Panel Backs Peginterferon for Stage III Melanoma

BY ELIZABETH MECHCATIE

GAITHERSBURG, Md. — Peginterferon alfa-2b has a favorable risk-benefit ratio as an adjuvant treatment for stage III melanoma, a Food and Drug Administration advisory panel said.

The FDAs Oncologic Drugs Advisory Committee voted 6-4 against recommending the use of pegylated interferon alfa-2b after complete lymphadenectomy for patients with stage III melanoma.

The committee recommended that the FDA should condition its approval of pegylated interferon alfa-2b, marketed by Schering-Plough Corp. as Pegintron and was approved as a treat- ment for chronic hepatitis C in 2001.

Interferon alfa-2b (Intron A), also manufac- tured by Schering-Plough, is approved for the treatment of chronic hepatitis C and also for the indication.

Importantly, the committee voted 6-4 after reviewing the complete prescribing information. The panel said that there was not enough evidence to recommend the use of pegylated interferon alfa-2b in patients with stage III melanoma.

The panel did not specifically vote on whether to recommend approval of peginterferon for the indication.

Peginterferon alfa-2b (Peg-IFN), a long- acting formulation of interferon alfa-2b, is marketed by Schering-Plough Corp. as Pegintron and was approved as a treat-ment for chronic hepatitis C in 2001.

Interferon alfa-2b (Intron A), also manufac- tured by Schering-Plough, is approved for the treatment of chronic hepatitis C and also for the indication.

The panel did not specifically vote on whether to recommend approval of peginterferon for the indication.

Peginterferon alfa-2b (Peg-IFN), a long- acting formulation of interferon alfa-2b, is marketed by Schering-Plough Corp. as Pegintron and was approved as a treat-ment for chronic hepatitis C in 2001.

Interferon alfa-2b (Intron A), also manufac- tured by Schering-Plough, is approved for the treatment of chronic hepatitis C and also for the indication.

The panel did not specifically vote on whether to recommend approval of peginterferon for the indication.

Peginterferon alfa-2b (Peg-IFN), a long- acting formulation of interferon alfa-2b, is marketed by Schering-Plough Corp. as Pegintron and was approved as a treat-ment for chronic hepatitis C in 2001.

Interferon alfa-2b (Intron A), also manufac- tured by Schering-Plough, is approved for the treatment of chronic hepatitis C and also for the indication.

The panel did not specifically vote on whether to recommend approval of peginterferon for the indication.

Peginterferon alfa-2b (Peg-IFN), a long- acting formulation of interferon alfa-2b, is marketed by Schering-Plough Corp. as Pegintron and was approved as a treat-ment for chronic hepatitis C in 2001.

Interferon alfa-2b (Intron A), also manufac- tured by Schering-Plough, is approved for the treatment of chronic hepatitis C and also for the indication.

The panel did not specifically vote on whether to recommend approval of peginterferon for the indication.

Peginterferon alfa-2b (Peg-IFN), a long- acting formulation of interferon alfa-2b, is marketed by Schering-Plough Corp. as Pegintron and was approved as a treat-ment for chronic hepatitis C in 2001.

Interferon alfa-2b (Intron A), also manufac- tured by Schering-Plough, is approved for the treatment of chronic hepatitis C and also for the indication.