Conclusion Adult arachnoid cysts are majority asymptomatic benign conditions but recognition of complex or cysts in areas that are sensitive to symptoms is a useful skill to counsel and treat patients with such a condition.

2258 NOVEL GENERATION OF REAL-WORLD EVIDENCE THROUGH MSGO, A DIGITAL SUPPORT PROGRAM SUPPORTING THE USE OF SIPONIMOD IN SECONDARY PROGRESSIVE MULTIPLE SCLEROSIS PATIENTS IN AUSTRALIA

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Objectives Siponimod is approved in Australia for adults with secondary progressive multiple sclerosis (SPMS). Initiating siponimod involves prescreening tests, including a *CYP2C9* genotype test to determine siponimod dosing. To support onboarding, an integrated digital platform, 'MSGo', was developed by Novartis and RxMx® for Healthcare Professionals and multiple sclerosis patients. Here, data derived exclusively from MSGo is used to characterise onboarding of siponimod patients in Australia.

Methods The study will enrol 350–500 adults registered in MSGo for siponimod treatment. The primary endpoint is the average time for onboarding with key secondary endpoints addressing adherence and the variables that influence onboarding and adherence.

Results As of April 19th, 2021, 211 patients have enrolled in the RWE study, with baseline patient characteristics revealing more females than males (70% vs 30%) and a median age range of 51–60 years. A total of 88 patients initiated the first titration dose; 75 with ≥1 day of maintenance. Mixture-cure modelling estimated a median time to initiation of 53 days in the predicted population of patients who will ever initiate on siponimod. Patients who nominated a care partner at registration (n=27, 13%) appeared more likely to initiate siponimod earlier (p=0.017). The median time to receiving *CYP2C9* genotype results from registration was 21 days (n=163, 95% CI:18–28 days). Of these, 87 patients listed their maintenance dose, with all selections following relevant dose recommendations.

Conclusions These interim results provide insights into siponimod onboarding for SPMS patients in Australia and demonstrate the utility of MSGo during a period challenged by COVID-19.

2262 STUDY 238: INTERIM SAFETY OF ADJUNCTIVE PERAMPANEL IN PATIENTS (AGED ≥1 TO <24 MONTHS) WITH EPILEPSY: TREATMENT-EMERGENT ADVERSE EVENTS (TEAES) OF INTEREST AND SERIOUS TEAES

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Objectives Here, we present the interim safety data from Study 238 (NCT02914314), an ongoing Phase II, multicentre, open-label study of adjunctive perampanel oral suspension in patients aged ≥1 to <24 months with a diagnosis of epilepsy with any type of seizure.

Methods The Core Study comprises Pretreatment (≤2 weeks) and Treatment Phases (12–16-week Titration; 4-week Maintenance) and a Follow-up Period (4 weeks; for patients not entering the Extension). The Extension Phase comprises 32–36-week Maintenance and 4-week Follow-up Periods. Perampanel is initiated at 0.5 mg/day and titrated to a maximum of 12 mg/day (patients taking non-enzyme-inducing anti-seizure medications [EIASMs]) or 16 mg/day (patients taking EIASMs) based on clinical response and tolerability. Safety endpoints during the Core Study: incidence of TEAEs, TEAEs of interest and serious TEAEs.

Results As of December 29, 2020, 15 patients (mean [standard deviation (SD)] age, 14.7 [6.1] months) initiated perampanel treatment (mean [SD] daily dose, 5.2 [2.7] mg) in the Core Study; 12/15 patients continued into the Extension. TEAEs occurred in 15 (100.0%) patients; 11 (73.3%) patients reported treatment-related TEAEs. No TEAEs led to treatment discontinuation. Overall, 17 TEAEs of interest were reported; the most common was somnolence (n=4). Six (40.0%) patients (aged 5–23 months) reported serious TEAEs (all unrelated to perampanel); no deaths occurred and all patients recovered from their TEAEs without any dose adjustments.

Conclusions These interim data suggest perampanel is generally well tolerated in paediatric patients aged ≥1 to <24 months with epilepsy; no unexpected safety signals emerged.

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2263 LONG-TERM SAFETY OF OFATUMUMAB IN PATIENTS WITH RELAPSING MULTIPLE SCLEROSIS

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Objective To assess the long-term safety and tolerability of ofatumumab treatment in patients with relapsing multiple sclerosis (RMS).

Methods Patients completing the core ASCLEPIOS I/II, APOLITOS and APLIOS clinical trials could enter ALITHIOS, an ongoing, open-label, umbrella extension trial. Here, we analyze

the cumulative data for up to 4 years of ofatumumab treatment (data cutoff: 25-Sep-2021) in the overall (N=1969), continuous (ofatumumab in core+extension; N=1292) and newly-switched (teriflunomide core and ofatumumab extension; N=677) groups. The proportion of patients with treatment-emergent adverse events (AEs), serious AEs, serious infections including opportunistic infections, and malignancies will be assessed. Laboratory parameters including neutrophils, lymphocytes, and serum immunoglobulin (Ig) G and IgM levels will be analyzed.

