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Press Release

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Eisai Co., Ltd.

AbbVie and Eisai Clear All-Case Surveillance Condition for Approval of HUMIRA®, a Fully Human Anti-TNF-α Monoclonal Antibody, in the Treatment of Ankylosing Spondylitis

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[Notes to editors]

1. Results of the special drug use-results survey*

The report submitted to the MHLW includes the results of analysis of the data obtained from 127 patients who were evaluated during the period between October 27, 2010 and March 15, 2013.
Adverse drug reactions developed in 27.6% of patients (35 of 127). The most common adverse drug reactions were “rash,” “gastroenteritis,” “nasopharyngitis,” and “abnormal hepatic function.” Serious adverse drug reactions developed in 3.9% of patients (5 of 127) including “dermatofibrosarcoma,” “anaphylactic shock,” “gastric ulcer perforation,” “hemorrhoids,” and “lupus-like syndrome” in 1 patient each. The outcome was “recovered/resolved” or “recovering/resolving” in all patients.
The efficacy of HUMIRA® in the treatment of ankylosing spondylitis was evaluated by the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) and global improvement. In patients who were evaluated with BASDAI at baseline and Week 24 of treatment, the BASDAI50 response rate (the proportion of patients achieving ≥50% improvement in BASDAI from baseline) was 50.0% (25 of 50) at Week 24. At Week 24, the global improvement as subjectively assessed by the physician was complete response in 38.8% (38 of 98). Responders and complete responders together accounted for 91.8% (90 of 98). This survey demonstrated that HUMIRA® improved symptoms in patients with ankylosing spondylitis who had an inadequate response to conventional therapy.

* Special drug use-results survey is a type of drug use-results survey. Please refer to 5) under Glossary of Terms.

2. Glossary of Terms

1) Ankylosing spondylitis

Ankylosing spondylitis (AS) is a chronic systemic inflammatory disease that manifests first as joint pain and stiffness in the neck, lower back, and hips, and in some cases the hands and feet, followed by fusion and rigidity of affected joints over time. This is nationally designated as an intractable disease. In rare cases, patients may develop severe AS with bony ankylosis or deformation of the spine and other joints. AS typically develops in young individuals, most often men, in their teens and twenties,

2) TNFα

3. About HUMIRA®

HUMIRA® is a fully human anti-TNF-α monoclonal antibody, and has already been approved for the following indications in Japan: “treatment of rheumatoid arthritis (including prevention of structural joint damage) and the following diseases that do not sufficiently respond to the existing treatments: psoriasis vulgaris; arthropathic psoriasis; ankylosing spondylitis; juvenile idiopathic arthritis affecting multiple joints; intestinal Behçet’s disease; moderate to severe active Crohn’s disease as remission induction and maintenance therapy; and moderate to severe ulcerative