CONCLUSIONS

- Post-marketing experience: more than 114,000 patients
- Interval between OCR therapy
- The observed number of carry-over PML cases in patients switching from natalizumab to ocrelizumab is low
- Clinical trials: more than 6,000 patients
- Five unconfirmed carry-over cases reported as PML, or suspicion of PML, that do not meet

RESULTS
- Post-marketing exposure estimations in the USA were based on Symphony Health claims and
- Cases of PML in patients with MS have been associated with other disease-modifying therapies (DMTs), e.g. fingolimod and dimethyl fumarate
- PML cases were also reported with anti-CD20 therapies in a variety of different disease areas and/or
- The purpose of these analyses was to describe cases reported as PML in OCR-treated patients with MS
- Post-marketing experience estimations were performed at the Neurology and Sclerosis
- Cases of PML, in all cases was within 6 months of last dose of previous natalizumab
- One patient had previously received fingolimod (treatment duration: 41 months) and was anti-JCV antibody-negative prior to the diagnosis of PML
- The time between the initiation of OCR therapy and the definite diagnosis of PML
- All patients had new and/or worsening clinical symptoms and/or MRI findings compatible with PML
- Unconfirmed Reports of PML
- Five reports suggestive of carry-over PML, but not fully meeting AAN diagnostic criteria
- Five cases had MRI findings compatible with PML: one patient also had clinical symptoms and one patient also had detection of JCV DNA in the cerebrospinal fluid
- All patients were in patients previously treated with natalizumab and already at higher risk for a relapse-associated PML
- One report was an unconfirmed consumer report of a potential PML; permission for follow-up was not given by the reporter and further assessment is not possible
- Five patients had previously received treatment with natalizumab (treatment duration, 22-26 months) and all lacked positive for serum anti-JCV virus antibodies (viral titer, range 1:20-1:40) prior to the diagnosis of PML
- The time between initiation of OCR therapy and a definite diagnosis of PML, 16-20 days
- Onset of PML in all cases was within 6 months of last dose of previous natalizumab
- One patient had previously received fingolimod (treatment duration: 41 months) and was anti-JCV antibody-negative prior to the diagnosis of PML
- The time between the initiation of OCR therapy and the definitive diagnosis of PML,
- All patients had new and/or worsening clinical symptoms and/or MRI findings compatible with PML prior to receiving OCR

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REFERENCES

DISCLOSURES

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