

Selected literature

■ **Solifenacin [YM905].** Gittelman M, Chu FM, Klimberg I, et al. Two randomized double-blind, placebo-controlled, parallel-group, fixed-dose, multicenter studies assess the efficacy and safety of daily oral administration of 10 mg YM905 versus placebo in male and female subjects with overactive bladder. Presented at the American Urological Association 98th Annual Meeting; Chicago; April 26–May 1, 2003. (Abstract DP43)

■ **Tadalafil.** Porst H, Padma-Nathan H, Giuliano F, et al. Efficacy of tadalafil for the treatment of erectile dysfunction at 24 and 36 hours after dosing: a randomized controlled trial. **Urology.** 2003;62:121–125.

Saenz de Tejada I, Anglin G, Knight JR, Emmick JT. Effects of tadalafil on erectile dysfunction in men with diabetes. **Diabetes Care.** 2002;25:2159–2164.

■ **Trospium.** Zinner N, Gittelman M, Harris R, et al. Trospium chloride improves overactive bladder symptoms: A multicenter phase III trial. Presented at the American Urological Association 98th Annual Meeting; Chicago; April 26–May 1, 2003. (Abstract DP51)

■ **Vardenafil.** Hellstrom WJ, Gittelman M, Karlin G, et al; Vardenafil Study Group. Sustained efficacy and tolerability of vardenafil, a highly potent selective phosphodiesterase type 5 inhibitor, in men with erectile dysfunction: results of a randomized, double-blind, 26-week placebo-controlled pivotal trial. **Urology.** 2003;61(4 Suppl 1):8–14.

Selected web sites

www.auanet.org
American Urological Association

www.bladder.org
National Bladder Foundation

kidney.niddk.nih.gov
National Kidney and Urologic Diseases Information Clearinghouse

Agents for genitourinary disorders

(Benign prostatic hyperplasia, erectile dysfunction, incontinence, and overactive bladder)

New drugs

	Product type/proposed indication	FDA status/notes
apomorphine (Uprima) TAP Pharmaceuticals	sublingual tablet formulation of dopamine receptor agonist/tx of erectile dysfunction	NDA refiled 10/25/02; recommended by advisory committee 4/10/00
darifenacin (Enablex) Novartis	selective muscarinic receptor antagonist/tx of overactive bladder	NDA filed 12/02
solifenacin [YM905] Yamanouchi	oral selective muscarinic receptor antagonist/tx of urinary frequency, urgency, and incontinence associated with overactive bladder	NDA filed 12/02
tadalafil (Cialis) Lilly/Icos Corp	oral phosphodiesterase-5 inhibitor/tx of erectile dysfunction, including diabetes-related erectile dysfunction	company provided additional data to FDA second quarter 2003; approvable 4/29/02
trospium Indevus	oral muscarinic receptor antagonist/twice-daily tx of symptoms of overactive bladder	NDA filed 4/29/03
vardenafil (Levitra) Bayer/GlaxoSmithKline	oral selective phosphodiesterase-5 inhibitor/tx of erectile dysfunction	recommended by advisory committee 5/29/03; approvable 7/23/02 with request for additional short-term studies

New indications/formulations

alprostadil (AlproX-TD) NexMed	cream formulation of prostaglandin E ₁ used with NexACT transdermal delivery technology/tx of mild-to-severe erectile dysfunction	two phase 3 trials completed; FDA lifted hold on open-label study 2/03; carcinogenicity trials in rats show no adverse effects
doxazosin (Cardura XL) Pfizer	α-adrenergic receptor antagonist/tx of benign prostatic hyperplasia	NDA filed 4/01
duloxetine Lilly/Boehringer Ingelheim	serotonin-norepinephrine reuptake inhibitor/tx of stress urinary incontinence	NDA filed fourth quarter 2002 (different brand name to be used for this indication than for depression [Cymbalta])
(S)-oxybutynin Sepracor	sustained-release formulation of single isomer of racemic oxybutynin/tx of overactive bladder	phase 3

Discontinued drug development

phentolamine (Vasomax) Zonagen	oral α-adrenergic receptor antagonist/single-dose treatment of erectile dysfunction	as of 11/02, company does not plan to conduct an additional 2-year rat carcinogenicity study as requested by FDA committee 10/02; on partial clinical hold 5/00; new data filed 4/00; not approvable 5/99
--	---	---

Editors' Notes: Sanofi-Synthelabo's alfuzosin extended-release tablets received FDA clearance on June 12, 2003, for treatment of the signs and symptoms of benign prostatic hyperplasia. The agent is an α-adrenergic blocker.

FDA also approved Watson Pharmaceuticals' oxybutynin transdermal system (Oxytrol) on February 26, 2003. The anticholinergic agent is indicated for the symptomatic treatment of overactive bladder, including urge urinary incontinence, urgency, and frequency.

In October, GlaxoSmithKline's dutasteride (Avodart) received supplemental FDA approval for the treatment of symptomatic benign prostatic hyperplasia. The agent is a second-generation 5-α-reductase inhibitor.

The purpose of Drug Watch is to keep drug decision-makers informed about pharmaceuticals in late-stage development. In each column, one or more disease areas or drug classes are presented. The column is coordinated with assistance from editorial board member Michele Kaufman, PharmD, project leader, clinical pharmacy programs, HIP Health Plan of New York.