FDA Expands The Use Of Rituxan Treatment For NHL Patients

(NAPSA)—There's encouraging news for patients diagnosed with a form of cancer that affects the lymphatic system known as non-Hodgkin's lymphoma (NHL): The U.S. Food and Drug Administration (FDA) has approved two additional uses for Rituxan® (Rituximab) for patients with CD20-positive, B-cell NHL.

About NHL

An estimated 360,000 Americans have NHL. Of those diagnosed, 31 percent have diffuse large B-cell lymphoma (DLBCL), a faster-growing subtype of NHL. About 30 percent have a slow-growing but incurable (low-grade) form of the disease—the most common type, called follicular lymphoma (FL).

Although FL progresses slowly, the median survival time is seven to 10 years. In addition, relapse is common and less than half of FL patients who experience a relapse will survive for five years, underscoring the need for treatments that delay disease progression, relapse or death.

"The goal of treating low-grade, or follicular, NHL, a chronic cancer marked by multiple recurrences, is to delay disease progression for as long as possible," said Howard Hochster, M.D., professor of medicine and clinical pharmacology, New York University School of Medicine and Cancer Institute.

New Indications

The first new indication for Rituxan is for first-line treatment of previously untreated patients with follicular NHL in combination with CVP (cyclophosphamide, vincristine and prednisolone) chemotherapy. The second is for the treatment of low-grade NHL in patients with stable disease or who achieve a partial or complete response following first-line treatment with CVP chemotherapy.

Lymphoma Facts

- NHL is a cancer that affects the lymphatic system.
- NHL is one of the most rapidly increasing types of cancer in the U.S.
- Currently, NHL is the sixth most fatal cancer in the U.S.
- More than 58,000 new cases of NHL are diagnosed annually.
- The two most common types of NHL are diffuse large B-cell lymphoma and follicular lymphoma.

"These approvals enable doctors and patients to select among different treatment options using Rituxan with or following CVP in the front-line setting," said Hochster.

Clinical Studies

The FDA approval of Rituxan as a first-line treatment in previously untreated patients with follicular, CD20-positive, B-cell NHL in combination with CVP chemotherapy is based on data from a Phase III, randomized, controlled study. The study evaluated the first-line use of Rituxan in combination with CVP chemotherapy versus CVP chemotherapy alone. Results indicated that:

- Rituxan plus CVP improved median progression-free survival to 2.4 years from 1.4 years for CVP chemotherapy alone.
- Rituxan plus CVP reduced the risk of disease progression, relapse or death by 56 percent compared to CVP chemotherapy alone (hazard ratio = 0.44 $p<0.0001$).

The FDA approval of Rituxan for the treatment of low-grade, CD20-positive, B-cell NHL in patients with stable disease or who achieve a partial or complete response following first-line treatment with CVP chemotherapy is based on a Phase III, randomized, controlled Eastern Cooperative Oncology Group study of 322 patients. Following CVP chemotherapy, study participants received Rituxan 375 mg/m2 given in four weekly infusions, every six months for up to 16 doses, or observation. Rituxan reduced the risk of disease progression, relapse or death by more than 50 percent over observation (hazard ratio estimate in the range of 0.36 - 0.49).

In non-Hodgkin's lymphoma, the majority of patients experience infusion-related symptoms with their first Rituxan infusion. These symptoms include but are not limited to flulike illness, fever, chills/rigors, nausea, urticaria, headache, bronchospasm, angioedema and hypotension. These symptoms vary in severity and are generally reversible with medical intervention. Rituxan therapy does involve risks. Serious side effects have occurred in patients treated with Rituxan. Death related to Rituxan therapy has been rare. In general, most deaths have occurred after the first Rituxan administration. Other rare causes of death were kidney failure and severe skin reactions.

Individual responses to treatment may vary. Rituxan is given only by a health care professional. If you have any questions about Rituxan treatment for non-Hodgkin's lymphoma, be sure to contact your doctor or nurse.

Experience with Rituxan has been established in more than 960,000 patient exposures over a period of nine years.

For a copy of the Rituxan full prescribing information, including Boxed Warning, please call (877) 474-8892 or visit www.rituxan.com.