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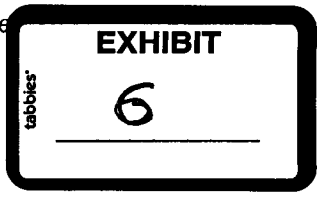

October 21st, 2002

THE-PINK-SHEET: Roche Pegasys Has $291 WAC; Launch Includes 12 Weeks of Free Samples

Roche's Pegasys has a wholesale acquisition cost of $291 for one week of the hepatitis C therapy.

FDA approved Pegasys (peginterferon alfa-2a) Oct. 16 for the treatment of adults with chronic hepatitis C who have compensated liver disease and have not previously been treated with interferon alpha.

Roche expects Pegasys to be available in pharmacies within two weeks at a comparable price to Schering-Plough's PEG-Intron (peginterferon alfa-2b).

Peg-Intron is available in four different vial sizes with an average wholesale price ranging from $309.20 to $357.95. PEG-Intron is used in combination with Rebetol (ribavirin). The average total cost of the combination therapy is $25,000 annually, Schering said.

Roche expects to have a sufficient supply of Pegasys to meet demand.

Schering is now meeting patient demand for its product as well. The company has increased production capacity at its Brinny, Ireland facility and cleared its patient waiting list for PEG-Intron/Rebetol in September. The patient registry program was put in place in January due to strong demand ("The Pink Sheet" Jan. 28, p. 32).

Pegasys monotherapy is being launched before approval of the combination alfa-2a/ribavirin product. The application for Pegasys combination therapy with ribavirin is pending and will be reviewed by FDA's Antiviral Drugs Advisory Committee Nov. 14 ("The Pink Sheet" Oct. 7, In Brief). Roche's ribavirin will be sold under the name Copegus.

Roche expects approval of the Pegasys/ribavirin combo by the end of the year. Ribapharm, which owns patents on ribavirin capsules, filed a patent infringement suit against Roche Aug. 26 in Los Angeles federal court. Roche said the lawsuit will not keep the combination off the market.

The company anticipates that the monotherapy launch will help prepare the market for the combo therapy ("The Pink Sheet" Aug. 19, p. 7).

A Pegasys sampling program will provide the product for 12 weeks free of charge for up to 15,000 patients.

Under the program, physicians can request samples of Pegasys by registering their patients with specialty pharmacy and distribution company Priority Healthcare.

"Samples will be provided at the request of a physician for the first 15,000 patients who are started on Pegasys therapy prior to Dec. 31, 2002," Roche said.

Roche will provide Pegasys to Priority Healthcare, which will distribute the drug to physicians. Roche says it will not have access to any patient information.

The 12-week duration for the sample program was selected because at 12 weeks, physicians can predict whether a patient will respond to Pegasys therapy, Roche said.

In clinical studies, "of patients who did not demonstrate by 12 weeks of Pegasys 180 mcg therapy, either

undetectable HCV RNA or at least a 2-log drop in HCV RNA titer from baseline, 2% (3/156) achieved a sustained virological response" with continued therapy, labeling states.

Approval for Pegasys was based on the results from three Phase III open-label, active-controlled trials in 1,425 patients. In the first two studies, 20% of patients had cirrhosis or transition to cirrhosis and the third study enrolled patients with a histological diagnosis of cirrhosis or transition to cirrhosis.

"In all three studies, treatment with Pegasys 180 mcg resulted in significantly more responding patients compared to treatment with [Roche's] Roferon-A" (interferon alfa-2a), labeling states.

The sustained virologic response at week 72 for Pegasys in the first study was 23% compared to 9% for Roferon-A. The response rate for Pegasys was 31% in the second study and 28% in the third study.

"Averaged over study 1, study 2, and study 3, response rates to Pegasys were 23% among patients with viral genotype 1 and 48% in patients with other viral genotypes," labeling states.

The labeled indication states that "patients in whom efficacy was demonstrated included patients with compensated cirrhosis."

The recommended dose for Pegasys is 180 mcg once weekly for 48 weeks by subcutaneous administration in the abdomen or thigh.

Pegasys was approved with fixed dosing, as opposed to the weight-based dosing for Schering's PEG-Intron.

PEG-Intron was approved in August 2001 at a recommended dose of 1.5 mcg/kg once weekly in conjunction with Rebetol capsules dosed at 800 mg/day for one year ("The Pink Sheet" Aug. 20, 2001, p. 24). PEG-Intron was approved in January 2001 as monotherapy.

Pegasys is available as a pre-mixed solution for subcutaneous injection. PEG-Intron must be reconstituted with the supplied diluent prior to use.

The most common adverse events in clinical trials for Pegasys compared to Roferon-A were psychiatric reactions, including depression (18% Pegasys vs. 19% Roferon-A), irritability (13% vs. 17%), anxiety (6% vs. 5%), and flu-like symptoms, such as fatigue (50% vs. 50%), pyrexia (36% vs. 41%), myalgia (37% vs. 38%), headache (54% vs. 58%) and rigors (32% vs. 42%).

"The most common reason for dose modification or withdrawal from studies was hematologic abnormalities," labeling says.

Roche will submit data to FDA on three ongoing studies and a new study as part of its postmarketing commitments.

The final report on a trial evaluating the safety and pharmacokinetics of peginterferon alfa-2a in pediatric patients aged two to eight is due to the agency by September 2003. Roche is also comparing Pegasys in African-American and Caucasian genotype 1 patients; the study report is due March 2003.

Roche will submit data on an ongoing study to evaluate the pharmacokinetics and pharmacodynamics of Pegasys in patients receiving methadone.

Roche will also submit a protocol to FDA by February 2003 to evaluate immunogenicity screening assays for detecting binding and neutralizing antibodies using Pegasys as the target molecule. The Phase IV trial will enroll 300 patients. An interim report will be submitted in May 2004 and the final report is due by August 2004.

The Pegasys BLA (1039640) was filed May 22, 2000; FDA sent a "complete response" letter April 10, 2001.