Important Safety Information for Gastroenterologists and Hepatologists About Potential Risks of Gastrointestinal Perforation and Transaminase Elevations With ACTEMRA®

ACTEMRA® (tocilizumab) is an interleukin-6 (IL-6) receptor antagonist that has been approved by the Food and Drug Administration (FDA) for three indications:

- Adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response to one or more Disease-Modifying Anti-Rheumatic Drugs (DMARDs) with a recommended ACTEMRA dosing interval of every 4 weeks for intravenous (IV) or every other week or weekly for subcutaneous (SC) administration.

- Children 2 years of age and older with active Polyarticular Juvenile Idiopathic Arthritis (PJIA) with a recommended ACTEMRA dosing interval of every 4 weeks for IV administration.

- Children 2 years of age and older with active Systemic Juvenile Idiopathic Arthritis (SJIA) with a recommended ACTEMRA dosing interval of every 2 weeks for IV administration.

The safety and efficacy of ACTEMRA for conditions other than RA, PJIA and SJIA have not yet been established.

Gastroenterologists and hepatologists should be aware of important safety information regarding ACTEMRA.

Gastrointestinal perforations: Gastrointestinal (GI) perforations have been reported in Phase 3 clinical trials, primarily as complications of diverticulitis, including generalized purulent peritonitis, lower GI perforation, fistula and abscess. Most patients who developed GI perforations were taking concomitant nonsteroidal anti-inflammatory medications (NSAIDs), corticosteroids or methotrexate. ACTEMRA should be used with caution in patients who may be at increased risk for GI perforation. Patients presenting with new-onset abdominal symptoms should be evaluated promptly for early identification of GI perforation.

Transaminase elevations: Treatment with ACTEMRA was associated with a higher incidence of transaminase elevations (ALT, AST) in Phase 3 clinical trials. These elevations did not result in apparent permanent or clinically evident hepatic injury with modification of the treatment regimen, which resulted in a decrease or normalization of liver enzymes. Monitor patients receiving ACTEMRA for elevated transaminase levels; dose modifications may be necessary. When clinically indicated, consider other liver function tests, such as bilirubin.

Please see the Prescribing Information for more information.
Reporting Adverse Events

It is important that you report any serious gastrointestinal adverse events, including GI perforation, hepatic disease or hepatic impairment, that occur in a patient being treated with ACTEMRA, even if you do not think there is a causal relationship. The information that you, as a gastroenterologist or hepatologist, provide about these events may inform therapy and monitoring decisions for future patients.

Reporting maintains patient confidentiality. Your patient’s name or contact information is not needed. HIPAA does not apply to this adverse event reporting. You can report your cases to Genentech or directly to the FDA:

- Genentech at 1-888-835-2555
- MedWatch (FDA safety information and adverse event reporting program) at 1-800-332-1088 or online at www.fda.gov/medwatch/report.htm

Please visit www.ACTEMRA.com for Prescribing Information and Medication Guide.