

less managed care hassles (46%). **CONCLUSIONS:** Treatment history and DMT selection drivers varied between patients with MS recently switched to different anti-CD20 agents. OFA is more likely to be used later line compared with OCR and among patients where the once-monthly subcutaneous dosing profile was influential in the switch decision. RTX, used off label for the treatment of MS, was used in place of OCR when market access was a concern.

DISCLOSURE: *Nothing to disclose.*

KEYWORDS: Disease-modifying treatments in MS

(DMT27) Adherence to Disease-Modifying Therapies in Patients With Multiple Sclerosis Across Health System Specialty Pharmacies

Abbi Blevins,¹ Evan Turco,¹ Autumn D. Zuckerman,² Aimee Banks,² Julie Wawrzyniak,³ Elizabeth Rightmier,³ Alicia Zagel,⁴ Dana Simonson,⁴ Josh DeClercq,⁵ Leena Choi⁶

¹Allied Health Solutions Specialty Pharmacy, WVU Medicine, Morgantown, WV; ²Vanderbilt Specialty Pharmacy, Vanderbilt University Medical Center, Nashville, TN; ³University of Rochester Specialty Pharmacy, UR Medicine, Rochester, NY; ⁴Fairview Specialty Pharmacy, Fairview Pharmacy Services, Minneapolis, MN; ⁵Department of Biostatistics, Vanderbilt University Medical Center, Nashville, TN

BACKGROUND: Adherence to disease-modifying therapy (DMT) for patients with multiple sclerosis (MS) can affect overall prognosis. Although DMT adherence rates have been low and variable (61%-87%), health system specialty pharmacies providing comprehensive DMT management have demonstrated higher adherence, greater than 90%, in populations using this model. Additional data are needed to evaluate the impact of the health system specialty pharmacy model on DMT adherence.

OBJECTIVES: To evaluate adherence to self-administered DMTs and factors associated with adherence among patients with MS treated in 4 health system-owned specialty pharmacies. **METHODS:** This prospective cohort study included patients diagnosed as having MS who filled 3 or more DMT prescriptions in 12 months at 1 of the 4 participating health system specialty pharmacies from January 2020 to June 2021. Patients were excluded if they became pregnant or died during the study. Deidentified pharmacy dispensing data were aggregated from each site to calculate adherence using proportion of days covered (PDC). The primary outcome was PDC, calculated as the proportion of days with medication available between the first and last fill within 12 months from the index prescription. Multiple logistic regression was used to evaluate factors associated with DMT adherence; covariates in the model included age, sex, insurance, presence of medication change, and study site. **RESULTS:** This study included 968 patients with 10528 prescription fills. Most patients were female (74%), with a median age of 51 years. Most participants were commercially insured (52%). The most common medications were glatiramer acetate (32%), fingolimod (18%), and dimethyl fumarate (18%). Patients had a median of 12 fills, and 31 patients (3%) switched DMT during the study. Overall DMT adherence was high, with a median PDC of 97% (interquartile range = 90%, 99%), and similar across all sites. Patients without a DMT switch were 3.8 times more likely to have a higher PDC than those who had at least 1 switch after adjusting for other covariates (95% CI, 2.1-6.9). **CONCLUSIONS:** This multisite prospective study affirms reports of high DMT adherence in health system specialty pharmacies. Patients who switched DMT during the study had lower adherence, indicating that these patients may require close monitoring. Further research is needed to investigate the financial and clinical outcomes tied to adherence.

DISCLOSURES: *Abbi Blevins, Aimee Banks, Elizabeth Rightmier, Alicia Zagel: Nothing to disclose. Evan Turco: Flip the Pharmacy (consulting fee). Autumn D. Zuckerman, Josh DeClercq, Leena Choi: AstraZeneca, Pfizer (research support). Julie Wawrzyniak: Alexion (focus group discussion). Dana Simonson: Pfizer (advisory board).*

KEYWORDS: Adherence, Disease-modifying treatments in MS

(DMT28) SOSTOS Study Design: Assessing Transition to Ofatumumab From Other Disease-Modifying Therapies in Relapsing-Remitting Multiple Sclerosis After Elevation of Serum Neurofilament Light Levels

Gina Mavrikis Cox,¹ Jeffrey A. Cohen,² Harald Kropshofer,³ Xiangyi Meng,¹ James Stankiewicz²

¹Novartis Pharmaceuticals Corp, East Hanover, NJ; ²Cleveland Clinic Mellen Center, Cleveland, OH;

