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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 I (NCT00530348) and II (NCT00548405), 2 courses of alemtuzumab resulted in significantly greater improvements on clinical and MRI outcomes versus SC IFNB-1a over 2 years[1,2]
- The most frequent adverse events (AEs) with alemtuzumab were infusion-associated reactions; other AEs of interest included autoimmune AEs[1,2]
- Alemtuzumab-treated patients who were followed up for an additional 5 years in 2 extension studies (CAMMS03409 [NCT00930553] and TOPAZ [NCT02255656]) experienced durable efficacy[3-7]
- Although >1400 patients have been treated with alemtuzumab in Sanofi-sponsored clinical trials,[5,8] 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 participants who completed a follow-up survey 1 year later were included in the analysis
- Due to timing of survey distribution, the Year 0 survey took place within 6 months after alemtuzumab initiation, and the 1-year follow-up survey may have taken place before or after alemtuzumab Course 2 was administered

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[9-11]
  - PDDS scores range from 0 (normal) to 8 (bedridden) and correlate highly with EDSS scores[11]
  - PS are Likert scales that capture impairment across multiple domains; PS scores range from 0 (normal) to 5 (total disability) with the exception of mobility, which ranges from 0 to 6[10]
  - Stable PDDS and PS scores were classified as being the same at the start of alemtuzumab and at 1-year follow-up; improved scores were classified as being decreased at 1-year follow-up compared with the start of alemtuzumab

Statistical Analysis

- Descriptive statistics were used to summarize relevant characteristics

CONCLUSIONS

- **After initiating alemtuzumab, the majority of participants reported improved/stable overall disability, as well as improved/stable function in multiple aspects of disability, including mobility, fatigue, and vision**
- **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**

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
  - Mean (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

Table 1. Demographics and Baseline Characteristics of Alemtuzumab-Treated NARCOMS Participants

Parameter	Alemtuzumab (N=50)
Age at alemtuzumab initiation, years, mean (SD)	40.4 (10.1)
Age at symptom onset, years, mean (SD)	28.3 (8.0)
Female, n (%)	37 (75.5)
Race Caucasian, n (%)	 39 (78.0)
Disease duration, years, mean (SD)	18.6 (10.2)
MS clinical course, n (%) RRMS SPMS PPMS Unsure/other	 24 (48.0) 14 (28.0) 1 (2.0) 11 (22.0)
Comorbidities, n (%) 0 1 2 3+	 37 (74.0) 7 (14.0) 4 (8.0) 2 (4.0)
Employed, n (%) Full time Part time	17 (34.0) 14 (84.6) 3 (15.4)

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% reported 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

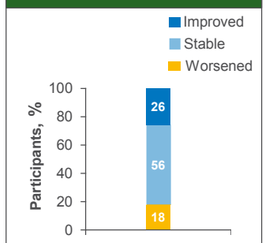
Table 2. PDDS Levels at the Start of Alemtuzumab and at Year 1

PDDS level, n (%)	Alemtuzumab	
	Year 0	Year 1
Normal	2 (4.0)	5 (10.0)
Minimal disability	0 (0.0)	0 (0.0)
Mild disability	6 (12.0)	4 (8.0)
Gait disability	4 (8.0)	7 (14.0)
Early cane	10 (20.0)	6 (12.0)
Late cane	10 (20.0)	6 (12.0)
Bilateral support	6 (12.0)	7 (14.0)
Wheelchair/scooter	8 (16.0)	10 (20.0)

Table 3. PS Scores at the Start of Alemtuzumab and at Year 1

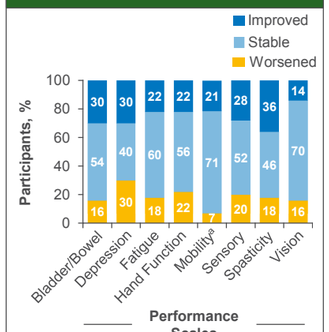
PS score, median (25th/75th quartile)	Alemtuzumab	
	Year 0	Year 1
Bowel/bladder	2 (1.75, 3)	2.5 (1, 3)
Depression	2 (1, 2)	1 (0.75, 3)
Fatigue	3 (2, 4)	3 (2, 4)
Hand function	1 (1, 2)	1 (1, 2)
Mobility	4 (2, 5)	4 (2, 5)
Sensory	2 (1, 3)	2 (1, 3)
Spasticity	2 (1, 3)	2 (1, 3)
Vision	1 (0.75, 2)	1 (0, 2)

