Fully 75 percent of Americans with autoimmune diseases are women, according to the American Autoimmune Related Diseases Association, Inc., and many of these women are of child-bearing age. Autoimmune conditions may improve, stay the same, or worsen during pregnancy. Psoriasis, for example, flares in about one third of women during pregnancy.

Active inflammatory disease during pregnancy can have serious consequences for both mother and baby, so extreme caution must be exercised when prescribing medication to pregnant women.

Cimzia (Certolizumab pegol) is FDA-approved for psoriasis, psoriatic arthritis, rheumatoid arthritis (RA), Crohn’s disease, and ankylosing spondylitis. Cimzia is an Fc-free, PEGylated to the Fab portion monoclonal antibody that binds tumor necrosis factor. Because there is no Fc component, Cimzia does not bind the neonatal Fc receptor (FcRn) for immunoglobulin G (IgG) and is not expected to undergo FcRn-mediated transfer across the placenta.

**HOW WELL DOES CIMZIA WORK?**

Cimzia’s FDA-approved dose for psoriasis for patients who weigh more than 90kg is 400mg at week 0, 2, and 4. For those weighing less than 90kg or for the patient who is pregnant or lactating, the dose is cut to 200mg every other week.

In a study designed to assess the safety and efficacy of Cimzia in adults with moderate to severe chronic plaque psoriasis, Lebwohl et al. report that at week 16, Psoriasis Area and Severity Index (PASI) 75 and PASI 90 response were 75 percent and 50 percent, respectively. Maintenance of PASI 75 response was 98 percent through week 48.

During the first 12 weeks of the trial, there were no malignancies, herpes zoster activations, cases of tuberculosis, or deaths in the Cimzia cohort. One cutaneous *Candida* infection and one serious infection (pneumonia) occurred during the study period. This tells us that Cimzia’s safety and efficacy are comparable to, if not better than that for Humira (adalimumab), Stelara (ustekinumab), and Enbrel (etanercept).

**CIMZIA IN PREGNANCY: WEIGHING THE EVIDENCE**

This brings us to the data regarding Cimzia’s safety during pregnancy and lactation, and there is a growing body of reassuring data suggesting that it is safe for mother and baby. The FDA approved a label update that includes pharmacokinetic data showing negligible to low transfer of Cimzia through placenta and minimal transfer to breast milk from mother to infant.

Current studies via the Organization of Teratology Specialists suggest that therapeutic monoclonal antibodies do not increase clinical risk of congenital anomalies during conception or early pregnancy. However, placental transfer of drug can occur during the third trimester. Therefore, weighing the data on Cimzia during pregnancy and lactation.

**TAKE-HOME POINTS**

75 percent of Americans with autoimmune diseases are women; many in their child-bearing years.

Psoriasis flares in about one third of women during pregnancy.

Cimzia is as safe and efficacious as other biologics approved to treat psoriasis.

The amount of Cimzia that transfuses through the placenta is less than one percent of the other biologics and less than controls.

Cimzia ingestion by suckling is minimal, and Cimzia treatment is compatible with breastfeeding.

Cimzia appears safe during pregnancy and lactation – including the third trimester.

The recommended Cimzia dose for pregnant and lactating women is 200mg every other week.
"The concept of adding ‘anti-immunoglobulins’ theoretically may interfere in the development of the immune system, especially during the third trimester and lactation. Hence, it would seem prudent to utilize a therapy that does not pass the placenta or get passed via lactation.”

The immune system of the neonate is immature. It depends on innate immunity as well as factors such as IgGs received through lactation. The concept of adding “anti-immunoglobulins” theoretically may interfere in the development of the immune system, especially during the third trimester and lactation. Hence, it would seem prudent to utilize a therapy that does not pass the placenta or get passed via lactation. Cimzia seems to have an advantage over other biologics in these areas.

A NEW ERA?

Until now, avoidance of biologics during the third trimester and lactation seemed prudent, but the Cimzia data tells us that we may have entered a new era and can now control psoriasis in the pregnant and lactating female without fear of harming the neonate.

Jerry Bagel, MD, MS is Director of the Psoriasis Treatment Center of Central New Jersey. He recently received the Excellence in Leadership Award from the National Psoriasis Foundation (NPF).