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Press Release

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< Notes to editors >

1. About Humira® pre-filled syringe 40 mg/0.8 mL for subcutaneous injection (Underlined information indicates newly approved indications/dosage and administration)

1) Indications

Humira[®] is indicated for:

Treatment of the following diseases in patients who have had an inadequate response to conventional therapy:

Rheumatoid arthritis

Plaque psoriasis, psoriatic arthritis

Ankylosing spondylitis

Induction and maintenance of clinical remission in patients with moderately to severely active Crohn's disease (only in patients who have had an inadequate response to conventional therapy)

2) Dosage and Administration Rheumatoid Arthritis

Crohn's disease is more prevalent among males, with a male/female ratio of 2:1, and a peak age of onset of late teens to early twenties. Crohn's disease is characterized by intestinal stenosis, ileus, intestinal abscesses (collections of pus resulting from infection) and perianal fistulas (ulcers in the intestine that form tunnels to surrounding intestinal wall or skin). When signs and symptoms cannot be controlled with nutrition or drug therapy, patients may require surgical treatment. Since patients with Crohn's disease often experience periods of both flare-ups and remission, long-term treatment is required to prevent recrudescence (recurrence of gastrointestinal inflammation) and recurrence (occurrence of inflammation in a new region) even after achieving remission.

2) 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. 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, and progresses slowly over several decades. Although the cause of AS is unknown, it is believed that genetic factors play an important role in the etiology of the disease. The prevalence of AS differs among ethnic groups, and is lower in Japanese (0.0065%) than Caucasians (0.9%).