and IFN-OCR patients maintained their reduction in ARR through the 4-year follow-up of the OLE period.

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Long Term Effectiveness of Cladribine in Patients Enrolled in the CLARITY Trial: Real World Experience from the Lebanese Cohort

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Cladribine has been recently approved for treatment of relapsing remitting and active secondary multiple sclerosis (MS). However, long term data regarding its effectiveness beyond the trial period is still lacking.

Objective: To assess retrospectively long term effectiveness of cladribine tablets in patients with relapsing remitting MS (RRMS) enrolled in the pivotal CLARITY/CLARITY Extension trial, at the American University of Beirut MS Center-Lebanon.

Patients receiving at least one dose of cladribine were included in the final analysis. Baseline characteristics were extracted including age, gender,disease duration, EDSS, number of relapses in the previous 2 years and MRI lesions. The following outcome events were collected from the time of enrollment till the last follow-up visit at our MS center: EDSS, relapses conversion to secondary progressive MS (SPMS), new or Gd+ lesions on MRI and initiation of new DMTs.

24 patients were enrolled in the Clarity study, 2 of whom received placebo during Clarity and did not go into the extension. The average study duration was 3.6 (SD=1) years and the average follow up duration after study end was 6.2 years (SD=2.9). Overall the whole follow up was 9.8 years (SD=2). Out of 22 patients 13 started a new DMT during follow up. The annualized relapse rate (ARR) was 0.20 (95%CI=0.12-0.33) during the study and 0.20 (95%CI=0.14-0.29) during the post-study follow up. Out of 22 patients only 3 had an EDSS increase (+1.5, +1.5, +3.5) over the whole follow up period, 13 had a decrease and 6 were stable. Out of 22 patient, 2 converted to SPMS during follow up. MRI data will be reported.

This is first report assessing the long term effectiveness of cladribine tablets in a cohort of patients enrolled in the original pivotal CLARITY/CLARITY Extension trials and followed for up to 10 years. Cladribine was highly effective inpreventing long term disability progression, relapses and conversion to SPMS.

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Pregnancy Outcomes in Patients Treated with Ocrelizumab

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Ocrelizumab (OCR) is a humanised anti-CD20+ monoclonal antibody approved for the treatment of relapsing and primary progressive forms of multiple sclerosis (MS) and has also been studied in clinical trials for rheumatoid arthritis (RA) and systemic lupus erythematosus (SLE). As many patients with MS are women of reproductive age, pregnancy outcomes in OCR-exposed patients are important. B-cell levels in neonates exposed to OCR in utero have not been studied in trials, and the effect of OCR on the immune system of the newborn is unknown.

Analysis includes pregnancies in women treated with OCR in clinical trials/post-marketing sources up to 31/03/2019. In the EU, women of childbearing potential are recommended to use contraception while receiving and for 12 months after the last OCR infusion; use of two contraceptive methods until 48 weeks after the last OCR infusion/until B-cell repletion (whichever longer) was required in trials. A foetus was considered to have in utero OCR exposure if the last infusion occurred within 3 months of conception or during pregnancy or if the date was unknown.

As of 31/03/2019, a total of 362 pregnancies exposed to OCR (MS, N=267; RA or SLE, N=33; no reported indication, N=62) have been reported. Of these, 267 were MS patients (trials, N=78; post-marketing, N=189); 118 were considered to have foetal OCR exposure (N=47 with no foetal exposure; N=102 foetal exposure unknown). Preliminary outcomes of the 267 pregnancies in women with MS exposed to OCR at cut-off include 62 live births, 86 ongoing pregnancies, 25 elective abortions, 10 spontaneous abortions, 1 stillbirth, 3 ectopic pregnancies, 22 lost to follow-up and 58 unknown or not reported outcomes.

Reviewed cases to date do not suggest an increased risk of adverse pregnancy outcomes, including spontaneous abortions or malformations, with OCR treatment. The current update remains in line with previous reports. Data will continue to be collected and assessed as part of post-authorisation commitments.

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Family Planning Decision Making is Affected in People with Multiple Sclerosis

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Many people diagnosed with multiple sclerosis (MS) are of child bearing age, therefore family planning is an important concern. This survey aimed to understand family planning decision making in people with MS (pwMS).

In total, 332 pwMS were recruited from a specialist patient panel agency to participate in a smartphone-enabled standing panel, conducted across the United States (USA; n=76), United Kingdom (UK; n=51), France (n=53), Germany (n=50), Italy (n=51) and Spain (n=51). We submitted a survey consisting of 70-80 questions that focussed on decision-making and information sources in family planning, and behaviour during/after pregnancy. Male patients did not respond to specific questions on pregnancy.

Of 332 participants, 271/332 (82%) were female; 185/271 (56%; n=185) of these females were of child bearing age (18-45 years). In the 35-45 age subgroup, 77/271 (28%) were less likely to have children (40% USA, 50% UK, 45% France, 60% Germany, 30% Italy, 38% Spain) than females of the same age in the general population USA and United Nations censuses (16-19%). Overall, 116/332 (35%) participants stated that the disease altered (69/332, 21%) or made them decide against (47/332, 14%) having children; 22/332 (6%) indicated the disease delayed their plans for having children, 50/332 (15%) led to minimal impact and 144/332 (44%) indicated no impact on plans. Primary sources of information on family planning were: 1.Healthcare professionals (HCPs): neurologists (41%), obstetricians (16%), general practitioners and family physicians (15%), MS nurses (9%); 2.Search engines and online (4%); 3.Various (5%). The remaining participants