A phase-3, randomized, double-blind, study comparing Risankizumab to Placebo in subjects with active psoriatic arthritis (PsA) who have a history of inadequate response to or intolerance to at least on disease modifying anti-rheumatic drug (DMARD) therapy (KEEPsAKE 1)

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Autoimmune disorders
Study type	Interventional

Summary

ID

NL-OMON55512

Source
ToetsingOnline

Brief title
M16-011

Condition

- Autoimmune disorders
- Joint disorders

Synonym
Arthritis psoriatica, psoriatic arthritis

Research involving
Human

Sponsors and support

Primary sponsor: AbbVie Deutschland GmbH & Co. KG
Source(s) of monetary or material Support: AbbVie

Intervention

Keyword: DMARD, Placebo, Psoriatic arthritis, Risankizumab

Outcome measures

Primary outcome

The primary endpoint is the proportion of subjects achieving American College of Rheumatology (ACR)20 Response (ACR20) at Week 24.

Secondary outcome

Secondary endpoints are:

1. Change from Baseline in Health Assessment Questionnaire-Disability Index (HAQ-DI) at Week 24;

2. Proportion of subjects achieving Psoriasis Area Severity Index (PASI) 90 response at Week 24 (in the subset of subjects with a BSA >=3% at Baseline);

3. Change from Baseline in modified Total Sharp Score (PsA-mTSS) at Week 24;

4. Proportion of subjects achieving Minimal Disease Activity (MDA) at Week 24;

5. Change from Baseline in Fingernail-Physician Global Assessment (PGA-F)/modified Nail Psoriasis Severity Index (mNAPSI, ex-US) at Week 24 (in the subset of subjects with nail psoriasis at Baseline); Note: PGA-F and mNAPSI assessments will be obtained in all patients, whether US or ex-US.

6. Proportion of subjects with resolution of enthesitis (LEI = 0) at Week 24 in subjects with enthesitis at Baseline;

7. Proportion of subjects with resolution of dactylitis (LDI = 0) at Week 24 in subjects with dactylitis at Baseline;

8. Change from Baseline in 36-Item Short Form Health Survey (SF-36) Physical Component Summary (PCS) at Week 24;

9. Change from Baseline in Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT Fatigue) Questionnaire at Week 24.

Other secondary endpoints without multiplicity adjustment are:

1. Proportion of subjects achieving ACR50 response at Week 24;

2. Proportion of subjects achieving ACR70 response at Week 24.

Study description

Background summary

Psoriatic arthritis (PsA) is a chronic systemic inflammatory disease classified as a subtype of spondyloarthritis (SpA) and characterized by the association of arthritis and psoriasis. Patients with PsA experience varying combinations of disease manifestations affecting the synovium, tendons, entheses, skin, and bone.

PsA patients require treatment of the entire spectrum of disease manifestations. Despite the beneficial results achieved with currently available treatments, there remains a medical need for additional therapeutic options for patients with PsA who have inadequate response to or intolerance to currently available therapies.

Study objective

The primary objective of the study is to compare the efficacy of risankizumab versus placebo for the treatment of signs and symptoms of PsA in subjects who

have a history of inadequate response to or intolerance to at least one conventional synthetic disease modifying anti-rheumatic drug (csDMARD) therapy.

Study design

This is a Phase-3, randomized, double-blind study. The study includes a Screening Period (up to 35 days), an initial double blind period from Week 0 through Week 24 (Period 1), an open label follow-up period from Week 24 up to Week 208 (Period 2), and a Follow-up Period consisting of a visit 12 weeks after the last study drug dose and a follow-up phone call 20 weeks after the last study drug dose.

Intervention

Eligible subjects will be randomized to receive blinded risankizumab or placebo in Period 1 through Week 24. The study is designed to enroll 880 subjects worldwide.

During Period 2, all subjects will receive risankizumab.

Risankizumab and placebo will be administrated subcutaneously with pre-filled syringes.

Study burden and risks

There is a higher burden for subjects participating in this study compared to receiving standard medical care. Subjects will be visiting the hospital more frequently. During these visits study procedures will be performed including blood sampling and questionnaires. Subjects will also be tested for tuberculosis (TB), hepatitis B (HBV), hepatitis C (HCV), and human immunodeficiency virus (HIV). Women of childbearing potential are required to practice a method of birth control both during the study and through 20 weeks after the last dose of study drug and are tested for pregnancy during the study. The most common side effects reported during previous studies of risankizumab were upper respiratory infections, feeling tired, fungal skin infection, injection site reactions and headache.

Contacts

Public
AbbVie Deutschland GmbH & Co. KG

Knollstrasse 50
Ludwigshafen 67061

DE
Scientific
AbbVie Deutschland GmbH & Co. KG

Knollstrasse 50
Ludwigshafen 67061
DE

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Clinical diagnosis of PsA with symptom onset at least 6 months prior to the Screening Visit and fulfillment of the Classification Criteria for PsA (CASPAR) at the Screening Visit.
• Subject has active disease at Baseline
• Diagnosis of active plaque psoriasis with at least one psoriatic plaque of >= 2 centimeter (cm) diameter or nail changes consistent with psoriasis at Screening Visit.
• Presence of either at Screening:
1. >= 1 erosion on radiograph as determined by central imaging review or;
2. hs-CRP >= 3.0 mg/L.
• Subject has demonstrated an inadequate response to previous or current treatment with at least 1 csDMARD OR subject must have an intolerance to or contraindication for csDMARDs as determined by the investigator.

Exclusion criteria

• Subject is considered by investigator, for any reason, to be an unsuitable candidate for the study.
• Subject has a known hypersensitivity to Risankizumab.

• Subject has previous treatment with biologic agent.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-01-2020
Enrollment:	10
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Risankizumab
Generic name:	Risankizumab

Ethics review

Approved WMO

Date:	13-11-2018
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date:	21-03-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	06-05-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-07-2019
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	29-07-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	21-08-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	05-06-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	02-07-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	15-07-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam

	(Rotterdam)
Approved WMO Date:	20-07-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	30-11-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	12-01-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	10-07-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	23-07-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	28-12-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	25-01-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2017-002465-22-NL
ClinicalTrials.gov	NCT03675308
CCMO	NL67936.078.18