Results In data reported from ALITHIOS with a cut-off of 29-Jan-2021, representing ofatumumab treatment for up to ~3.5 years, 83.8% of patients had ≥1 AEs (exposure-adjusted incidence rate [EAIR], 148.7) and 9.7% had ≥1 serious AEs (EAIR, 4.8) with a low incidence of serious infections (2.9%; EAIR, 1.4) and malignancies (0.6%; EAIR, 0.3). Updated safety data representing continuous ofatumumab treatment for up to 4 years will be presented, focusing on the incidence of serious infections including opportunistic infections, incidence of malignancies, and deaths. The long-term trend of IgG/IgM levels and their association with serious infections will also be investigated.

Conclusions Safety findings for up to 3.5 years showed ofatumumab treatment to be well-tolerated with no new safety risks identified. This additional safety data will help confirm ofatumumab's longer-term safety profile and provide further confidence to the MS community.

2264 TRACKING THE IMMUNE RESPONSE TO SARS-COV-2 MRNA VACCINES IN AN OPEN-LABEL MULTICENTER STUDY IN PARTICIPANTS WITH RELAPSING MULTIPLE SCLEROSIS TREATED WITH OFATUMUMAB S.C

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Objective This study aims at understanding the impact of ofatumumab treatment on the development of cellular and humoral immune responses to initial and booster SARS-CoV-2 mRNA vaccines.

Methods KYRIOS is an open-label, prospective, two-cohort study at eight sites in Germany including 40 MS patients who receive SARS-CoV-2 mRNA vaccination either before starting ofatumumab treatment (cohort 1) or during stable ofatumumab treatment for at least 4 weeks (cohort 2). The impact of ofatumumab treatment on the proportion of patients having established SARS-CoV-2 reactive T-cells (primary endpoint) and developing SARS-CoV-2 neutralizing antibodies (secondary endpoint) after initial and booster vaccination will be assessed. Additionally, cellular and humoral immune responses will be monitored for up to 18 months and cellular response will be further described by immunophenotyping.

Results Results of this second interim analysis show the efficacy of SARS-CoV-2 mRNA vaccines to induce cellular and humoral immune responses in MS patients depending on the timing of ofatumumab treatment initiation. First data indicate that in patients vaccinated during stable ofatumumab treatment, specific immune response is detectable as soon as 1 week after the initial vaccination cycle and further increases afterwards.

Conclusions KYRIOS data show for the first time that patients vaccinated during stable ofatumumab treatment can mount immune responses to SARS-CoV-2 mRNA vaccines. The presented data further emphasize the importance of considering both, humoral and cellular immune response, for interpretation of vaccine efficacy.

2265 LONG-TERM EFFICACY OF OFATUMUMAB IN PATIENTS WITH RELAPSING MULTIPLE SCLEROSIS

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Objective To assess long-term efficacy of ofatumumab treatment for up to 4 years in patients with relapsing multiple sclerosis (RMS).

Design/Methods This analysis (data cut-off:25-Sep-2021) will include cumulative data from patients randomized to ofatumumab/teriflunomide in the ASCLEPIOS I/II trials (core study) and the ongoing, open-label, ALITHIOS extension study. Patients will be analyzed in two groups: those randomized to ofatumumab in the core (continuous group) and those randomized to teriflunomide in the core with potential switch to ofatumumab in the extension (switch group). Annualized relapse rate (ARR), disability worsening (time-to-3-month/6-month confirmed disability worsening), disability improvement (time-to-6-month confirmed disability improvement), and brain MRI outcomes (number of Gd+T1 lesions and annualized T2 lesion rate) will be assessed.

Results Overall, 1882 patients who were randomized in the ASCLEPIOS I/II trials (ofatumumab/teriflunomide: 946/936) will be included. Baseline demographics and disease characteristics have previously been reported for the ASCLEPIOS I/II trials (mean age,~38 years; female,~68%, mean EDSS,~2.9; mean±SD of number of Gd+T1 lesions: ~1.5±3.9; mean volume of T2 lesions, ~13.2 cm^3). Previously reported data showed superiority of ofatumumab versus teriflunomide in reducing ARR, suppressing MRI lesion activity, and delaying disability worsening. In total, 690/946 patients treated with ofatumumab and 677/936 patients treated with teriflunomide entered ALITHIOS. Updated efficacy results for up to 4 years will be presented at the congress.

Conclusions These analyses will provide insights on the sustained efficacy of continuous ofatumumab treatment for up to 4 years in patients with RMS, and also on the efficacy of ofatumumab in patients newly switched from teriflunomide.