Why carry out this study?

- Delayed-release dimethyl fumarate (DMF; also known as gastro-resistant DMF), an oral agent for the treatment of relapsing forms of multiple sclerosis (MS), demonstrated robust efficacy and an acceptable safety profile in clinical trials.
- No formal studies of DMF were conducted in pregnant women, although pregnancies have occurred during clinical trials (63 pregnancies total as of June 30, 2014, including 42 pregnancies in subjects receiving DMF) and in the postmarketing setting (135 pregnancies as of June 30, 2014).

What was learned from the study?

- Animal studies showed no evidence of impaired fertility or teratogenicity with DMF.
- Outcomes are known for 39 of 42 pregnancies in subjects receiving DMF in clinical trials (26 live births [67%], three spontaneous abortions [8%], and 10 elective terminations [26%]) and for 30 of 135 pregnancies in the postmarketing setting (including 10 live births, 13 spontaneous abortions, and five elective terminations).
- Although data are limited and all known exposures have occurred in the first trimester, no increased risk of fetal abnormalities or adverse pregnancy outcomes associated with gestational exposure to DMF has been observed.

This summary slide represents the opinions of the authors. Sponsorship for this study was funded by Biogen, Inc. Karyn M. Myers, PhD, of Biogen and Michelle McDermott, PharmD, provided writing support based on input from authors. For a full list of acknowledgments and disclosures for all authors of this article, please see the full text online.