

### Drugs recently approved or pending approval

#### PEG-INTRON

Schering-Plough Corporation (Kenilworth, NJ) received approval to market PEG-Intron (peginterferon alfa-2b) Powder for Injection as monotherapy for the treatment of chronic hepatitis C in patients not previously treated with alpha interferon who have compensated liver disease and are at least 18 years of age. Safety and efficacy of PEG-Intron have been demonstrated in a randomized study which compared treatment with PEG-Intron (0.5, 1.0, or 1.5 µg/kg body weight once weekly, subcutaneously) to treatment with interferon alfa-2b (3 million units 3 times weekly, subcutaneously) in 1219 adults with chronic hepatitis C who were not previously treated with interferon alfa. Patients were treated for 48 weeks and were followed for 24 weeks post-treatment. Response to treatment was defined as undetectable hepatitis C virus RNA and normalization of alanine aminotransferase (ALT) at 24 weeks post-treatment. Patients in the 0.5 µg/kg body weight and 1.0 µg/kg body weight PEG-Intron groups achieved response rates of 17% and 24%, respectively, in combined virologic response and ALT normalization, compared with a 12% treatment response rate in patients receiving interferon alfa. PEG-Intron is contraindicated in patients with autoimmune hepatitis or decompensated liver disease. The most common adverse events associated with PEG-Intron are flu-like symptoms, injection site irritation or inflammation, and depression. PEG-Intron is administered subcutaneously once weekly for 1 year.

#### FEMARA

The US Food and Drug Administration approved marketing of Femara (letrozole tablets) by Novartis Pharmaceuticals Corporation (East Hanover, NJ) for a new indication. Femara is now indicated for the first-line treatment of postmenopausal women with hormone receptor-positive or hormone receptor-unknown locally advanced or metastatic breast cancer. Femara is indicated also for the treatment of advanced breast cancer in postmenopausal women with disease progression following anti-estrogen therapy. The new indication is based on data from a randomized, double-blind, multinational Phase III trial that compared Femara 2.5 mg with tamoxifen 20 mg in 907 postmenopausal patients with locally advanced (stage IIIB or locoregional recurrence not amenable to treatment with surgery or radiation) or metastatic breast cancer. The primary endpoint of the trial was time to tumor progression. The study demonstrated that Femara delays progression of advanced breast cancer for 9.4 months, compared with 6.0 months for tamoxifen. Results

also indicated significant differences between Femara and tamoxifen with respect to overall tumor response rates (30% vs 20%), clinical benefit (49% vs 38%), and time to treatment failure (9.1 months vs 5.7 months). Clinical responses after 4 months of preoperative therapy were significantly better for Femara than for tamoxifen (55% vs 36%). The most frequently reported side effects associated with Femara include bone pain, hot flushes, back pain, nausea, dyspnea, and arthralgia. The recommended dose of Femara is one 2.5 mg tablet administered once daily. Treatment should continue until tumor progression is evident.

#### REMICADE

Approval was granted to Centocor, Inc (Malvern, PA) to market Remicade (infliximab), in combination with methotrexate, for inhibiting the progression of structural damage in patients with

moderately to severely active rheumatoid arthritis who have had an inadequate response to methotrexate. Remicade had been previously approved for the treatment of signs and symptoms of rheumatoid arthritis in patients who have had an inadequate response to methotrexate. Approval was based on 54-week data from the 2-year Anti-TNF Trial in Rheumatoid Arthritis with Concomitant Therapy. In

this double-blind, placebo-controlled, randomized clinical study, patients (N = 428) were treated with Remicade plus methotrexate or methotrexate plus a placebo. Progression of joint damage was measured radiographically using the van der Heijde modified Sharp system, which evaluates changes in joint-space narrowing and bone erosion on a 5-point scale. Among all Remicade treatment groups, patients in the Remicade-plus-methotrexate group (n = 285) had an overall median change from radiographic baseline of 0.0, compared with a 4.0 change for patients in the methotrexate-plus-placebo group (n = 64). A total of 53% of Remicade patients demonstrated 0% progression. Remicade should not be given to patients with a clinically important active infection. The most common adverse events associated with Remicade include upper respiratory infection, nausea, and headache. The recommended dose of Remicade is 3 mg/kg body weight given as an intravenous infusion, followed with additional similar doses at 2 and 6 weeks after the first infusion and then every 8 weeks thereafter.



*Compiled from press reports and pharmaceutical company press releases. For more information, contact Jennifer Vander Bush, Hospital Physician, 125 Strafford Avenue, Suite 220, Wayne, PA 19087-3391.*

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