(W15) EVALUATING THE LONG-TERM SAFETY OF CLADRIBINE TABLETS IN PREMIERE, AN EIGHT-YEAR SAFETY REGISTRY

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Background: Cladribine is an oral immunomodulator that offers targeted, sustained effects on T and B lymphocytes as an annual short-course oral dosing regimen. In the phase 3, 96-week CLARITY study, cladribine tablets demonstrated treatment benefits compared with placebo in a cohort of patients with relapsing-remitting multiple sclerosis (RRMS). Objectives: The PREMIERE registry (Prospective observational long-term safety registry of multiple sclerosis patients who have participated in cladribine clinical trials) has been established as an active surveillance system to collect long-term safety information in those patients who have participated in cladribine tablets clinical trials. Methods: This is a subject registry with an observational cohort design. All subjects previously enrolled in selected phase 1 to 3 clinical trials with cladribine tablets (including patients randomized to placebo) are eligible for enrollment. The duration of follow-up will be 8 years (including years in the clinical trial) or up to the end of the registry (preliminary estimate is mid-2018), whichever occurs first. Primary end points include the cumulative incidence of selected infections, malignancies, and deaths; dynamics of treatment-induced lymphocyte reduction; and frequency of pregnancies and pregnancy outcomes occurring among female subjects exposed to cladribine, as well as among female partners of male subjects. During the first 2 years, each subject will be interviewed every 3 months, and thereafter the contacts will occur every 6 months until the end of follow-up. This information was also presented at the Congress of the European Committee for Treatment and Research in Multiple Sclerosis in 2009. Results: Approximately 2000 subjects enrolled in the cladribine tablets clinical development program will be available for enrollment in the registry. It is estimated that 75% of these subjects, enrolled at 377 sites, will participate in the PREMIERE registry. Enrollment of patients started in November 2009. Conclusions: The PREMIERE registry will provide long-term active safety surveillance in subjects formerly enrolled in cladribine tablets clinical trials in MS to build on existing knowledge about the safety profile of cladribine tablets and support long-term risk-benefit evaluation.

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