Early Data Suggest Adalimumab Safe in Pregnancy

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BERLIN — Treatment of pregnant women with the biologic immunomodulator adalimumab did not appear to adversely affect the fetuses or pregnancies in preliminary data from a prospective study that currently includes 23 exposed pregnancies.

"The findings do not suggest an increased risk for adverse pregnancy outcomes with exposure to adalimumab early in pregnancy," although additional data from more pregnancies exposed to the drug are needed, Diana L. Johnson said at the 14th United European Gastroenterology Week.

Adalimumab (Humira) is a fully human antibody to tumor necrosis factor (TNF)–α, which gives it a mechanism of action that's similar to other biologic TNF-α inhibitors including etanercept (Enbrel), infliximab (Remicade), and certolizumab (Cimzia). To date, there is no evidence that the use of these drugs during pregnancy leads to malformations, spontaneous abortions, or prematurity, said Ms. Johnson, a toxicologist and study manager at the University of California, San Diego.

However, only limited data are available so far for all of these exposures.

The analysis of data from women who were treated with adalimumab during pregnancy comes from a larger study of autoimmune diseases in pregnancy that has been developed by the Organization of Teratology Information Specialists (OTIS).

The OTIS group is a network of university-based pregnancy-risk counseling services in North America.

The centerpiece of the autoimmune disease study is a prospective cohort study of women with rheumatoid arthritis who are being treated with an anti-TNF drug.

In addition, pregnant women who have similar drug exposures for other autoimmune diseases, such as psoriatic arthritis, ankylosing spondylitis, psoriasis, or Crohn's disease, are enrolled in a registry.

Women with severe Crohn's disease who are on a successful anti-TNF regimen are usually advised to continue their medication if they become pregnant.

The OTIS study so far has data on the birth outcomes of 23 women who were treated with adalimumab early in pregnancy. Twelve of the women are in the prospective cohort, and 11 are in the registry.

These women have had a total of 21 live births and two spontaneous abortions, reported Ms. Johnson at the meeting, which was sponsored by the United European Gastroenterology Federation.

Twenty of the deliveries were term, and the single premature birth involved an infant with congenital hip dysplasia.

Women who are diagnosed with severe Crohn's disease and are on a successful anti-TNF regimen are usually advised to continue their medication if they become pregnant, although the pros and cons of ongoing treatment are discussed with them, commented Dr. Pia Munkholm, a gastroenterologist at Herlev Hospital in Copenhagen.

"There is an incentive to keep these patients in remission," she said.

OTIS receives funding from eight pharmaceutical companies, as well as from other organizations. ■