Figure 1. Most Participants Had Improved or Stable PDDS Score After 1 Year of Alemtuzumab Treatment



Stable PDDS is defined as no change in score from baseline to 1-year follow-up; improvement and worsening are defined as a 1-point decrease or increase, respectively, from baseline to 1 year

Figure 2. Most Participants Had Improved or Stable PS Scores After 1 Year of Alemtuzumab Treatment



[a]Sum of percentages do not equal to 100 due to rounding; Stable PS domain score is defined as no change in score from baseline to 1-year follow-up; improvement and worsening are defined as a 1-point decrease or increase, respectively, from baseline to 1 year

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Acknowledgments and Disclosures

The authors and Sanofi would like to thank all NARCOMS participants for their active involvement in the registry. This poster was reviewed by Darren P Baker, PhD, Ericka M Bueno, PhD, and Colin Mitchell, PhD, of Sanofi. Editorial support for the poster was provided by Noopur Mandrekar, PhD, and Linda Wychowski, PhD, Envision Scientific Solutions, and was funded by Sanofi. The CARE-MS I study (NCT00530348) and its extension study, CAMMS03409 (NCT00930553), were funded by Sanofi and Bayer HealthCare Pharmaceuticals. The analysis of data from the NARCOMS registry was funded by Sanofi. NARCOMS is supported in part by the Consortium of Multiple Sclerosis Centers (CMSC) and the Foundation of the CMSC. Performance Scales Copyright Registration Number / Date: TXu000743629 / 1996-04-04; assigned to DeltaQuest Foundation, Inc., effective October 1, 2005. U.S. Copyright law governs terms of use. **ASa:** Nothing to disclose. **TT:** Nothing to disclose. **RJF:** Consulting fees (Actelion, Biogen, Genentech, Novartis, and Teva); advisory committees (Actelion, Biogen, and Novartis); clinical trial contract and research grant funding (Biogen and Novartis). **RAM:** Nothing to disclose. **TC:** Employee of Sanofi; holds Sanofi stock. **LH, KM, and ASm:** Employees of Sanofi. **GC:** Data and safety monitoring boards (AMO Pharmaceuticals, Apotek, BioLineRx, Horizon Pharmaceuticals, Merck, Merck/Pfizer, ModigeneTech/Prolor, Neurim, NHLBI [Protocol Review Committee], NICHD [OPRU oversight committee], Opko Biologics, Reata Pharmaceuticals, Receptos/Celgene, Sanofi, and Teva); consulting or advisory boards (Argenix, Atara Biotherapeutics, Genentech, Genzyme, GW Pharma, Klein-Buendel Incorporated, MedDay, MedImmune, Novartis, Opexa Therapeutics, Roche, Savara Inc, Somahlution, Teva, TG Therapeutics, and Transparency Life Sciences).

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TOPAZ=a long-Term follow-up study for multiple sclerOsis Patients who have completed the AlemtuZumab extension study

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Alemtuzumab is approved in >65 countries around the world for treatment of adults with relapsing forms of multiple sclerosis (MS). In the US, the indication provides that, because of its safety profile, the use of alemtuzumab should be reserved for patients who generally have had an inadequate response to 2 or more therapies indicated for the treatment of MS. In the EU, it is approved to treat patients with relapsing-remitting MS with active disease defined by clinical or imaging features. This material may contain information that is outside of the approved labeling in some countries.

Presented at the 2018 Annual Meeting of the Consortium of Multiple Sclerosis Centers (CMSC), May 30–June 2, 2018, Nashville, TN, USA

Funding was provided by Sanofi