**Avonex® Pregnancy Registry** The Avonex® Pregnancy Registry is an FDA mandated program to monitor pregnancy exposures to Avonex® (Interferon Beta-1a). It is a voluntary, prospective exposure-registration and follow-up study designed to collect data on pregnancies exposed to Avonex® around the time of conception or during the first trimester of pregnancy. The primary objective of the Registry is to assess the potential risk of birth defects, and secondarily to detect any potential increase in the risk of spontaneous fetal loss.

## Why is the Registry important?

Avonex® is a recombinant human interferon beta product indicated for the treatment of patients with relapsing forms of multiple sclerosis. Because women of childbearing potential comprise a considerable segment of the patient population affected by MS, it is likely that women may be exposed to Avonex® around conception and during pregnancy. Interferon beta exhibited abortifacient activity in reproduction studies in female rhesus monkeys. Therefore, Avonex® has been given an FDA Pregnancy Category C, indicating animal studies have shown an adverse effect in the fetus. However, adequate studies in humans have not been conducted. If a woman becomes pregnant or plans to become pregnant while taking interferon beta-1a, she should be informed of the potential hazards to the fetus, and she should discontinue therapy.

This Registry was expressly established to evaluate exposures to Avonex® around conception and during the first trimester of pregnancy. Registry data may supplement other sources of data and assist clinicians and patients in weighing the risks of Avonex® exposure around conception and during the first trimester of pregnancy when compared with the general population. The lack of data on human pregnancy exposures to Avonex® makes such a Registry an essential component of the ongoing program of epidemiologic studies on the safety of this product.

## How are data collected by the Registry?

The Registry collects prospective reports (before outcome of pregnancy is known) of pre- and first trimester pregnancy exposures to Avonex® from pregnant patients. After the initial enrollment, data are collected from the patient once during her pregnancy and again a few weeks after delivery. The patient-provided information is forwarded to the patient's obstetrician for verification and supplementation. Further follow-up is conducted at 2 months after a live birth through the pediatric health care provider. The data collected are minimal and targeted.

## How are data analyzed and reported?

The Registry is overseen by a Scientific Advisory Board comprised of specialists in obstetrics, neurology, teratology, epidemiology, and biostatistics. The Scientific Advisory Board meets periodically to evaluate the data, develop an aggregate summary of the findings, and assist in disseminating Registry information. Registry reports will be published after 150 and 300 prospective pregnancies of exposures have been collected and analyzed.

## How does the Registry benefit me and my patients?

This Registry is the primary source for collecting and evaluating exposures to Avonex® around conception and during the first trimester of pregnancy and to compare these exposed pregnancies to the general population. This collaborative program enables you and your colleagues to obtain essential information on the safety of Avonex® in pregnancy. You can contribute to the Registry by making patients and your colleagues aware of the Registry and encouraging them to participate.

**The success of the Registry depends on health care providers, like you and your colleagues, to refer patients who have been exposed to Avonex® around conception and during the first trimester of pregnancy to the Registry.**

**How can I get more information? Write, call, or fax:**

Biogen Idec Pregnancy Registries
Research Park; 1011 Ashes Drive; Wilmington, North Carolina 28405
**US (800) 811-0104 (Toll-free phone) (800) 800-1052 (Toll-free fax)**

Please refer to the enclosed package insert for full prescribing information on Avonex®