

Supplemental Online Content

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This supplemental material has been provided by the authors to give readers additional information about their work.

eAppendix 1.

Methods

Study Design Details

A total of 1133 patients were randomized in a 1:1 ratio to receive once-daily oral ponesimod or teriflunomide. Randomization was stratified by use of MS DMTs in the last two years prior to randomization (yes, no) and by baseline expanded disability status scale (EDSS) score ($EDSS \leq 3.5$, $EDSS > 3.5$). The study consisted of a pre-randomization period with 2 visits for patient screening and baseline measurements, a randomization visit, which was the first day of a 108-week double-blind treatment period that included visits at 2, 4, and 12 weeks after randomization, and 12-weekly visits thereafter, followed by a safety follow-up (FU) period of approximately 14–30 days after the last study dose, with in-between visits scheduled for testing liver function abnormalities. To reduce the first-dose effect of ponesimod, a gradual up-titration scheme (or a mock up-titration for patients randomized to teriflunomide) from a starting dose of 2mg to 10mg was implemented from Day 1 to Day 14 followed by the ponesimod 20mg maintenance dose on Day 15 to end of treatment (EOT [Week 108]). To accelerate the reduction of teriflunomide plasma concentrations at the end of treatment, all patients underwent an accelerated teriflunomide elimination procedure with cholestyramine or activated charcoal during the post-treatment FU period. Patients who completed treatment up to Week 108 had the option of enrolling into an extension study with ponesimod, conducted under a separate protocol.

A gradual up-titration of ponesimod from a 2 mg starting dose to a 20 mg maintenance dose over a period of 14 days was found to successfully mitigate first-dose effects. This

2-week up-titration regimen was implemented in the study on initiation of treatment (Day 1) and on days of re-initiation of treatment following treatment interruption of more than 3 days (Supplementary table 1)

Inclusion/Safety Assessments

The following safety assessments were made by the predefined adverse events of special interest (AESIs) criteria: effect on heart rate and rhythm (including hypotension), hypertension, hepatobiliary disorders/liver enzyme abnormality, pulmonary events, macular edema, infection (serious or severe), herpetic infection, skin malignancy, non-skin malignancy, and seizure. In addition, major adverse cardiac event (MACE) were adjudicated to the MACE subcategories (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) by the MACE adjudication board.

Statistical Analysis

A sample size of 1100 patients (550 per treatment group) provided a power of approximately 90% for a significance level of 0.01, assuming a ARR rate reduction of 33% (ARR of 0.320 for teriflunomide and 0.215 for ponesimod). The main analyses of the primary and all secondary endpoints were based on the full analysis set (FAS) that included all randomized patients. Safety was summarized descriptively based on the safety analysis set (SAF) that included all randomized patients who received at least one dose of study drug.

The primary statistical analysis was performed using a negative binomial (NB) regression model for the number of confirmed relapses from baseline to EOS adjusting for the log time on study (in years) as an offset. The null hypothesis was tested with a two-sided significance level of 0.01 for conclusive evidence and 0.05 for a positive study.

An overall multiple testing strategy was applied to the planned efficacy analyses, which started with testing the primary endpoint, followed hierarchically by a fallback type procedure for the secondary endpoints at an overall two-sided alpha of 0.05.²⁸ See supplementary Figure S2) for details. Secondary endpoints analyses: Change from baseline in fatigue symptoms scores to Week 108 was analyzed with a mixed model repeated measurements model, number of new combined unique active lesions up to EOS was analyzed with a negative binomial regression model adjusting for the log time up to last available MRI scan as an offset, and time to 12-week and 24-week CDA were analyzed using stratified log rank test and cox proportional hazards model.

Definition of Relapse and Confirmed Relapse

A relapse was defined as new, worsening or recurrent neurological symptoms that occurred at least 30 days after the onset of a preceding relapse, and that lasted at least 24 hours, in the absence of fever or infection. The new, worsening or recurrent neurological symptoms were to be evaluated by the treating neurologist and, if all the elements of the above definition had been verified, and in the absence of another, better explanation of the patient's symptoms, the event was considered as a relapse. The onset date of the relapse corresponded to the onset date of the symptoms.

