Long-term Efficacy and Safety of Daclizumab HYP in Relapsing-Remitting Multiple Sclerosis: Results From the SELECTED Extension Study

Gold R,1 Giovannoni G,2 Selmaj K,1 Havrdova E,1 Radue E-W,2 Sprenger T,1 Stefeksi O,3 Montalban X,1 Riester K,1 Greenberg S,1 Ozen G,1 Elkins J

Presented by: Dr. Steven C. Cohen, Providence Multiple Sclerosis Center, Portland, Oregon, USA

1 St. Joseph Hospital/Rutgers University, Bochum, Germany; 2 Queen Mary University of London, London School of Medicine and Dentistry, London, UK; Medical University of Lodz, Lodz, Poland; 3First Faculty of Medicine, Charles University in Prague, Prague, Czech Republic; 4Medical Image Analysis Center, University Hospital Basel, Basel, Switzerland; 5Rush University Medical Center, Chicago, IL, USA; 6Hospital de Valderrubio University, Barcelona, Spain; 7Biogen, Cambridge, MA, USA; 8AbbVie Biopharmaceutical Inc., Redwood City, CA, USA

INTRODUCTION

Daclizumab high-yield process (DAC HYP) is a humanized monoclonal antibody that binds the high-affinity interleukin 2 (IL-2) receptor alpha subunit (CD25) and modulates IL-2 signaling.2 The SELECT T Trial of clinical studies was designed to evaluate the efficacy and safety of DAC HYP in patients with relapsing-remitting multiple sclerosis (RMS) (Figure 1). The objectives of these analyses are to report interim safety and efficacy data after approximately 3 years of duration of the SELECTED study.

METHODS

Study Design and Treatment

SELECTED is an ongoing, single-arm, open-label extension study of DAC HYP 150 mg subcutaneous (SC) every 4 weeks for up to 6 years (Figure 2).

Analyses

- An interim analysis was performed on data collected through January 20, 2016.
- Safety results were based on data collected from the baseline visit in SELECT.
- Efficacy analyses were based on the time from first dose of DAC HYP and included the subset of SELECTED patients receiving DAC HYP 150 mg who had not been randomized to the washout period in SELECT and who did not have a gap in DAC HYP 150 mg SC treatment between 2.5 years between studies.

Patients

- The safety population consisted of 410 patients and the efficacy population comprised 367 patients.
- At the time of this interim analysis, median time on treatment in SELECTED was 3.5 years (range: 1–6 years; 845 patient-years).
- Patients in SELECTED had received a median (range) of 48 (13–74) doses of DAC HYP since the start of the trial (910 patient-years).
- The yearly incidence of adverse events (AEs), serious AEs (SAEs), and AEs leading to discontinuation did not increase over time and no deaths were reported (Table 1).

SAE leading to treatment discontinuation consisted of 2 deaths (0.5%) which occurred within the first 6 months of enrolment in SELECTED.

Safety Overview

- The incidence of adverse events (AEs), serious AEs (SAEs), and AEs leading to discontinuation did not increase over time and no deaths were reported (Table 1).
- The most common serious AEs were rash (1%), allergic dermatitis (1%), and pancreatitis (1%).
- One serious cutaneous AE was reported as Stevens-Johnson syndrome, but the diagnosis was not supported by the case details per the central independent dermatologist.
- Hepatic AEs were observed in 1% of patients (Table 2).

CONCLUSIONS

- In these interim results, reductions in MS disease activity observed in Years 1 and 2 were maintained in Year 3 of treatment with DAC HYP 150 mg SC.
- The findings provide evidence that treatment with DAC HYP 150 mg SC over 3 years provides consistent reduction in MS disease activity.
- The safety profile of DAC HYP 150 mg SC in patients with RMS in this interim analysis of SELECTED was comparable to that observed in SELECT and SELECTED.
- No new safety signals were observed with DAC HYP 150 mg SC treatment.
- The SELECTED study is ongoing and will provide data on up to 8 years of treatment to inform the long-term safety and efficacy profile of DAC HYP 150 mg SC monotherapy in patients with RMS.

References


Disclosures

The study was supported by Boehringer Ingelheim and AbbVie Biopharmaceuticals, Inc. (ABBV). Consulting fees from Boehringer Ingelheim and ABBV; Honoraria from ABBV, Novartis, Merck Serono, and Teva; and grants from the National Institute of Neurological Disorders and Stroke and the Multiple Sclerosis Society to D.S. and C.P.C.; and grants from the University Hospital Basel (employer) received funds for speaker fees/advisory board and honoraria from Bayer HealthCare, Biogen, Merck Serono, and Novartis; research support from Actelion, Bayer HealthCare, Biogen, Merck Serono, and Novartis; research support from Biogen, Merck Serono, and Teva; speaker fees from Biogen; and editorial of Expert Opin. Biol. Ther.

Acknowledgments

The authors acknowledge their colleagues Boehringer Ingelheim, Gueul, C., Merzeau, G., Mark Bourey, and Paula Wilke, for their contributions to these analyses. Dr. C.P.C. is the guarantor for the final approval of the manuscript. The authors have no potential conflicts of interest.

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