Information for Healthcare Professionals

Interferon Gamma 1-b
(marketed as Actimmune)

FDA ALERT [03/9/2007]: FDA is issuing this alert to advise you of the early termination of the INSPIRE clinical study of Actimmune for idiopathic pulmonary fibrosis (IPF). The study was stopped because an interim analysis showed that patients with IPF who received Actimmune did not benefit. The trial compared survival in patients getting Actimmune or an inactive injection (placebo). An analysis showed that 14.5% of patients treated with Actimmune died as compared to 12.7% of patients treated with placebo. Actimmune is not approved by the FDA to treat IPF.

This information reflects FDA's current analysis of data available to FDA concerning this drug. FDA intends to update this sheet when additional information or analyses become available.

To report any serious adverse events associated with the use of Actimmune or other medical products, please contact the FDA MedWatch program using the contact information at the bottom of this sheet.

Considerations for Physicians and Other Health Care Professionals

Physicians and other healthcare professionals should consider that the INSPIRE study showed no mortality benefit in treating IPF patients with Actimmune. INSPIRE was a clinical trial designed to evaluate survival of patients with mild to moderate IPF treated with Actimmune or placebo. The trial was stopped early because 14.5% of patients treated with Actimmune died as compared to 12.7% of patients treated with placebo. Side effects of Actimmune treatment reported in this study included constitutional symptoms, neutropenia, and possibly pneumonia.

Although Actimmune has not been approved for use in IPF, some patients with IPF may be receiving this product off-label. Physicians and other health care professionals should discuss the results of this trial with their patients receiving Actimmune for IPF and carefully consider whether patients should continue to receive treatment with Actimmune.

Information for the Patient.

Patients being treated with Actimmune for IPF should discuss with their physicians whether they should continue to receive Actimmune treatment.

Data Summary

INSPIRE was a randomized, double-blind, placebo-controlled study designed to evaluate the safety and efficacy of Actimmune in IPF patients with mild to moderate lung function impairment. The primary endpoint was survival time. On February 28, 2007, an independent data monitoring committee (DMC) recommended the early termination of the INSPIRE study due to lack of therapeutic benefit from Actimmune. Among the 826 randomized patients there

were a total of 115 deaths, 14.5% in the Actimmune group as compared to 12.7% in the placebo group. InterMune concluded that the drug would not show a mortality benefit to IPF patients and stopped the study. In this study, InterMune reported that Actimmune use was associated with several adverse effects, including constitutional symptoms, neutropenia, and possibly pneumonia.

Actimmune is a synthesized version of interferon gamma-1b, a naturally occurring biologic response modifier. Actimmune is FDA-approved to reduce the frequency and severity of infections in patients with chronic granulomatous disease and to delay the progression of severe, malignant osteopetrosis. Both of these hereditary diseases are life-threatening and there are no other FDA-approved treatments. Actimmune is not FDA-approved to treat IPF.

IPF is a chronic progressive interstitial lung disease of unknown etiology. It is characterized by fibrosis of the lung parenchyma. IPF progression is variable and unpredictable. Some patients experience a rapidly progressive fatal course over several months, while others experience a protracted deterioration of lung function. Median survival is 3-5 years from the onset of symptoms.

FDA intends to evaluate the INSPIRE study results and, if the review reveals additional important information to share, will notify healthcare providers and patients.