Here we provide updated pregnancy outcomes in alemtuzumab-treated female patients in phase 2 (CAMMS223 [NCT00050778]) and phase 3 (CARE-MS I [NCT00530348], CARE-MS II [NCT00548405]) studies. Patients received annual treatment courses of alemtuzumab and could enter an extension study (NCT00930553), with as-needed alemtuzumab retreatment (≥1 year apart). Pregnant/lactating patients were treatment-ineligible but remained on study for safety follow-up. As of July 1, 2015, 193 pregnancies occurred in 136 of 972 alemtuzumab-treated female patients; 167 were completed, 16 were ongoing, and 10 had unknown outcomes. Of completed pregnancies, 110 (66%) were live births with no congenital abnormalities or birth defects among 94 patients (at conception: mean age, 31.5 years; mean EDSS, 1.7; mean time since initial MS relapse, 6.6 years; mean time since last MS relapse, 3.5 years; mean time from previous alemtuzumab infusion, 27.9 months). There were 37 (22%) spontaneous abortions, 19 (11%) elective abortions, and 1 (0.6%) previously reported stillbirth. In alemtuzumab MS clinical studies, the most common pregnancy outcome was full-term live birth, with no evidence of teratogenicity to date. The rate of spontaneous abortion with alemtuzumab was comparable with rates observed in other MS patients and general populations. Ongoing surveillance is needed.

Study supported by Sanofi Genzyme and Bayer Healthcare Pharmaceuticals.
PREGNANCY OUTCOMES IN ALEMTUZUMAB-TREATED PATIENTS WITH RRMS

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J Neurol Neurosurg Psychiatry 2016 87: e1
doi: 10.1136/jnnp-2016-315106.155

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