

Ocrevus in Patients with a History of Malignancy

This article responds to your request for information on the use of Ocrevus® (ocrelizumab) in patients with a history of malignancy.

Roche is unable to provide treatment recommendations for individual patients. Any decision to use Ocrevus in patients with a history of malignancy will be a clinical decision, taking into consideration individual risk-benefit. Appropriate clinical caution and monitoring is recommended.

In brief

- Limited data are available on the use of Ocrevus in patients with a history of malignancy.
 - In the pivotal clinical trials of Ocrevus, patients with a history of malignancy were excluded.
 - In the ongoing ACAPELLA study, none of the patients with a history of malignancy had recurrence of their cancer.
- Individual benefit risk should be considered in patients with known risk factors for malignancies and in patients who are being actively monitored for recurrence of malignancy.

Exclusion of patients with a history of malignancy in Ocrevus pivotal trials

In the pivotal clinical trials of Ocrevus in patients with multiple sclerosis (OPERA I and II and ORATORIO), patients with a history of malignancy were excluded.^{1,2} The exclusion criteria included a history of malignancy, including solid tumors and hematological malignancies, with the exception of the following carcinomas, if they had been previously completely excised with documented, clear margins^{1,2}

- basal cell carcinoma,
- in situ squamous cell carcinoma of the skin, and
- in situ carcinoma of the cervix of the uterus.

Inclusion of patients with a history of malignancy in the ACAPELLA study

Geils et al. are conducting an observational study evaluating the frequency of adverse events in a real-world MS population treated with Ocrevus.³ The study includes patients who would have fallen outside the criteria for the pivotal phase III studies, including those with a history of malignancy. All subjects will be followed for 5 years.

At the time of the report of the three year data, 21 of 306 enrolled patients had a history of malignancy. The types of malignancies are reported in Table 1.³ None of the patients had a recurrence of their cancer as of the report.³

Table 1. Types of historical malignancies in patients in ACAPELLA³

Type of malignancy	Number of patients
Breast cancer	9

Thyroid cancer	3
non-Hodgkins lymphoma	2
Prostate cancer	2
Squamous cell carcinoma	5

Ocrevus prescribing considerations

In the clinical trials of Ocrevus, the incidence of malignancies was within the background rate expected for an MS population. Individual benefit risk should be considered in patients with known risk factors for malignancies and in patients who are being actively monitored for recurrence of malignancy.⁴

References

1. 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. <https://www.ncbi.nlm.nih.gov/pubmed/28002679>
2. Montalban X, Hauser S, Kappos L, et al. Ocrelizumab versus Placebo in Primary Progressive Multiple Sclerosis. N Engl J Med 2017;376:209-220. <https://www.ncbi.nlm.nih.gov/pubmed/28002688>
3. Geils H, Stribling I, Katz J, et al. ACAPELLA Real-World Experience with Ocrelizumab, Year Three Data. Presented at the e Joint Americas and European Committee for Treatment & Research in Multiple Sclerosis in virtual; September 11-13, 2020. ACTRIMS-ECTRIMS Poster.
4. Roche Internal Regulatory Report (Accessed on 8 August 2023).