

Mepolizumab Treatment Leads to Clinical Remission in Patients With Severe Eosinophilic Asthma: Results From the Real-World REDES Study

Poster No. 606

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Introduction

Mepolizumab, a humanized anti-IL-5 monoclonal antibody, is approved as an add-on treatment for use in patients with severe eosinophilic asthma,^{1,2} and has been shown to reduce exacerbations and maintenance OCS use, while improving symptom control.³⁻⁹

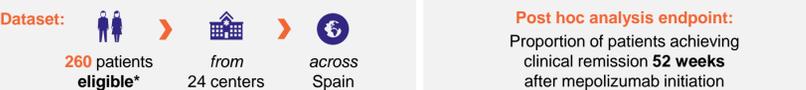
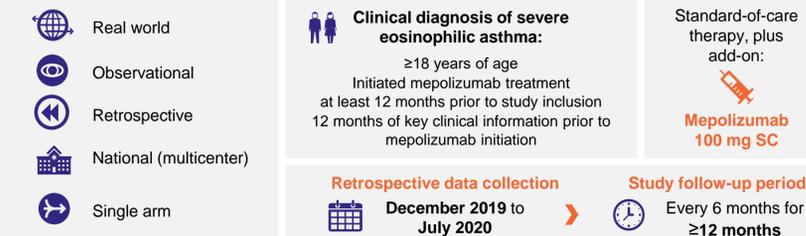
Several real-world studies, including the REDES study,¹⁰ have further demonstrated that mepolizumab is effective at enabling patients with severe eosinophilic asthma to achieve treatment goals such as OCS elimination, exacerbation reduction, or symptom control.^{10,11}

There is currently an ambition in clinical practice to move from single measures of disease control to a relevant composite measure when assessing impact of treatment in patients with severe eosinophilic asthma.

This post hoc analysis assessed the proportion of patients achieving a multicomponent treatment goal of clinical remission (based on OCS-free, exacerbation-free, and asthma control) after 1 year of treatment with mepolizumab.

Methods

REDES (GSK ID: 213172) Study design



*Only patients with data available across all 3 contributing components for measuring clinical remission were included in these post hoc analyses (N=260/318, 82% of the total treated population). 58 patients were excluded due to missing ACT score at Week 52; †Not receiving OCS at baseline and remained off OCS at Week 52 or tapered off during the study; ‡The proportion of patients achieving one or two components of the clinical remission criteria was also described

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Abbreviations

ACT, Asthma Control Test; BMI, body mass index; FEV₁, forced expiratory volume in 1 second; IL, interleukin; IQR, interquartile range; OCS, oral corticosteroids; Pred, predicted; SC, subcutaneous; SD, standard deviation.

Disclosures

This post hoc analysis and the parent study (GSK ID: 213172) were funded by GSK. CDR has received funding for travel or speaker fees from ALK, Almirall, AstraZeneca, Boehringer-Ingelheim, Chiesi, Esteve, Ferrer, GSK, Menarini, Novartis, Stallergenes, and Pflizer. IP reports speaker's honoraria for sponsored meetings from AstraZeneca, Boehringer Ingelheim, Aerocrine, Almirall, Novartis, Teva, Chiesi, Sanofi/Regeneron, and GSK; payments for organizing educational events from AstraZeneca, GSK, Sanofi/Regeneron, and Teva; honoraria for attending advisory panels with Genentech, Sanofi/Regeneron, AstraZeneca, Boehringer Ingelheim, GSK, Novartis, Teva, Merck, Circassia, Chiesi, and Knopp; payments to support US Food and Drug Administration approval meetings from GSK; sponsorship to attend international scientific meetings from Boehringer Ingelheim, GSK, AstraZeneca, Teva, and Chiesi; a

