KURZPROTOKOLL
Evolution RMS1

Öffentlicher Titel	Phase III Studie zu Evobrutinib bei schubförmiger Multipler Sklerose
Wissenschaftl. Titel	A Phase III, Multicenter, Randomized, Parallel Group, Double Blind, Double Dummy, Active Controlled Study of Evobrutinib Compared with Teriflunomide, in Participants with Relapsing Multiple Sclerosis to Evaluate Efficacy and Safety
Kurztitel	Evolution RMS1
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, Pharma-Studie, doppelblind, zweiarmig
Studienphase	Phase III
Erkrankung	Nervensystem: Multiple Sklerose
Einschlusskriterien	- Participants are diagnosed with RMS (relapsing-remitting multiple sclerosis [RRMS] or secondary progressive multiple sclerosis [SPMS] with relapses) in accordance with 2017 Revised McDonald criteria (Thompson 2018) - Participants with one or more documented relapses within the 2 years before Screening with either: a. one relapse which occurred within the last year prior to randomization, OR b. the presence of at least 1 gadolinium-enhancing (Gd+) T1 lesion within 6 months prior to randomization - Participants have Expanded Disability Status Scale (EDSS) score of 0 to 5.5 at Screening and Baseline (Day 1). Participants with an EDSS score <= 2 at Screening and Baseline (Day 1) are only eligible for participation if their disease duration (time since onset of symptoms) is no more than 10 years - Participants are neurologically stable for >= 30 days prior to both screening and baseline - Female participants must be neither pregnant nor breast-feeding or must lack child-bearing potential (as defined by either: post-menopausal or surgically sterile), or use an effective method of contraception for the duration of the study and at least 2 years after study intervention due to the long elimination period for teriflunomide of 2 years, unless the participant undergoes an accelerated elimination procedure - Male participants must refrain from donating sperm and/or abstain from intercourse with women of child-bearing potential or use an effective method of contraception for the duration of the study and at least 2 years after study intervention due to the long elimination period for teriflunomide of 2 years, unless the participant undergoes an accelerated elimination procedure - Participants have given written informed consent prior to any study-related procedure - Other protocol defined inclusion criteria could apply.
Ausschlusskriterien	- Participants diagnosed with Progressive MS, in accordance with the 2017 Revised McDonald criteria as follows: a). Participants with Primary Progressive MS. b). Participants with secondary progressive MS without evidence of relapse. - Disease duration more than (>) 10 years in participants with an EDSS =< 2.0 at screening. - Immunologic disorder other than MS, or any other condition requiring oral, intravenous (IV) , intramuscular, or intra-articular corticosteroid therapy, with the exception of well-controlled Type 2 diabetes mellitus or well controlled thyroid disease. - Other protocol defined exclusion criteria could apply.
Alter	18 - 55 Jahre
Prüfzentren	**Neurologie** (Rekrutierung beendet) Schleusenweg 2-16 60590 Frankfurt am Main Dipl. Psych. Dr. Yavor Yalachkov yavor.yalachkov@unimedizin-ffm.de
Sponsor	Merck KGaA

Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT04338022 EudraCT 2019-004972-20 (primäres Register)