Restarting Ocrevus after a Prolonged Interruption of Therapy

This article responds to your request for information on restarting Ocrevus[®] (ocrelizumab) after a prolonged interruption of therapy.

In brief

- Roche does not have a recommendation on restarting Ocrevus after a prolonged interruption of therapy.
- No formal studies have been conducted to determine the risk of infusion-related reactions after one or more missed doses of Ocrevus.

Ocrevus dosing recommendations

First and subsequent doses

The recommended dose of Ocrevus is 600 mg every six months:1

- The first dose is administered as two separate 300 mg IV infusions two weeks apart.
 - This is to reduce the incidence of infusion-related reactions (IRRs).
- Subsequent doses are administered as a single 600 mg IV infusion every 6 months.

Please refer to the locally approved prescribing information for further information on Ocrevus.

Roche is unable to provide treatment recommendations for individual patients. Any decision on administering Ocrevus after a prolonged interruption of therapy will be a clinical decision, taking into consideration individual risk-benefit. Appropriate clinical caution and monitoring is recommended.

The impact of missed doses of Ocrevus in clinical trials

Patients who miss one or more doses of Ocrevus may have a higher risk of IRRs due to B cell repletion. However, based on limited data from the pivotal studies in multiple sclerosis, there is no evidence that after one or more missed Ocrevus doses:^{2,3}

- The administration of Ocrevus as a single 600 mg infusion will increase the risk of an IRR, nor
- The re-initiation of Ocrevus treatment with two separate 300 mg infusions will mitigate the potentially higher risk of an IRR.

References

1. Roche Internal Regulatory Report.

2. Hauser S, Bar-Or A, Comi G, et al. Ocrelizumab versus Interferon Beta-1a in Relapsing Multiple Sclerosis. N Engl J Med 2017;376:221-234. <u>https://www.ncbi.nlm.nih.gov/pubmed/28002679</u>

3. Montalban X, Hauser S, Kappos L, et al. Ocrelizumab versus Placebo in Primary Progressive Multiple Sclerosis. N Engl J Med 2017;376:209-220. <u>https://www.ncbi.nlm.nih.gov/pubmed/28002688</u>