grant from Chiesi to support a Phase II clinical trial in Oxford. He is co-patent holder of the rights to the Leicester Cough Questionnaire and has received payments for its use in clinical trials from Merck, Bayer, and Inamed. FG, RGP, PH, EP, and DBC are employees of GSK and hold stocks/shares in GSK. JO has served on adjudication committees or data and safety monitoring boards for AstraZeneca, GSK, Novartis, and Sanofi; received consultancy fees from AstraZeneca, GSK, and Sanofi; and received grants and personal fees from GSK. LH is the Academic Lead for the UK MRC Consortium for Stratified Medicine in Severe Asthma - Industrial Pharma partners Amgen, AstraZeneca, MedImmune, Janssen, Novartis, Roche/Genentech, GSK, and Boehringer Ingelheim; has received project grant funding from MedImmune, Novartis, Roche/Genentech, and GSK; has attended advisory boards/lectures supported by Novartis, Roche/Genentech, GSK, Evelo Biosciences, Teva, Theravance and Vectura; has received travel funding to attend international respiratory

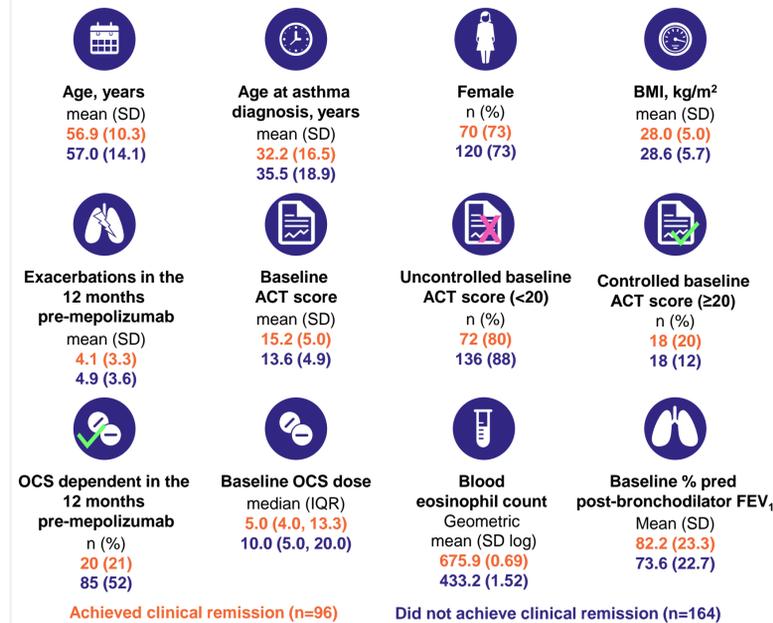
meetings from AstraZeneca, Chiesi, Novartis, Boehringer Ingelheim, Teva, and GSK; and has been involved in asthma clinical trials with GSK, Schering Plough, SynGene, Novartis, and Roche/Genentech for which his institution was remunerated. HN has received speaker fees from AstraZeneca, GSK, Novartis, and Sanofi; has been an advisory board member for GSK, and has received research grants from Boehringer Ingelheim. Editorial support (in the form of writing assistance, including preparation of the draft poster under the direction and guidance of the authors, collating and incorporating authors' comments for each draft, assembling tables and figures, grammatical editing and referencing) was provided by Sarah Farrar, PhD, at Fishawack Indicia Ltd, UK, part of Fishawack Health, and was funded by GSK.

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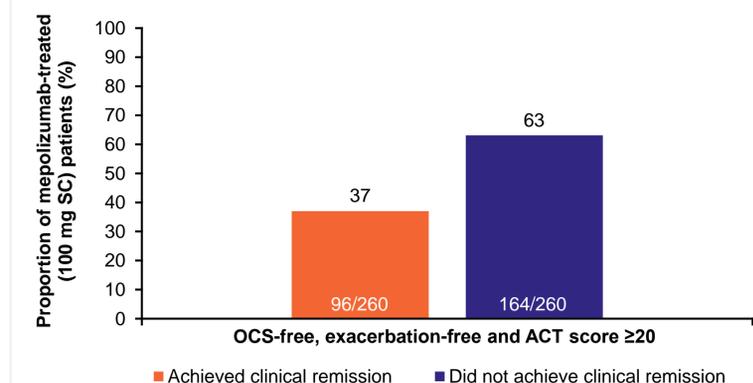