A relapse was confirmed by the treating neurologist only when the patients' symptoms were accompanied by an increase in EDSS/FS scores, which was consistent with the patients' symptoms, from a previous clinically stable EDSS/FS assessment (ie, performed at least 30 days after the onset of any previous relapse), obtained by the efficacy assessor and consistent with the following:

- An increase of at least half a step (0.5 points; unless EDSS=0, then an increase of at least 1.0 points was required) or
- An increase of at least 1.0 point in at least two FS scores, or
- An increase of at least 2.0 points in at least one FS score (excluding bladder/bowel and cerebral).

Definition of Highly Active Disease

Highly active disease was defined as ≥ 2 relapses within the 1 year prior to study entry and baseline EDSS score > 2 and baseline MRI ≥ 1 Gd+ T1 lesion or any DMT received within 12 months prior to randomization and one or both of the following: 1) ≥ 1 relapse within 1 year prior to study entry and the baseline MRI either ≥ 1 Gd+ T1 lesion and/or ≥ 9 T2 lesions or 2) number of relapses within 1 year prior to study entry $\geq$ number of relapses between 2 and 1 year prior to study entry, for patients with ≥ 1 relapse within 2 years prior to study entry.

FSIQ-RMS

The FSIQ-RMS is a validated PRO measure that was developed by the sponsor to evaluate fatigue-related symptoms and the impacts of those symptoms on the lives of people with RMS. The development of FSIQ-RMS was in accordance with the requirements set forth in FDA's Guidance for Industry on Patient-Reported Outcome Measures. A questionnaire (electronic format) consisting of 7 items included in the fatigue-related symptom domains was administered daily over 7 days. The total score for each domain was standardized onto a scale of 0-100 with higher scores indicating more fatigue.

Results

Efficacy

Primary endpoint

Annualized relapse rate

Sensitivity analysis: negative binomial regression for annualized relapse rate up to end of study adjusting for presence of GD+ T1 lesions at baseline (Supplementary table 4).

Safety

Treatment emergent lymphocyte counts $< 0.2 \times 10^9$ /L were reported for 3.2% of patients in the ponesimod group and none in the teriflunomide group. Lymphocyte counts returned to the normal range ($>1.0 \times 10^9$) in 94% of patients and to above 0.8×10^9 cells/L in 99% of patients at the first scheduled follow-up visit (Day 15, n=484) upon permanent discontinuation of double-blind ponesimod treatment.

eTable 1. Up-titration of ponesimod dose regimen

Treatment period	Duration	Dose regimen in the ponesimod group	Dose level
Titration	Days 1 and 2	2 mg	1 and 2
Titration	Days 3 and 4	3 mg	3 and 4
Titration	Days 5 and 6	4 mg	5 and 6
Titration	Day 7	5 mg	7
Titration	Day 8	6 mg	8
Titration	Day 9	7 mg	9
Titration	Day 10	8 mg	10
Titration	Day 11	9 mg	11
Titration	Days 12 to 14*	10 mg	12 to 14
Maintenance	Day 15 until EOT	20 mg	NA

* Visit 4 is to take place at Day 15 ± 1 day. The titration kit will therefore include an additional capsule and tablet (if applicable) for treatment on Day 15 (i.e., dose regimen in the ponesimod group = 10 mg). EOT: End-of-Treatment; NA: not applicable

eTable 2. Summary of TE-AESIs on HR and Rhythm[†] on Day 1[‡] (Safety Analysis Set)

	Ponesimod 20 mg N=565 n (%)	Teriflunomide 14 mg N=566 n (%)
	12 (2.1)	2 (0.4)
Bradycardia	4 (0.7)	-
Atrioventricular block first degree	3 (0.5)	-
Intraventricular conduction delay	2 (0.4)	-
Bundle branch block left	1 (0.2)	-
Bundle branch block right	1 (0.2)	-
Sinus arrhythmia	1 (0.2)	-
Sinus bradycardia	1 (0.2)	-
Electrocardiogram QT prolonged	-	1 (0.2)
Presyncope	-	1 (0.2)

