NEW DRUGS

Two Agents for Weight Loss

Belviq
An appetite suppressant, lorcaserin HCl (Belviq, Arena/Eisai), can be used in addition to a reduced-calorie diet and exercise. The approval marks the first new weight-management therapy in more than a decade. The medication activates the serotonin (5-HT<sub>2C</sub>) receptor in the brain and helps to promote satiety.

In clinical studies, treated patients lost an average of 3% to 3.7% of their weight, compared with placebo. Therapy should be stopped in patients who do not lose 5% of their body weight after 12 weeks of treatment.

Sources: FDA and The Wall Street Journal, June 27, 2012

Qsymia

The FDA has approved a phentermine/topiramate extended-release combination (Qsymia, Vivus) as an addition to a reduced-calorie diet and exercise for weight management in adults with a body mass index (BMI) of 30 or greater (obese) or with a BMI of 27 or greater (overweight) who have at least one weight-related condition, such as hypertension, type-2 diabetes, or dyslipidemia.

In two trials, with the recommended and highest daily doses, patients had an average weight loss of 6.7% and 8.9%, respectively, over treatment with placebo. Therapy should be stopped if patients do not lose at least 5% of their body weight after 12 weeks of treatment.

Qsymia was approved with a Risk Evaluation and Mitigation Strategy (REMS).

Source: FDA, July 17, 2012

Kyprosil for Myeloma

Onyx Pharmaceuticals has been granted an accelerated approval for carfilzomib (Kyprosil) in patients with refractory or relapsed multiple myeloma that has not responded to at least two prior regimens, one of which must have been therapy with bortezomib (Velcade, Millennium). Carfilzomib, a second-generation proteasome inhibitor, has activity against bortezomib-refractory myeloma.

Sources: MedPage Today, July 20, 2012; http://kyprolis.com

Tudorza Pressair for COPD

Acclidinium bromide inhalation powder (Tudorza Pressair, Forest Laboratories/Almirall SA) has been approved for the treatment of chronic obstructive pulmonary disease (COPD). Acclidinium loosens the muscles around the lungs to improve airflow.

Source: Reuters, July 23, 2012

Myrbetriq for Overactive Bladder

Mirabegron (Myrbetriq, Astellas Pharma) is indicated for the treatment of adults with overactive bladder. An extended-release tablet taken once daily, mirabegron improves the storage capacity of the bladder by relaxing the bladder muscle during filling. Mirabegron is not recommended for patients with uncontrolled hypertension, end-stage kidney disease, or severe liver impairment.

Source: FDA, June 28, 2012

Prepopik Colon-Cleansing Prep

A combination of sodium picosulfate, magnesium oxide, and citric acid (Prepopik, Ferring) is now approved as a preparatory mixture for adults undergoing a colonoscopy. One dose consists of two packets of powder; each packet is dissolved in cold water and is taken at separate times.

Patients must drink additional fluids during and after use of the product to reduce the risk of fluid and electrolyte imbalance. Adverse effects may include nausea, headache, and vomiting.

Ferring will be required to conduct studies to determine whether the preparation can be used safely and effectively in children.

Source: FDA, July 17, 2012

Generic Approvals

Boniva

On June 29, Dr. Reddy’s Laboratories launched once-monthly ibandronate sodium tablets (150 mg), a bioequivalent generic version of Boniva tablets following the FDA’s approval of an abbreviated New Drug Application (aNDA).


Arthrotec

Watson Laboratories has received approval from the FDA on its aNDA for diclofenac sodium/misoprostol delayed-release tablets, the generic equivalent of G.D. Searle’s Arthrotec. Arthrotec is indicated for treating signs and symptoms of osteoarthritis or rheumatoid arthritis in patients at risk of developing gastric and duodenal ulcers induced by nonsteroidal anti-inflammatory drugs (NSAIDs). Arthrotec was approved by the FDA in December 1997.


NEW INDICATIONS

Truvada for AIDS Prevention

Truvada (Gilead Sciences) has been approved to prevent contraction of the virus that causes AIDS in healthy patients considered at high risk of becoming infected with HIV, such as those with an HIV-infected partner. The once-daily tablet, approved in 2004, is to be used in combination with safe-sex practices.

Truvada combines emtricitabine (Emtriva) and tenofovir (Viread). This is the first approval of a drug for the prevention of HIV infection. Patients will need to be tested every 3 months to ensure that they are HIV-negative before using Truvada.

A Risk Evaluation and Mitigation Strategy (REMS) is included to minimize the risk to uninfected individuals of acquiring the infection and to reduce the risk of development of resistant strains.
**NEW MEDICAL DEVICES**

**Lyrica for Spinal Cord Injury**

Pfizer’s pregabalin capsules (Lyrica) are approved to treat neuropathic pain resulting from spinal cord injury. This Schedule C-V controlled substance is also approved for neuropathic pain associated with diabetic peripheral neuropathy, postherpetic neuralgia, fibromyalgia, and seizures.


**Afinitor for Breast Cancer**

Everolimus (Afinitor, Novartis) has been approved to treat postmenopausal women with hormone receptor–positive, HER2–negative breast cancer. Everolimus is given with exemestane (Aromasin, Pfizer) to treat cancer recurrence or progression after treatment with two other therapies. Everolimus is also used to treat four other types of cancer.

Source: Reuters, July 20, 2012

**Erbitux for KRAS-Screened Colorectal Cancer**

Cetuximab (Erbitux, Bristol-Myers Squibb/Eli Lilly) is indicated for use with irinotecan, 5-fluorouracil, and leucovorin (FOLFIRI) as a first-line treatment of metastatic colorectal cancer in patients with epidermal growth factor receptor (EGFR)-expressing and KRAS wild-type tumors (no KRAS mutations).

This is the first approval in nearly a decade for treating newly diagnosed metastatic colorectal cancer. Boxed warnings mention serious infusion-related and rare fatal reactions. Cetuximab was first approved in 2004 to treat EGFR-expressing late-stage refractory colorectal cancer. The drug should not be used in patients with KRAS mutation–positive colorectal cancer.


**Recall**

Nidek’s Mark 5 Nuvo, Nuvo 8, and Nuvo Lite oxygen concentrators were recalled on May 1, 2012, because of the possibility of capacitor failure, possibly resulting in a fire hazard and a loss of supplemental oxygen. The concentrators provide supplemental oxygen to patients at home. The devices were made from January 1, 2004, to May 15, 2010. Patients may continue to use the concentrators while they wait for a replacement.

Source: FDA, June 21, 2012

**Sources:**

Lyrica	for	Spinal	Cord	Injury

Afinitor	for	Breast	Cancer

Erbitux	for	KRAS-Screened	Colorectal	Cancer

Recall