Sargramostim Improves Quality of Life in Crohn’s Disease

BY MITCHEL L. ZOLER
Philadelphia Bureau

COPENHAGEN — Daily treatment with sargramostim led to significantly improved quality of life in patients with moderate to severe Crohn’s disease in a study with 124 patients. In addition to reducing disease severity scores, sargramostim appears to significantly improve quality of life,” as measured with both the Inflammatory Bowel Disease Questionnaire (IBDQ) and the Short Form-36 (SF-36), researchers reported in the American Journal of Gastroenterology.

Remissions occurred in 40% of the sargramostim patients and 19% of the placebo group; clinical response occurred in 48% and 26%, respectively. Remissions occurred in 40% of the sargramostim patients and 19% of the placebo group.

The study was sponsored by Therapeutic ImmunoGen, Inc., and Biogen Idec. The companies jointly developed sargramostim, a yeast-derived recombinant human granulocyte-macrophage colony-stimulating factor, which is being marketed in the United States: following induction chemotherapy in patients with acute myelogenous leukemia or non-Hodgkin lymphoma, treatment for regenerative therapy in patients with aplastic anemia, and treatment for bone marrow transplant failure or engraftment delay.

Safety Issues Call for Selective Use

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Despite natalizumab’s safety issues, the drug remains a viable option for treating selected patients with Crohn’s disease. Dr. Feagan said at the meeting.

After the drug was withdrawn from the market, the two companies that market it as Tysabri offered an extensive safety evaluation to the more than 3,500 patients who had participated in the drug’s trials. This offer was accepted by about 90% of all patients in the multiple sclerosis, rheumatoid arthritis, and Crohn’s disease trials—a total of more than 3,000 patients—said a spokeswoman for Biogen Idec, one of the two companies jointly developing and marketing natalizumab.

The investigation turned up no additional cases of multifocal leukoencephalopathy beyond the three patients that had been reported previously, noted Biogen Idec and Elan Pharmaceuticals in written statements.

“That’s good news,” Dr. Feagan said. “What it comes down to is, will we, as physicians, accept this rare but serious and often fatal complication?” I think we will pick our spots, and focus on patients who fail other treatments, at least until there are more safety component scores of the SF-36, including bodily pain, social function, and mental health.

In addition, the analysis showed no significant differences between individual component scores for patients in the active-treatment arm and scores from an age-adjusted sample of normal Americans, except for the categories of vitality and general health.

In contrast, the scores of patients in the placebo arm were consistently and significantly lower than scores of the normal, general population, Dr. Feagan said.