Results

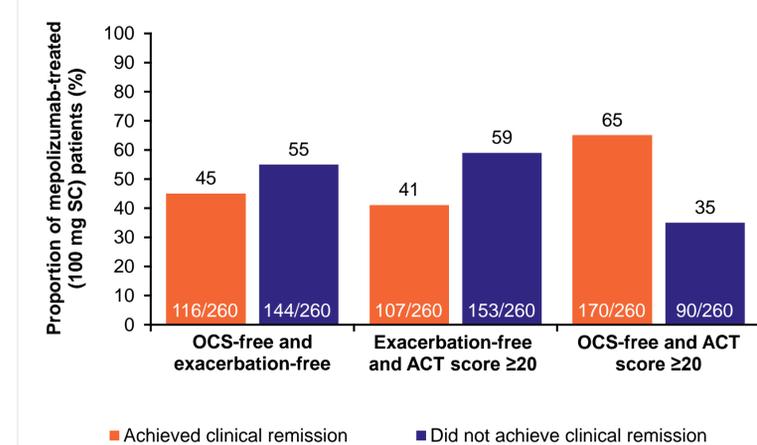
Patient baseline demographics and clinical characteristics for those who did/did not achieve the three-way definition of clinical remission



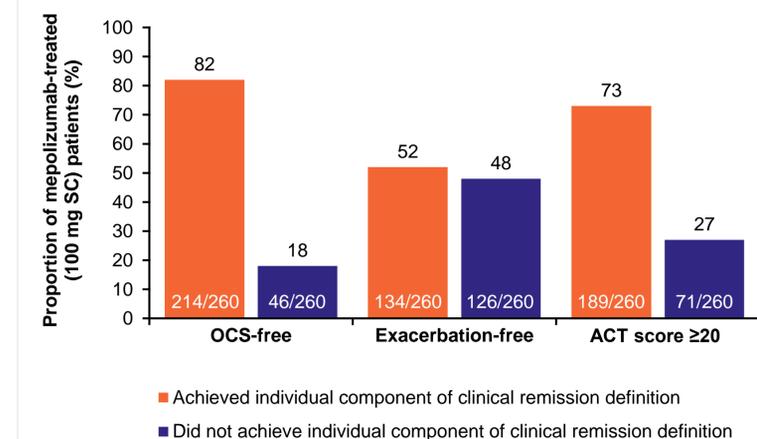
Overall, 37% of patients achieved clinical remission based on the composite three-way definition



Between 41 to 65% of patients achieved two components of clinical remission



At least 50% of patients met the individual components of clinical remission; majority met the OCS-free (82%) and ACT score ≥20 (73%) components



Discussion & Conclusions

In this analysis, lung function was not included as a component of the three-way clinical remission definition as a consensus definition for FEV₁ improvement has not yet been established.

It is also recognized that patients with severe asthma often have irreversible airway remodeling,¹² which prevents them from meeting optimized or desirable lung function targets.

The clinical remission criteria applied were based on a modified Delphi survey approach¹³ but did not consider remission from a patient's perspective.

A key focus in asthma management is earlier treatment initiation to halt disease progression, prevent permanent consequences of the disease, and improve the likelihood of patients being able to achieve remission, and ultimately lead a normal life.

This post hoc analysis using data from the REDES study showed that 37% of patients met the three-way definition of clinical remission, 41-65% met the different combinations of the two-way definitions, and ≥50% met each individual component of clinical remission.

These real-world data demonstrate that mepolizumab is effective at enabling patients with severe eosinophilic asthma to achieve a status of clinical remission. Clinical remission is an ambitious multicomponent treatment goal comprising key clinical criteria for patients treated in routine clinical practice.