Golimumab May Reverse Joint Damage in PsA

**Major Finding:** Structural improvement continued through 52 weeks with golimumab, independent of methotrexate.

**Source of Data:** The GO-REVEAL study enrolled 405 patients at 58 sites in the United States, Canada, and Europe.

**Disclosures:** Centocor Ortho Biotech Products LP, the company that developed golimumab (Simponi), sponsored the study. Dr. Kavanaugh said that he and five of his associates on the study were research investigators for Centocor. Another five study associates are Centocor employees.

**Brief Summary of Full Prescribing Information**

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**PHARMACOLOGY**

Golimumab is a human monoclonal antibody directed against TNF-α. TNF-α is a cytokine that plays a key role in the pathogenesis of inflammatory diseases. The mechanism of action of golimumab is not fully understood, but it is thought to be primarily responsible for the inhibition of TNF-α activity, which is involved in the inflammation and destruction of articular tissues in psoriatic arthritis.

**CONTRAINDICATIONS**

Use of TNF-α inhibitors, including golimumab, is contraindicated in patients with tuberculosis or other active infections. Patients with active infections should not start treatment with golimumab until the infection is controlled and the patient is clinically stable.

**WARNINGS**

**Immunogenicity effects:** If a patient develops anti-drug antibodies, the drug should be discontinued and another anti-TNF agent should be considered. There have been reports of rare cases of hypersensitivity reactions, including anaphylaxis, in patients treated with golimumab. These reactions should be managed with appropriate medical interventions, including the use of epinephrine, and be closely monitored.

**Pregnancy:** Use of golimumab during pregnancy is not recommended. Women of childbearing potential should be advised to avoid becoming pregnant during treatment. If a pregnancy occurs during treatment, golimumab should be discontinued and replaced with another anti-TNF agent.

**Lactation:** It is unknown if golimumab is excreted in human milk. Women who are breastfeeding should be advised to avoid breastfeeding during treatment with golimumab.

**ADVERSE REACTIONS**

The most common adverse reactions reported in clinical trials were upper respiratory infections, nasopharyngitis, nasopharyngitis, and nasopharyngitis.

**Adverse Events in Clinical Trials:** The most common adverse events reported in patients treated with golimumab were nasopharyngitis, upper respiratory tract infection, and nasopharyngitis. These events were generally mild to moderate in severity and were not considered to be drug-related.

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**6 NEWS**

**JANUARY 2010**

*SKIN & ALLERGY NEWS*

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