

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.

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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.

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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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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, APOLI-TOS and APLIOS clinical trials could enter ALITHIOS, an ongoing, open-label, umbrella extension trial. Here, we analyze