[†] Including hypotension. [‡] Patients received ponesimod 2 mg on Day 1
MedDRA version 21.0

eTable 3. Summary of Liver Test Abnormalities up to EOT + 1 day (Safety set)

Elevation	Ponesimod 20 mg N=560 n (%)	Teriflunomide 14 mg N=566 n (%)
ALT $\geq$ 3 x ULN	97 (17.3)	47 (8.3)
ALT > 5 x ULN	26 (4.6)	14 (2.5)
ALT $\geq$ 8 x ULN	4 (0.7)	12 (2.1)
ALT $\geq$ 10 x ULN	3 (0.5)	10 (1.8)
ALT $\geq$ 20 x ULN	-	2 (0.4)
TBIL $\geq$ 2 x ULN	8 (1.4)	2 (0.4)
ALT or AST $\geq$ 3xULN + TBIL $\geq$ 2xULN	1 (0.2) [†]	-

ALT, alanine aminotransferase; AST, aspartate aminotransferase; TBIL, total bilirubin; ULN, upper limit of normal

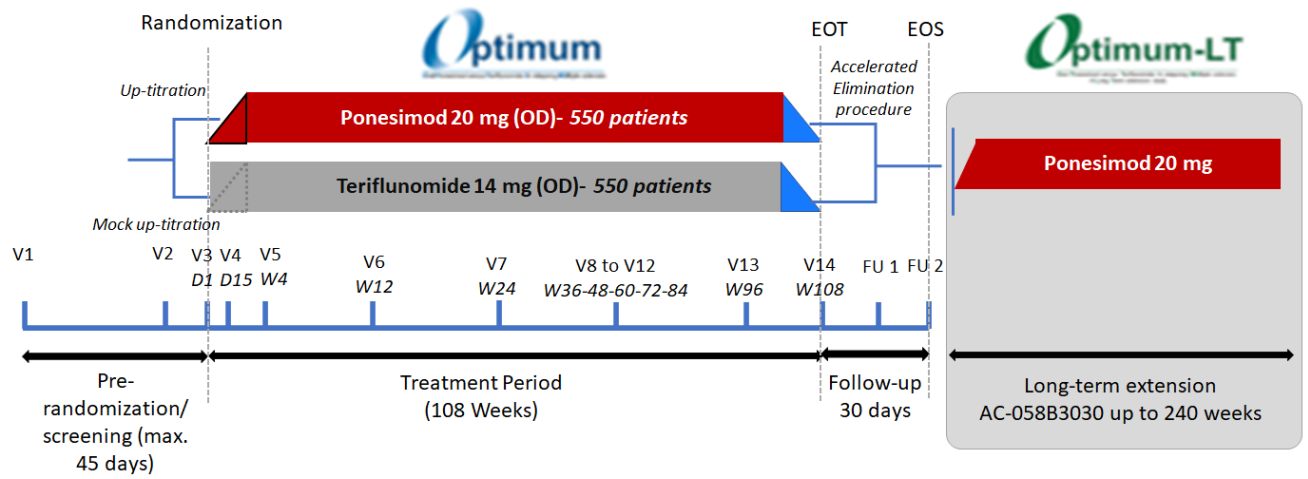
[†]patient with pre-existing ALT elevation (>5xULN), and resolved after discontinuation
ALT ULN: 44 U/L (men) and 33 U/L (women). AST ULN: 39 U/L (men) and 34 U/L (women)

eTable 4. Annualized relapse rate from negative binomial regression

	Ponesimod 20 mg N=567	Teriflunomide 14 mg N=566
Mean estimate (ARR); 95% CL	0.201; (0.173, 0.234)	0.286; (0.250, 0.327)
Treatment effect (rate ratio)	0.704; (0.577, 0.858); P= 0.0005	

