

Selected literature

■ **Etoricoxib.** van der Heijde D, Baraf HS, Ramos-Remus C, et al. Evaluation of the efficacy of etoricoxib in ankylosing spondylitis: results of a fifty-two-week, randomized, controlled study. *Arthritis Rheum.* 2005;52:1205-1215.

Curtis SP, Bockow B, Fisher C, et al. Etoricoxib in the treatment of osteoarthritis over 52-weeks: a double-blind, active-comparator controlled trial [NCT00242489]. *BMC Musculoskelet Disord.* 2005;6:58.

■ **Lumiracoxib.** Matchaba P, Gitton X, Krammer G, et al. Cardiovascular safety of lumiracoxib: a meta-analysis of all randomized controlled trials > or =1 week and up to 1 year in duration of patients with osteoarthritis and rheumatoid arthritis. *Clin Ther.* 2005;27:1196-1214.

■ **Diclofenac solution.** Towheed TE. Pennsaid therapy for osteoarthritis of the knee: a systematic review and metaanalysis of randomized controlled trials. *J Rheumatol.* 2006;33:567-573.

Selected websites

www.aapainmanage.org
American Academy of Pain Management

www.rheumatology.org
American College of Rheumatology

www.hopkins-arthritis.com.jhmi.edu
Johns Hopkins Arthritis Center

www.niams.nih.gov
National Institute of Arthritis and Musculoskeletal and Skin Diseases

Ankylosing spondylitis, osteoarthritis, and related pain

New drugs	Product type/proposed indication	FDA status/notes
ANKYLOSING SPONDYLITIS		
etoricoxib (Arcoxia) Merck	selective cyclo-oxygenase (COX)-2 inhibitor/treatment of ankylosing spondylitis	approvable 10/04; company conducting cardiovascular studies; revised NDA filed 12/03
golimumab Johnson & Johnson/ Schering-Plough	subcutaneously injectable anti-tumor necrosis factor (TNF)-alpha monoclonal antibody/treatment of ankylosing spondylitis	phase 3
OSTEOARTHRITIS		
etoricoxib (Arcoxia) Merck	selective COX-2 inhibitor/treatment of osteoarthritis	approvable 10/04; company conducting cardiovascular studies; revised NDA filed 12/03
lumiracoxib Novartis	selective COX-2 inhibitor/treatment of osteoarthritis	Not approvable 9/03; NDA filed 11/02; (NDA expected to be refiled first half 2007; European trade name is Prexige)
naproxcinod Nicox SA/PRA International	nitric oxide-donating derivative of naproxen/treatment of the signs and symptoms of knee osteoarthritis, including patients with co-existing hypertension	phase 3
PAIN		
GW406381 GlaxoSmithKline	COX-2 inhibitor/treatment of chronic pain, including osteoarthritis pain	phase 3
New indications/formulations		
OSTEOARTHRITIS		
diclofenac solution (Pennsaid) Nuvo Research	topical nonsteroidal anti-inflammatory drug (NSAID) combined with 1.5% proprietary carrier/treatment of knee osteoarthritis	User fee goal date 12/28/06; NDA refiled 7/06; not approvable 8/02
PAIN		
hylan G-F 20 (Synvisc) Genzyme	viscosupplementation product/treatment of pain due to hip osteoarthritis	phase 3
hylan G-F 20 (Synvisc 2) Genzyme	viscosupplementation product/single-injection treatment of osteoarthritis pain for at least 6 months' relief	phase 3
hylastan Genzyme	microbial formulation of viscosupplementation product/treatment of pain due to knee osteoarthritis	phase 3
tramadol Labopharm/Purdue Pharma	once-daily formulation of analgesic using Contramid controlled-release technology/management of moderate-to-moderately severe pain, including osteoarthritis pain	approvable 9/06 subject to resolution of issues; NDA filed 11/05

Editors' Note: In July 2006, FDA approved adalimumab (Humira, Abbott) for an additional indication: reduction in the signs and symptoms of active ankylosing spondylitis.

The purpose of Drug Watch is to keep drug decision-makers informed about pharmaceuticals in late-stage development. In each column, 1 or more disease areas or drug classes are presented. The column is researched and compiled by contributing editor **Jean M. Stevenson** and coordinated with assistance from editorial advisory board member **Michele B. Kaufman, PharmD**, president, PRN Communications, Inc, a consulting/medical writing and editing firm.