Introduction and Objectives Asthma remission is characterized by long-term disease stabilization and control with or without ongoing treatment. This post hoc exploratory analysis assessed the proportion of patients who received tezepelumab in DESTINATION (NCT03706079) who achieved on-treatment remission over 2 years.

Methods DESTINATION was a phase 3, multicentre, randomized, placebo-controlled, double-blind extension study. Patients (12–80 years old) included in this analysis received tezepelumab in both NAVIGATOR (NCT03347279) and DESTINATION (tezepelumab only) or placebo in both NAVIGATOR and DESTINATION (placebo only). Patients received treatment up to week 104. Remission was predefined as an Asthma Control Questionnaire-6 score ≤ 1.5, stable lung function (a forced expiratory volume in 1 second > 95% of baseline) at the end of each year, and no exacerbations or use of oral corticosteroids during the time periods assessed.

Results The proportion of patients who achieved remission in the tezepelumab only and placebo only groups are summarized in the table 1. An intercurrent exacerbation requiring systemic corticosteroid use was the main reason why a patient no longer met the definition of remission.

Conclusion Among patients with severe, uncontrolled asthma, a numerically greater proportion of patients who received tezepelumab than placebo achieved remission during the time periods assessed.

Please refer to page A294 for declarations of interest related to this abstract.

M23 EFFICACY OF TEZEPELUMAB IN PATIENTS WITH SEVERE, UNCONTROLLED ASTHMA BY PRIOR OMALIZUMAB USE: A POST HOC ANALYSIS OF THE PHASE 3 NAVIGATOR STUDY

1A Menzies-Gow, 2G Colice, 3C S Ambrose, 4J-P Llanos, 5A Hellquist, 6B Cook, 7M Caminati, 1Royal Brompton and Harefield Hospitals, School of Immunology and Microbial Sciences, Kings College, London, UK; 1Late-stage Development, Respiratory and Immunology, BioPharmaceuticals RandD, AstraZeneca, Gothenburg, MD, USA; 2Respiratory and Immunology, BioPharmaceuticals Medical, AstraZeneca, Gothenburg, MD, USA; 3Respiratory and Immunology, BioPharmaceuticals Medical, AstraZeneca, Cambridge, UK; 4University of Leicester, Leicester, UK; 5Global Medical Affairs, Amgen, Thousand Oaks, CA, USA; 6Biometrics, Late-stage Development, Respiratory and Immunology, BioPharmaceuticals RandD, AstraZeneca, Gothenburg, Sweden; 7Department of Medicine, University of Verona, Verona, Italy

Introduction and Objectives Omalizumab, an anti-immunoglobulin E humanized monoclonal antibody, was the first biologic approved for the treatment of severe allergic asthma. Tezepelumab, a human monoclonal antibody, blocks thymic stromal lymphopoietin (TSLP). In the phase 3 NAVIGATOR study (NCT03347279), tezepelumab significantly reduced exacerbations and improved lung function, asthma control and health-related quality of life versus placebo in patients with severe, uncontrolled asthma. This post hoc analysis assessed the efficacy of tezepelumab in NAVIGATOR patients with and without reported prior omalizumab use.

Methods NAVIGATOR was a multicentre, randomized, double-blind, placebo-controlled study. Patients (12–80 years old) who were not currently receiving biologic treatment and who were receiving medium- or high-dose inhaled corticosteroids and at least one additional controller medication with or without oral corticosteroids, were randomized 1:1 to receive tezepelumab 210 mg or placebo subcutaneously every 4 weeks for 52 weeks. Patients who had received biologic treatments were enrolled if the last dose was taken over 4 months, or over five half-lives, before screening. The annualized asthma exacerbation rate (AAER) over 52 weeks was assessed in patients with and without prior omalizumab use.

Results Of 1059 patients included in the study, 81 (8%) reported previous omalizumab use (tezepelumab, n = 45; placebo, n = 36). Baseline demographics and clinical characteristics were generally similar between those with and without prior omalizumab use. More patients with prior omalizumab use (n = 53, 65%) had over two exacerbations in the past 12 months versus those who had not used omalizumab (n = 371, 38%). Among the placebo group, the AAER was numerically higher in those who had received omalizumab (3.09)