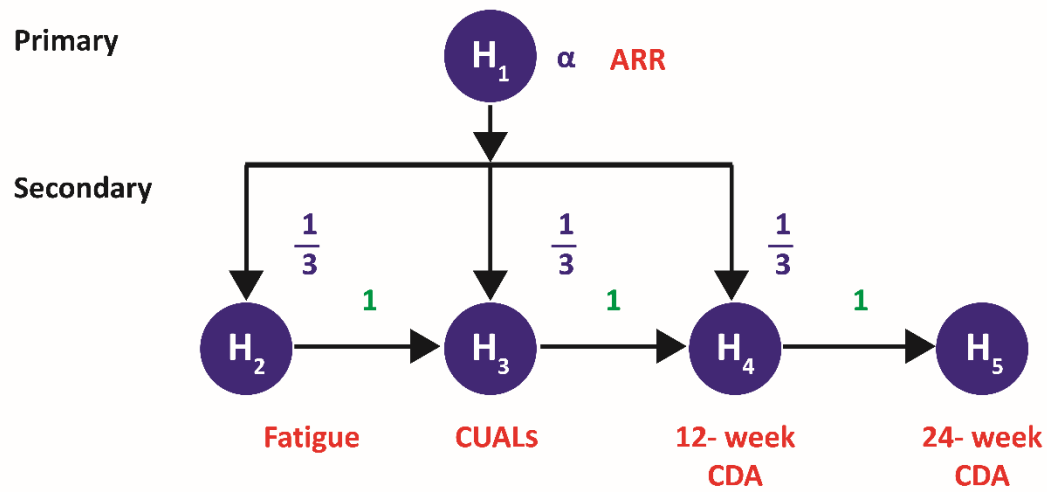
ARR: annualized relapse rate (confirmed relapses per year), rate ratio: ponesimod vs. teriflunomide. Negative binomial model is applied with Wald confidence limits and p-value. Offset: log time (years) up to end of study (EOS)

eFigure 1. Study Design



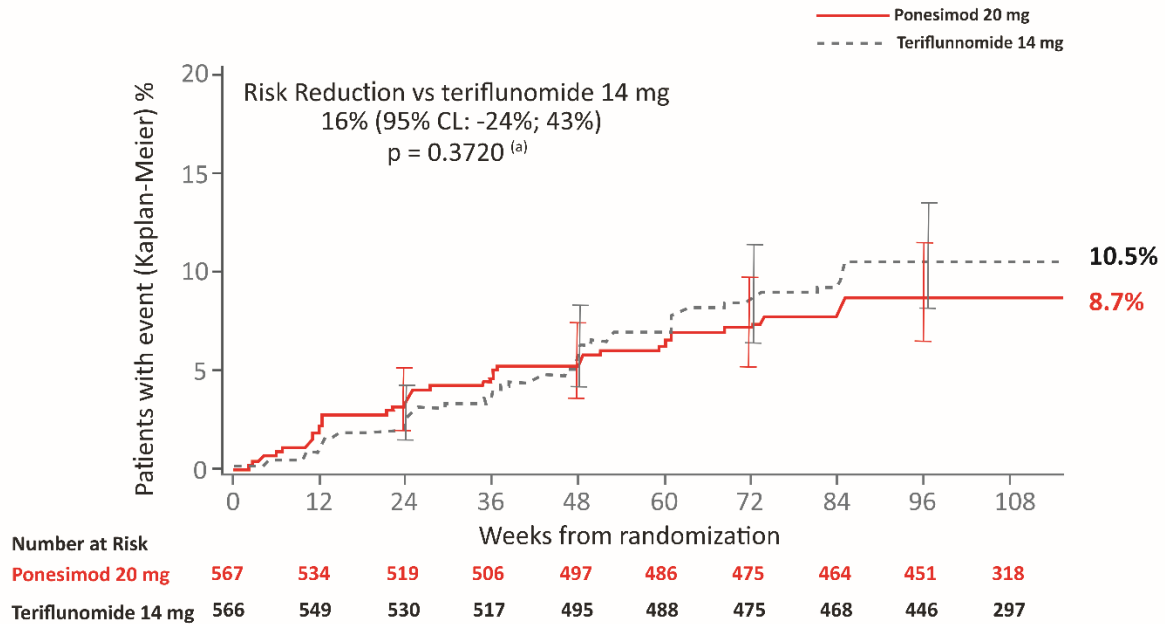
D: day; EOS: End of study; EOT: end of treatment; FU: Follow-up; M; Month; V: visit; W: week

eFigure 2. Overall Testing Strategy



ARR: annualized relapse rate; CDA: confirmed disability accumulation; CUALs: combined unique active MRI lesions per year

