News Release

Astellas Pharma Inc.: Submits Supplemental New Drug Application for the Selective COX-2 Inhibitor Celecox® Tablet in Japan

Tokyo, March 30, 2011 - Astellas Pharma Inc. ("Astellas"; headquarters: Tokyo; President and CEO: Masafumi Nogimori) and Pfizer Japan Inc. ("Pfizer"; Headquarters: Tokyo; President: Ichiro Umeda) announced today that it submitted a supplemental new drug application to the Ministry of Health, Labour and Welfare in Japan seeking an approval for the indication of anti-inflammatory and analgesic effects in post-operation, post-trauma, and post-tooth extraction for the selective cox-2 inhibitor Celecox® (generic name: celecoxib).

Originally developed by Pfizer Inc. in the United States, Celecox® is the first COX (cyclooxygenase)-2 targeting anti-inflammatory agent to interfere with the production of prostaglandin and other chemicals involved in inflammation by selectively inhibiting COX-2 enzyme.
Inflammation and pain in post-operation, post-trauma, and post-tooth extraction is typical condition of acute pain. Celecox® selectively inhibits COX-2 enzyme which is involved in inflammation and pain and therefore is expected to be a non-steroidal anti-inflammatory drug (NSAID) with preferable efficacy and safety.

In Japan, Celecox® was launched for the indication of relief of inflammation and pain associated with rheumatoid arthritis (RA) and osteoarthritis (OA) in June 2007. Subsequently, relief of inflammation and pain associated with lumbago, scapulohumeral periarthritis, cervico-omo-brachial syndrome, and tendinists/tendosynovitis were approved as additional indications in June 2009. For marketing of Celecox® in Japan, Pfizer imports the active pharmaceutical ingredient and Astellas manufactures and distributes the finished products. Promotion is undertaken jointly by the both companies (co-promotion).

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