



MaxorPlus Clinical Newsletter

April 2011

Now available

Yervoy® (ipilimumab) is a recombinant, human monoclonal antibody for the treatment of unresectable or metastatic malignant melanoma. Dosing is 3 mg/kg IV over 90 minutes every 3 weeks for a total of 4 doses. AWP \$7200 for 50 mg vial or \$28,800 for the 200mg vial.

Based on **Yervoy's®** indication and cost, we recommend restricting to a specialty pharmacy.

Viramune XR® (nevirapine) is a first-generation oral non-nucleoside reverse transcriptase inhibitor for the treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents. Patients must first receive 200 mg a day of an immediate-release **nevirapine** formulation for 14 days in combination with other antiretrovirals. The 14-day lead-in period decreases the incidence of **nevirapine**-associated rash. The 200 mg immediate release tablet is due out in generic May 2012. AWP \$ 20.48/ 400 mg XR tablet

New generics available:

docetaxel generic for **Taxotere®** used to treat various metastatic cancers

exemestane generic for **Aromasin®** used to treat for advanced breast cancer in postmenopausal women

Nulecit generic for **Ferrlecit®** used for the treatment of iron-deficiency anemia in patients undergoing chronic hemodialysis who are receiving supplemental epoetin alfa therapy

In the news

Currently, positive diagnosis of Alzheimer's is only possible upon autopsy. But a radioactive molecular imaging compound called **AV-45** and a **PET** scan can allow doctors to "see" inside patients' brains to detect beta-amyloid plaques, the tell-tale signature of Alzheimer's. Subjects had PET scans using 11C Pittsburgh Compound-B (11C-PIB), a PET imaging agent that binds to beta-amyloid in neural tissues. Results of the two-year study showed that beta-amyloid plaque builds slowly over time, and extensive build-up of the protein preceded cognitive impairment and was associated with 13 times the level of risk of progressing to Alzheimer's disease within 20 months. Researchers found that development of the disease could begin as early as 10 years before signs of dementia. Patients with a strong family history of Alzheimer's or who show mild signs of memory loss could be screened for the development of the disease in order to help them plan for the future. This imaging technique could also be used to evaluate the effectiveness of new treatments as they become available.

eScience news march 2011

Updates in the News

Will KV's 55% Makena price cut satisfy critics?

Answering a firestorm of criticism, as well as an unusual move by FDA, KV Pharmaceutical took an axe to the \$1,500 price on its new prenatal drug **Makena**®, cutting it back by 55 percent. The treatment, designed to prevent premature births, will now run \$690 per weekly injection, and KV will offer additional rebates to make the drug more affordable to Medicaid programs.

KV had been facing an outcry ever since it first announced **Makena**®'s pricing. The newly approved drug is a commercialized version of a hormone injection that compounding pharmacists have been supplying to pregnant women for years, at \$10 to \$20 per shot. Patient groups, physician organizations, U.S. Senators and even the March of Dimes attacked the company, accusing it of price gouging.

"We understand the concerns that key stakeholders raised under our original pricing structure," CEO Greg Divis said in a statement. "We also recognize the current budget challenges facing state Medicaid programs and other payers."

KV's statement did not mention the FDA's unusual announcement Wednesday: That it would not go after compounding pharmacies that continued to supply their versions of the hormone injection, except in cases where quality was suspect. KV had sent pharmacies cease-and-desist letters, saying they'd violate FDA exclusivity rules if they kept selling their unapproved versions. But the agency's pledge reopened the door to those low-cost competitors.

It's unclear whether KV's price cut will be enough to woo women away from the compounded versions of the drug. In its statement, the company raised questions about the quality of compounded drugs, emphasizing the quality control and standardization of FDA-approved meds. And some organizations that have been criticizing KV actually supported its bid for **Makena**® approval, welcoming the advent of an FDA-blessed version of the treatment.