³Novartis Pharma AG, Basel, Switzerland

BACKGROUND: Ongoing disease activity may not be clinically apparent and may remain under the threshold of detection. As such, it is possible that patients who appear stable on their current disease-modifying therapy (DMT) would benefit from

transitioning to a higher-efficacy agent. In addition, although serum neurofilament light (NFL) holds promise as a potential biomarker for disease activity, the threshold at which a patient with multiple sclerosis (MS) might benefit from a transition to a higher-efficacy DMT is currently not defined. **OBJECTIVES:** The SOSTOS study (trial registration: NCT05090371) will assess whether patients with relapsing-remitting MS (RRMS) without a relapse in the past year would benefit from a transition to ofatumumab (OMB) vs continuing their current DMT. It also seeks to address whether serum NFL levels before randomization can inform prediction of benefit from a switch. **METHODS:** SOSTOS is a randomized, open-label, prospective, active-comparator phase 4 study. It will include patients with RRMS, aged 18 to 45 years, with an Expanded Disability Status Scale score of 0 to 5.5, with no relapse within a year before randomization, and currently receiving an injectable/oral DMT for at least 6 months before screening. After screening, patients will enter a 6-month run-in period during which NFL levels will be obtained every 2 months. Patients will then be randomized (1:1) to either switch to OMB or continue their current DMT, and then will be followed for 15 months, with a 4-week safety follow-up. Proportion of patients achieving no evidence of disease activity-3 (NEDA-3) (relapse free, 3-month clinical disability progression free, magnetic resonance imaging [MRI] activity free) in months 3 to 15 will serve as the primary outcome. Key secondary objectives include achievement of NEDA-3 by baseline NFL levels, various clinical (NEDA, disability, relapse, MS functional composite-3) and conventional MRI metrics, patient-reported outcomes, brain volume loss, and safety/tolerability. Exploratory end points will include additional immunologic and biomarker assessments, digital assessment of patient biometrics, and treatment adherence/persistence. **RESULTS:** The study aims to enroll approximately 150 patients at up to 40 US and 10 Canadian centers. The first study visit is expected to occur in the first quarter of 2022, with study completion in 2025. **CONCLUSIONS:** This study will provide important information on the merit of continuing on an oral/injectable DMT vs transitioning to OMB in patients with RRMS without a relapse in the past year but with imaging/biomarker evidence of ongoing disease activity. It will also provide insights on the utility of NFL as a potential biomarker to identify patients who could clinically benefit from a switch to OMB.

DISCLOSURES: *Gina Mavrikis Cox, Harald Kropshofer, Xiangyi Meng, James Stankiewicz: Novartis (employee). Jeffrey A. Cohen: Adamas, Atara, Bristol Myers Squibb, Convelo, MedDay, Mylan (consulting fee); Multiple Sclerosis Journal (editor).*

KEYWORDS: Disease-modifying treatments in MS

(DMT29) Cladribine Tablets: Collaborative Study to Evaluate Impact on Central Nervous System Biomarkers in Multiple Sclerosis (CLOCK-MS): Current Baseline Characteristics

Gregory F. Wu,¹ Claudia Cantoni,¹ Amber Salter,² Kenneth Lee,² Olaf Stuve,² Amit Bar-Or,³ Gabriel Pardo,⁴ Ursula Boschert,⁵ Brooke Hayward,⁶ Julie Korich,⁶ Lori A. Lebson,⁶ Anne H. Cross¹

¹Department of Neurology, Washington University in St Louis, St Louis, MO; ²Department of Neurology, University of Texas Southwestern Medical Center, Dallas, TX; ³Department of Neurology, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA; ⁴Oklahoma Medical Research Foundation, Oklahoma City, OK; ⁵Ares Trading SA, Eysins, Switzerland (an affiliate of Merck KGAA, Darmstadt, Germany); ⁶EMD Serono, Rockland, MA

BACKGROUND: Increasing evidence suggests that in relapsing multiple sclerosis (RMS), early signs of neuronal degeneration are dependent on inflammatory activity in the central nervous system (CNS). Previous investigations on the effect of MS disease-modifying treatments on cerebrospinal fluid (CSF) immune biomarkers reflect different features of MS immunopathogenesis. Cladribine tablets, approved for RMS, are proposed to function as an immune reconstitution therapy with the potential to exert effects within the CNS. Questions remain regarding the effect of cladribine tablets on CSF biomarkers relevant to RMS. **OBJECTIVES:** To provide initial assessment of mechanisms of action of cladribine tablets in RMS by assessing blood and CSF levels of immune cells and soluble immunologic and neuronal injury markers. **METHODS:** CLOCK-MS is an open-label, randomized, multicenter, collaborative phase 4 biomarker research study. Approximately 50 patients aged 18 to 65 years with RMS initiating treatment with cladribine tablets per the US prescribing information will participate. Patients will undergo CSF analysis at baseline and be randomized 1:2:2:1 for a second CSF analysis at 5 weeks, 10 weeks, 1 year, or 2 years. Blood samples before and after treatment (5 weeks, 10 weeks, 1 year, or 2 years) will be examined along with features on magnetic resonance imaging. Humoral vaccine responses will be captured in a subset of participants. **RESULTS:** To date, 22 patients have been enrolled (11 men, 11 women). At study entry, mean