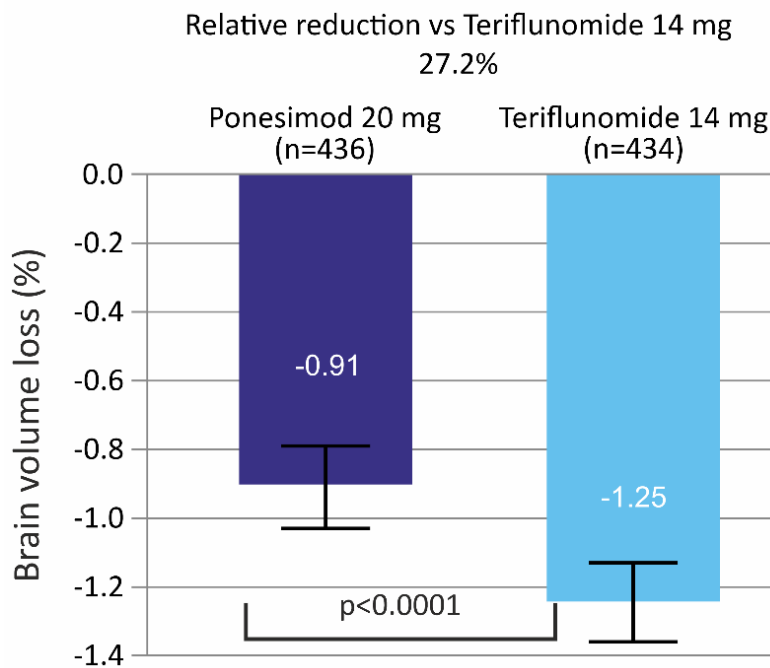
eFigure 3. Time to 24-week confirmed disability accumulation (Full Analysis Set)



^(a)Exploratory, not formally tested. Stratified log-rank test p-values and stratified Cox regression risk reduction estimate displayed. Analyses by EDSS strata and DMTs in the 2 years prior to randomization strata. CL: Confidence limits; Event: 24-week CDA up to EOS. Unstratified Kaplan-Meier curve with KM-estimate at Week 108 presented.

eFigure 4. Brain volume loss – mean percent change from baseline to Week 108;

Full Analysis Set



Brain volume loss displayed as mean (95% CL) % change from baseline

eAppendix 2. Personnel

Independent Data Monitoring Committee

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Composition of the Ophthalmology Safety Board

• Prof. Dr. med. Selim Orgül (Ophthalmologist), Basel (Switzerland)
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List of the Major Adverse cardiovascular event adjudication committee

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Member / Cardiologist
Prof. Andreas Zeller University Hospital of Liestal & Centre for Primary Health Care, University of Basel, Switzerland
Member / Cardiologist
Prof. Dragos Vinereanu University and Emergency Hospital of Bucharest, Bucharest, Romania

Central MRI Reading center = MIAC AG (Medical Image Analysis Center)

Jens Wuerfel, Stefan Traud, Michael Amann, Alexandra Palatini, Silje Nickell, Esther Ruberte https://miac.swiss/en/#home
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eTable 5. Composition of the Advisory Board

Name	Role	Area of expertise	Affiliation
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Xavier Montalban	Advisory board member	Neurologist	Department of Neurology-Neuroimmunology, Multiple Sclerosis Center of Catalonia, Vall d'Hebron University Hospital, Barcelona, Spain.
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eTable 6. List of investigators

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