaneous
Disease
Pathologic Processes

Lymphoma, Non-Hodgkin
Lymphoma
Neoplasms by Histologic Type
Neoplasms
Lymphoproliferative Disorders
Lymphatic Diseases
Immunoproliferative Disorders
Immune System Diseases

ClinicalTrials.gov processed this record on December 30, 2016