

## **KURZPROTOKOLL** **Evolution RMS1**

<b>Öffentlicher Titel</b>	Phase III Studie zu Evobrutinib bei schubförmiger Multipler Sklerose
<b>Wissenschaftl. Titel</b>	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
<b>Kurztitel</b>	Evolution RMS1
<b>Studienart</b>	multizentrisch, prospektiv, Therapiestudie, randomisiert, Pharma-Studie, doppelblind, zweiarmig
<b>Studienphase</b>	Phase III
<b>Erkrankung</b>	Nervensystem: Multiple Sklerose
<b>Einschlusskriterien</b>	<ul style="list-style-type: none"><li>- 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)</li><li>- 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</li><li>- Participants have Expanded Disability Status Scale (EDSS) score of 0 to 5.5 at Screening and Baseline (Day 1). Participants with an EDSS score <math>\leq 2</math> 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</li><li>- Participants are neurologically stable for <math>\geq 30</math> days prior to both screening and baseline</li><li>- 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</li><li>- 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</li><li>- Participants have given written informed consent prior to any study-related procedure</li><li>- Other protocol defined inclusion criteria could apply.</li></ul>
<b>Ausschlusskriterien</b>	<ul style="list-style-type: none"><li>- 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.</li><li>- Disease duration more than (<math>&gt;</math>) 10 years in participants with an EDSS <math>\leq 2.0</math> at screening.</li><li>- 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.</li><li>- Other protocol defined exclusion criteria could apply.</li></ul>
<b>Alter</b>	18 - 55 Jahre
<b>Prüfzentren</b>	<b>Neurologie</b> (Rekrutierung beendet) Schleusenweg 2-16 60590 Frankfurt am Main Dipl. Psych. Dr. Yavor Yalachkov <a href="mailto:yavor.yalachkov@unimedizin-ffm.de">yavor.yalachkov@unimedizin-ffm.de</a>
<b>Sponsor</b>	Merck KGaA

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**Registrierung in anderen  
Studienregistern**

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