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Preliminary Results of the OPERA I and OPERA II Open-Label Extension Study

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Background: The efficacy and safety of ocrelizumab in relapsing multiple sclerosis (RMS) have been demonstrated in the OPERA trials. Upon completion of the controlled treatment period, all patients were eligible to enter an ocrelizumab open-label exten-sion (OLE) phase. The objective is to preliminarily assess annual-ized relapse rate (ARR) at 144 weeks among patients with RMS who received ocrelizumab or interferon beta-1a (IFNß-1a) in the Phase III 96-week OPERA I and II trials, followed by ocrelizumab in an OLE.

Methods: During the controlled treatment period, patients received intravenous ocrelizumab 600 mg every 24 weeks or sub-cutaneous IFNß-1a 44 µg three times weekly for 96 weeks. During the OLE, patients from the IFNß-1a group were switched to ocrelizumab.

Results: Patients from OPERA I (ocrelizumab, 352/410; IFNß-1a, 326/411) and OPERA II (ocrelizumab, 350/417; IFNß-1a, 297/418) enrolled in the OLE. At the time of analysis, 317 (90.1%) and 322 (92.0%) continuous ocrelizumab patients and 307 (94.2%) and 268 (90.2%) patients switching from IFNß-1a in OPERA I and II, respectively, had =48 weeks of follow-up in the OLE (144 weeks total). Across groups, patients received a median of two doses of ocrelizumab in the OLE. Among patients switching from IFNß-1a to ocrelizumab, the unadjusted ARR improved from 0.245 and 0.254 over 96 weeks in OPERA I and II, respectively, to 0.092 and 0.115 in the OLE. Among continuous ocrelizumab patients, the unadjusted ARR was 0.136 and 0.138 in OPERA I and II, respec-tively; during the OLE, the ARR in this group was 0.118 and 0.100, respectively. Imaging metrics will be presented.

Conclusion: Patients who originally received ocrelizumab in the OPERA studies continued to have favorable ARR outcomes in the OLE. Patients who switched from IFNß-1a to ocrelizumab in the OLE rapidly experienced ARR outcomes consistent with those of patients who received continuous ocrelizumab.