Alemtuzumab Use Among NARCOMS Registry Participants

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OBJECTIVE
To describe the clinical characteristics and sociodemographic factors of persons with MS participating in the North American Research Committee on Multiple Sclerosis (NARCOMS) Registry who received alemtuzumab treatment and had 1 year of follow-up

INTRODUCTION
Alemtuzumab is an anti-CD52 monoclonal antibody therapy that is approved in over 65 countries for treatment of adults with relapsing forms of MS – Approved dosing 12 mg/day on 5 consecutive days at baseline and at Month 12 on 3 consecutive days – In CARE-MS (NCT03503348) and II (NCT02544946), 2 courses of alemtuzumab resulted in significantly greater improvements on clinical and MRI outcomes versus SC-IFN-β1a over 2 years
– The most frequent adverse events (AEs) with alemtuzumab were infusion-associated reactions; other AEs of interest included autoimmune AEs
– Alemtuzumab-treated patients who were followed up for an additional 5 years in 2 extension studies (CAMMS34009 [NCT09105552] and TOPAZ [NCT02255668]) experienced durability efficacy
– Although >1400 patients have been treated with alemtuzumab in Sanofi-sponsored clinical trials, real-world data are limited
– NARCOMS registry will contribute data on the real-world alemtuzumab treatment experience

METHODS
NARCOMS Participants
– NARCOMS is a voluntary registry that collects self-reported health-related information from people with MS
– Participants enroll by completing either an online or paper survey; information is then updated semi-annually
– NARCOMS participants who reported initiating alemtuzumab treatment in surveys between 2014 and 2016 were selected for the study; those who completed a follow-up survey 1 year later were included in the analysis

Assessments
– Demographics, clinical characteristics, employment status, and MS clinical course (relapsing/remitting MS [RRMS], primary progressive MS [PPMS], and secondary progressive MS [SPMS]) were reported
– Disability was evaluated using Patient-Determined Disease Steps (PDDS) scale, NARCOMS Depression scale, and Performance Scales (PS) scores at alemtuzumab initiation and 1 year later

Statistical Analysis
– Descriptive statistics were used to summarize relevant characteristics

RESULTS

Participants and Baseline Characteristics
– 50 NARCOMS participants reported initiating alemtuzumab and completed the 1-year survey
– Baseline demographic and clinical characteristics are listed in Table 1
– Participants were predominantly female and Caucasian
– Median (SD) age at alemtuzumab initiation was 40.4 (10.1) years, mean age at symptom onset was 28.3 (8.0) years, and mean age at diagnosis was 33.8 (9.0) years
– Most participants had RRMS or SPMS, and the remaining reported either “unsure/other” or PPMS
– Mean disease duration was 18.6 (10.2) years, with 26.0% of participants reporting at least 1 comorbidity

Outcomes
– At the start of alemtuzumab treatment, 68.0% of NARCOMS participants had at least moderate disability based on PDDS level (early cane) (Table 2)
– At Year 1, 82.0% of participants had stable or improved PDDS (Figure 1)
– PS scores at the initiation of alemtuzumab treatment and at 1-year follow-up are shown in Table 3
– Most of the NARCOMS participants had stable or improved PS scores after 1 year of alemtuzumab treatment (Figure 2)
– 32.0% reporting having a relapse treated with steroids 1 year before alemtuzumab compared with 18.0% at 1-year follow-up after alemtuzumab initiation
– Of those employed at the initiation of alemtuzumab treatment, 100% remained employed 1 year later

CONCLUSIONS
• Alemtuzumab treatment was also associated with reduced incidence of steroid-treated relapses, and all employed participants remained employed
• These data show a favorable real-world patient experience after alemtuzumab treatment, supporting the positive outcomes shown in clinical trials

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References

On December 25, 2017, Sanofi was granted EU registration for OFXYLA® (alemtuzumab) in the EU, including in the United Kingdom (UK), as an immunomodulatory treatment for the management of patients with relapsing forms of multiple sclerosis (MS) who have had an inadequate response to or intolerance of at least one disease-modifying therapy (DMT) or patients with primary progressive MS (PPMS) who have had an inadequate response to or intolerance of at least two DMTs. On December 8, 2017, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicine Agency (EMA) adopted a positive opinion for the marketing authorization of OFXYLA® (alemtuzumab) in the EU, including in the United Kingdom (UK), as an immunomodulatory treatment for the management of patients with relapsing forms of multiple sclerosis (MS) who have had an inadequate response to or intolerance of at least one disease-modifying therapy (DMT) or patients with primary progressive MS (PPMS) who have had an inadequate response to or intolerance of at least two DMTs. The main reason for positive opinion is the efficacy and safety profiles observed in the Extension Study (RAM: Receptos/Celgene, Sanofi, and Teva) and the CARE-MS I study.