





## Real-world mepolizumab in the prospective severe asthma REALITI-A study: initial analysis

Tim Harrison<sup>1</sup>, Giorgio Walter Canonica <sup>2,3</sup>, Geoffrey Chupp<sup>4</sup>, Jason Lee<sup>5</sup>, Florence Schleich<sup>6</sup>, Tobias Welte <sup>7</sup>, Antonio Valero<sup>8</sup>, Kim Gemzoe<sup>9</sup>, Aoife Maxwell<sup>10</sup>, Sandra Joksaite<sup>11</sup>, Shibing Yang<sup>12</sup>, Peter Howarth<sup>13</sup> and Melissa K. Van Dyke <sup>14</sup>

Affiliations: <sup>1</sup>Nottingham NIHR Biomedical Research Centre, Nottingham City Hospital, University of Nottingham, Nottingham, UK. <sup>2</sup>Personalized Medicine Asthma and Allergy Clinic, Dept of Biomedical Sciences, Humanitas University and Research Hospital, Rozzano, Milan, Italy. <sup>3</sup>Dept of Biomedical Science, Humanitas University, Pieve Emanuele, Milan, Italy. <sup>4</sup>Division of Pulmonary, Critical Care, and Sleep Medicine, Dept of Internal Medicine, Yale School of Medicine, New Haven, CT, USA. <sup>5</sup>Toronto Allergy and Asthma Clinic, Toronto, ON, Canada. <sup>6</sup>Dept of Pulmonary Medicine, CHU Sart-Tilman and GIGA-I3 Research Group, University of Liège, Liège, Belgium. <sup>7</sup>Dept of Respiratory Medicine and German Center for Lung Research, Hannover Medical School, Hannover, Germany. <sup>8</sup>Sección de Alergología, Servicio de Neumología y Alergia, Hospital Clínic de Barcelona, Universitat de Barcelona, IDIBAPS, CIBER de Enfermedades Respiratorias (CIBERES), Barcelona, Spain. <sup>9</sup>Real World Study Delivery, Value Evidence and Outcomes, Global Medical, GSK, Stevenage, UK. <sup>11</sup>Clinical Statistics, R&D Projects Clinical Platforms and Sciences, GSK, Uxbridge, UK. <sup>12</sup>Value Evidence and Outcomes, GSK, Collegeville, PA, USA. <sup>13</sup>Global Specialty & Primary Care, GSK, Brentford, UK. <sup>14</sup>Epidemiology, GSK, Upper Providence, PA, USA.

**Correspondence**: Peter Howarth, Global Specialty & Primary Care, GSK, GSK House, 980 Great West Road, Brentford, Middlesex, TW8 9GS, UK. E-mail: peter.h.howarth@gsk.com

## @ERSpublications

Mepolizumab has demonstrated efficacy in patients with severe eosinophilic asthma in the controlled environment of clinical trials. These initial data from the prospective REALITI-A study show that similar results are obtained in a real-world setting. https://bit.ly/3hINnFO

**Cite this article as:** Harrison T, Canonica GW, Chupp G, *et al.* Real-world mepolizumab in the prospective severe asthma REALITI-A study: initial analysis. *Eur Respir J* 2020; 56: 2000151 [https://doi.org/10.1183/13993003.00151-2020].

This single-page version can be shared freely online.

## ABSTRACT

**Introduction:** Efficacy of mepolizumab, an anti-interleukin-5 monoclonal antibody, was demonstrated in randomised controlled trials; data on its real-world impact in routine clinical practice are starting to emerge. We assessed the effectiveness and safety of mepolizumab prescribed for patients in the real world. **Methods:** REALITI-A is a global, prospective, observational cohort study, collecting data from routine healthcare visits from patients with asthma. Patients newly prescribed mepolizumab for severe asthma with 12 months of relevant medical history pre-mepolizumab (collected retrospectively) were enrolled. An initial analysis of data from early initiators who had completed 1 year of follow-up (as of February 28, 2019) was conducted. The primary objective was to compare the rate of clinically significant exacerbations (requiring oral corticosteroids (OCS) and/or hospitalisation and/or emergency department visit) before and after mepolizumab; exacerbations requiring hospitalisation and/or emergency department visit and change in maintenance OCS use were secondary objectives. Treatment-related adverse events were reported.

Copyright ©ERS 2020. This article is open access and distributed under the terms of the Creative Commons Attribution Non-Commercial Licence 4.0.

**Results:** Overall, 368 mepolizumab-treated patients were included. Rates of clinically significant exacerbations were reduced by 69% from 4.63 per person per year pre-treatment to 1.43 per person per year during follow-up (p<0.001), as were those requiring hospitalisation and/or emergency department visit (from 1.14 to 0.27 per person per year; 77% reduction). In 159 patients with maintenance OCS dose data available during the pre-treatment period, median daily dose decreased from 10.0 (pre-treatment) to  $5.0 \text{ mg} \cdot \text{day}^{-1}$  by week 21–24 of follow-up, sustained until week 53–56. No new safety signals were reported.

**Conclusion:** These data demonstrate that the effectiveness of mepolizumab is consistent with clinical trial results under real-world settings, with significant reductions in exacerbations and daily maintenance OCS dose.