Multiple Sclerosis and Related Disorders 37 (2020) 101589

Safety of Ocrelizumab in Multiple Sclerosis: Updated Analysis in Patients with Relapsing and Primary Progressive Multiple Sclerosis

Raed Alroughani [1], Stephen L. Hauser [2], Ludwig Kappos [3], Xavier Montalban [4], Licínio Craveiro [6], Richard Hughes [6], John Mcnamara [7], Ashish Pradhan [8], David Wormser [6], Harold Koendgen [5,6,9]

[1] *Division of Neurology, Department of Medicine, Amiri Hospital, Kuwait, Kuwait*
[2] *University of California, San Francisco, San Francisco, United States*
[3] *University Hospital Basel, University of Basel, Basel, Switzerland*
[4] *Division of Neurology, University of Toronto, Toronto, Canada*
[5] *Vall d'Hebron University Hospital, Barcelona, Spain*
[6] *F. Hoffmann-La Roche Ltd, Basel, Switzerland*
[7] *John McNamara Consulting Limited, Cambridge, United Kingdom*
[8] *Genentech, Inc., South San Francisco, United States*
[9] *McGovern Medical School The University of Texas Health Science Center at Houston (UTHealth), Houston, United States*

Ongoing safety reporting is crucial to understanding the long-term benefit–risk profile of ocrelizumab (OCR) in patients with multiple sclerosis (MS). The safety and efficacy of OCR have been characterised in one Phase II study in relapsing-remitting MS (NCT00676715), two identical Phase III trials in relapsing MS (RMS; OPERA I/II [NCT01247324]/[NCT01412333]) and the Phase III trial in primary progressive MS (PPMS; ORATORIO [NCT01194570]).

Safety outcomes were reported for all patients who received OCR during the controlled treatment and associated OLE periods of the Phase II and Phase III clinical trials, plus the ongoing Phase IIIb trials VELOCE, CHORDS/CASTING, OBOE, ENSEMBLE and associated substudies (OCR all-exposure population). The number of post-marketing patients exposed to OCR is based on estimated total number of vials sold, as well as US claims data. To account for the different exposure lengths, the incidence rate per 100 patient years (PY) is presented. Adverse events (AEs) were classified according to the Medical Dictionary for Regulatory Activities.

As of July 2018, 4,501 patients with MS received OCR in clinical trials resulting in 12,559 PY of exposure. Reported rates per 100 PY in the OCR all-exposure population (95% confidence interval) were as follows: AEs, 255 (252–258); serious AEs, 7.52 (7.05–8.02); infections, 77.1 (75.5–78.6); serious infections, 2.01 (1.77–2.27); malignancies, 0.47 (0.36–0.61); and AEs leading to treatment discontinuation, 1.15 (0.97–1.35). As of April 2019, approximately 96,000 patients with MS have initiated OCR globally in the post-marketing setting and the data remain generally consistent with that observed in clinical trials. Updated OCR all-exposure population data using a January 2019 cut-off and selected post-marketing data will be presented.

The reported rates of events per 100 PY in the ocrelizumab all-exposure clinical trial population and post-marketing settings continue to be generally consistent with those seen during the controlled treatment period in the RMS and PPMS populations. The rate of AEs leading to treatment discontinuation also remained stable with additional patient exposure. Long-term safety data will continue to be reported on a regular basis.

doi: 10.1016/j.msard.2019.11.064

Multiple Sclerosis and Related Disorders 37 (2020) 101590

Preliminary Clinical Experience with Ocrelizumab, a New Recombinant Humanized Monoclonal Antibody for Multiple Sclerosis

Ameneh A. Baghestani [1], Ghadah A. Al-Sharif [1], Derk W. Krieger [2]

[1] *Mohammed Bin Rashid University of Medicine and Health Sciences (MBRU), Dubai, United Arab Emirates*
[2] *Mediclinic City Hospital, Dubai, United Arab Emirates*

Multiple Sclerosis (MS) is a disease affecting the central nervous system with disabling consequences. Several treatments have been identified for reducing the frequency of relapses, modifying disease course and even delaying disability progression. Ocrelizumab (Ocrevus, Roche) is a recently approved Disease Modifying Drug (DMD) for MS. We report our initial experience on patient profile and safety of consecutive patients with MS who have received ocrelizumab.

A retrospective study on patients with MS in a private healthcare setting, between September 2017 and 2019. Participants received an initial dose of two ocrelizumab 300mg IV infusion, followed by one 600mg every 6 months. Data was extracted from the electronic medical records and variables assessed included gender, age, disease onset, disease course, previous medications, ocrelizumab treatment duration, adherence and adverse effects. Analysis was done using the Statistical Package for Social Sciences (SPSS).

The study identified 26 patients diagnosed with MS for an average duration of 4.8 years (over 0 to 12 years) (figure 1). More than half were female patients (61.5%), with overall average age of 40 years. It was identified that 22 patients (77%) had RRMS, while five (19.2%) had PPMS (figure 2). Only two patients were lost to follow up (7.7%), with the remainder being adherent to ocrelizumab treatment for an average of 9.6 months (over 6 to 18 months) (figure 3). One hospital admission was reported from symptomatic urinary tract infection (3.8%). Furthermore, six patients (23%) were naive to treatment before the initiation of ocrelizumab, 10 (38.5%) were switched from fingolimod, with 10 (38.5%) on various other disease modifying treatments.

This study provides preliminary insight into the demographics of patients with MS in Dubai. Our results demonstrate good adherence to ocrelizumab with low complication rates.

doi: 10.1016/j.msard.2019.11.065

Multiple Sclerosis and Related Disorders 37 (2020) 101591

No Effect on Infant Birth Weight and Head Circumference After Exposure to Interferon Beta Prior to Or During Pregnancy: A Register-Based Cohort Study in Finland and Sweden Among Women with Multiple Sclerosis

Pia Vattulainen [1], Sarah Burkill [2], Yvonne Geissbuehler [3], Meritxell Sabidó [4], Catrinel Popescu [5], Kiliana Suzart-Woischnik [6], Kjell-Morten Myhr [7], Scott Montgomery [2], Pasi Korhonen [1]

[1] *StatFinn and EPID Research (an IQVIA company), Espoo, Finland*
[2] *Karolinska Institute, Stockholm, Sweden*
[3] *Novartis Pharma AG, Basel, Switzerland*
[4] *Merck KGaA, Darmstadt, Germany*
[5] *Biogen Ltd, Maidenhead, United Kingdom*
[6] *Bayer AG, Berlin, Germany*
[7] *Haukeland University Hospital, Bergen, Norway*

Women with multiple sclerosis (MS) are in most cases diagnosed and treated at childbearing age. Some studies with limited sample size suggested that MS and interferon-beta (IFNβ) exposure might affect birth weight and head circumference. Prevalence of these two measures at birth was determined in IFNβ-exposed and unexposed pregnant women with MS from health registers in Finland and Sweden.

Health register data from Finland (1996-2014) and Sweden (2005-2014) were used to study women with MS: 1)dispensed only IFNβ within 6-months prior to date of last menstrual period or during pregnancy (IFNβ-exposed) and 2)without any dispensed MS disease modifying drugs (unexposed). Prevalence (95% confidence interval