



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

Tokyo, December 22, 2011 - [Astellas Pharma Inc.](#) (“Astellas”; Tokyo:4503; President and CEO: Yoshihiko Hatanaka) and Pfizer Japan Inc. (“Pfizer”; Headquarters: Tokyo; President: Ichiro Umeda) announced today that it was granted approval for a supplemental new drug application 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[®] 100mg, 200mg (generic name: celecoxib), in Japan.

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 and pain by selectively inhibiting the COX-2 enzyme. Celecox[®] has been developed to be a non-steroidal anti-inflammatory drug (NSAID) with preferable efficacy and safety also for the management of inflammation and pain in post-operation, post-trauma, and post-tooth extraction.

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 both companies (co-promotion).

Inflammation and pain in post-operation, post-trauma, and post-tooth extraction are typical conditions of acute pain. Astellas and Pfizer expect to contribute to the management of acute pain by providing an additional option.

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