Who can participate in the Study?

Women who have taken TEGSEDI® (inotersen) during pregnancy or have taken TEGSEDI within 25 weeks of becoming pregnant;

OR

Women with the **polyneuropathy of hereditary transthyretin amyloidosis** (hATTR-PN) and are pregnant.

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Please notify your HCP if you become pregnant or plan to become pregnant while taking TEGSEDI.

To speak to a study representative, contact THE TEGSEDI-PRG PREGNANCY OBSERVATIONAL STUDY toll-free at:
1-877-465-7510.

For more information visit:
www.tegsedipregnancystudy.com

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THE TEGSEDI-PRG PREGNANCY OBSERVATIONAL STUDY

TEGSEDI-PRG
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Patient Information Pamphlet

What is the TEGSEDI-PRG Pregnancy Observational Study?

Akcea Therapeutics, Inc., the manufacturer of TEGSEDI® (inotersen), is conducting a study to monitor and collect information about the outcomes of women who have taken TEGSEDI while pregnant. In addition, pregnant women with hATTR-PN who have not taken TEGSEDI are encouraged to join so that more information could be collected that could help women in the future and their doctors make more informed decisions. Pregnant women are typically excluded from clinical studies when new medicines are being tested so the effects of those new medicines on the health of a baby are often not known. Information obtained from this study may help doctors and future pregnant women understand how their pregnancies and babies may or may not be affected by TEGSEDI.

This is an observational study which means your treatment or care will not change in any way as a result of your participation in this study. You will continue to receive care as decided by your doctor.

Why should I participate in this Study?

Your participation is voluntary but will provide important information that may eventually be used by healthcare providers and future patients when weighing the benefits and/or risks of taking TEGSEDI during pregnancy. The success of the study is dependent upon the participation of eligible patients and healthcare providers. There will be no change to the care you receive by your doctor, as this is an observational study.

How do I enroll?

To learn more about the TEGSEDI-PRG Pregnancy Observational Study and to find out if you qualify for enrollment, contact a study representative at 1-877-465-7510. You may also ask your healthcare provider to enroll you.

If you are eligible and would like to participate, you will be asked to provide verbal informed consent to acknowledge your understanding of the study and to provide your permission for your personal and your infant's healthcare information to be collected. After consent is received, a study representative will contact your healthcare provider to confirm your personal health information.

What will my participation involve once I am enrolled?

Your participation in the study may last throughout your pregnancy and up to one year after your delivery date. You will be contacted once per trimester, at the estimated date of delivery, and when your baby is 3, 6, 9 and 12 months of age to provide basic information about your pregnancy or your infant's health. At each time point, you will be asked to confirm your contact information.

Will my privacy be protected?

All personal and medical information will be kept strictly confidential. Information about your health while you are enrolled in the TEGSEDI-PRG Pregnancy Observational Study will be kept anonymous and any identifying information will not be used.

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