June 17, 2009

Astellas Pharma Inc.
Pfizer Japan Inc.

Announcement of Approval of Additional Indications for the Selective COX-2 Inhibitor Celecox® Tablets in Japan

Tokyo, Japan/June 17, 2009 - Astellas Pharma Inc. ("Astellas"; Headquarters: Tokyo; President and CEO: Masafumi Nogimori) and Pfizer Japan Inc. ("Pfizer"; Headquarters: Tokyo; President and CEO: Hiromitsu Iwasaki) announced today that "lumbago, scapulohumeral periarthritis, cervico-omo-brachial syndrome, and tendinitis/tendosynovitis" were approved as additional indications for their selective COX-2 inhibitor Celecox® (generic name: celecoxib) on June 17, 2009.

By selectively inhibiting an enzyme called COX-2 (COX: cyclooxygenase), celecoxib specifically reduces the production of prostaglandin, a chemical mediator involved in inflammation. Developed by Pfizer Inc. in the United States, celecoxib is the world's first non-steroidal anti-inflammatory drug (NSAID) designed to target COX-2. First launched in the U.S. in 1999, celecoxib has been approved in 118 countries and prescribed to over 103.7 million patients as Celebrex® or Celebra®.

In Japan, celecoxib was jointly developed by Astellas and Pfizer and was launched for the relief of inflammation and pain associated with rheumatoid arthritis (RA) and osteoarthritis (OA) in June 2007. A New Drug Application for "the relief of inflammation and pain associated with lumbago, scapulohumeral periarthritis, cervico-omo-brachial syndrome, and tendinitis/tendosynovitis" was filed in February 2007 as additional indications. 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 two companies (co-promotion).

It was revealed in 1991 that cyclooxygenase has two different subtypes in the human body, COX-1, which plays a major role in the protection of the gastrointestinal mucosa, and COX-2, which is involved in inflammation and pain. Upper gastrointestinal adverse reactions present a major problem in the use of conventional non-selective NSAIDs, which non-selectively inhibit both COX-1 and COX-2. Efforts have been made to develop drugs that selectively inhibit COX-2 involved in inflammation and pain. Celecoxib is the first selective COX-2 inhibitor developed and marketed worldwide. When administered twice daily, celecoxib exhibits proven efficacy for not only RA and OA but also lumbago, scapulohumeral periarthritis, cervico-omo-brachial syndrome, and tendinitis/tendosynovitis.

Astellas and Pfizer are confident that with approval of the additional indications, Celecox will make even greater contribution to patients in Japan as a new treatment option among NSAIDs.

Details of Celecox tablets 100mg and 200mg are as follows:

Date of marketing approval:	January 26, 2007
Brand name:	Celecox® tablets 100mg and 200mg
Generic name:	celecoxib
Classification:	NSAID
Indications:	Relief of inflammation and pain associated with the following diseases and symptoms: RA, OA, lumbago, scapulohumeral periarthritis, cervico-omo-brachial syndrome, and tendinitis/tendosynovitis
Dosage and administration:	In adults with RA, the recommended oral dosage of Celecox is 100-200mg twice daily, once after breakfast and once after evening meal. In adults with OA, lumbago, scapulohumeral periarthritis, cervico-omo-brachial syndrome, and tendinitis/tendosynovitis, the recommended oral dosage of Celecox is 100mg twice daily, once after breakfast and once after evening meal.
Characteristics:	1. World's first coxib anti-inflammatory/analgesic agent designed targeting COX-2 2. Selective inhibition of COX-2 induced in the presence of inflammation (rat data) 3. Proven efficacy for RA, OA, lumbago, scapulohumeral periarthritis, cervico-omo-brachial syndrome, and tendinitis/tendosynovitis when administered twice daily 4. Incidence of gastroduodenal ulcers under endoscopy at Week 12 of treatment: 6.1% (9/148) at 100mg twice daily and 4.1% (6/145) at 200mg twice daily (overseas data) 5. Approved in 118 countries and used in over 103.7 million patients (as of February 2009) 6. In clinical trials conducted in Japan, the incidence of adverse reactions including abnormal lab tests was 24.6%, 426 of 1,734 patients with RA or OA evaluable for safety and 34.6%, 451 of 1,304 patients with lumbago, scapulohumeral periarthritis, cervico-omo-brachial syndrome, or tendinitis/tendosynovitis evaluable for safety

Approval holder:	Astellas Pharma Inc.
Packaging:	100mg tablets: 100 tablets (PTP), 140 tablets (PTP), 700 tablets (PTP), and 500 tablets (not packed) 200mg tablets: 100 tablets (PTP), 140 tablets (PTP), 700 tablets (PTP), and 500 tablets (not packed)
NHI reimbursement prices:	80.20 Japanese yen/100mg tablet 123.20 Japanese yen/200mg tablet
Date of NHI price listing:	March 16, 2007
Date of launch:	June 12, 2007
Marketed by:	Astellas Pharma Inc.
Copromoted with:	Pfizer Japan Inc.

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