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Leukemia & Lymphoma Society applauds FDA's recent approval of two new multiple myeloma drugs

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The Leukemia & Lymphoma Society (LLS) applauds the FDA's recent approval of two new drugs -- daratumumab and ixazomib -- to treat patients with relapsed multiple myeloma. These therapies are the latest in a growing arsenal to fight this blood cancer that impacts nearly 100,000 patients in the U.S. Advances in treatments for many different types of multiple myeloma blood cancers are happening with dizzying speed and these two approvals in just one week are the latest evidence of this phenomenon.

The FDA approved two additional multiple myeloma drugs earlier this year: panobinostat (Farydak ®), in February and carfilzomib (Kyprolis ®) in July. Another promising myeloma therapy still in the pipeline is elotuzumab.

Blood cancer research has been the gateway to better therapies and even cures for all cancers. Over the past 15 years, approximately 40 percent of therapies approved by the FDA to treat cancers have been specifically for blood cancers, and many are now helping patients with other cancers and serious diseases.

The past 12 years have seen remarkable changes in the treatment for patients diagnosed with multiple myeloma (MM), a painful blood cancer that begins in the bone marrow and causes the bones to become brittle. While myeloma remains incurable, ixazomib and daratumumab are the latest in an array of new therapies that are extending survival rates for patients coping with this painful and difficult to treat cancer.

"We are seeing rapid progress in new therapies coming on line for patients with multiple myeloma, as well as for all types of blood cancers. LLS applauds the FDA's accelerated approval of ixazomib and daratumumab this week," said Louis J. DeGennaro, president and CEO of The Leukemia & Lymphoma Society (LLS). "LLS continues to support cutting-edge research to advance more effective treatments for multiple myeloma, and for all blood cancers."

Ixazomib (Ninlaro ®) was approved today for relapsed and refractory multiple myeloma patients, in combination with another drug, lenalidomide. It works by cutting off the production of proteins the tumor cells need to grow. Daratumumab (Darzalex ®) was approved Monday for patients who have failed on at least three prior lines of therapy. The FDA hastened its approval based on data showing the drug's safety and effectiveness. It works by targeting a protein called D38 on the surface of myeloma cells.

The most current data on these two therapies, as well as other emerging therapies for multiple myeloma is anticipated to be a major topic of discussion during the upcoming American Society of Hematology Annual Meeting in Orlando next month, when more than 20,000 researchers from around the world will convene to share their latest findings.

LLS-Supported Research on Multiple Myeloma

LLS supports a large portfolio of research seeking to better understand the mechanisms of multiple myeloma, to help approved therapies work better, and to support novel approaches to treatment. For example,

- Through LLS's Therapy Acceleration Program ® (TAP), LLS is supporting a company, OncoPep, in developing a vaccine designed to prevent pre-myeloma conditions from advancing to myeloma.
- Another TAP project at Johns Hopkins is developing an adoptive cellular therapy approach to treating myeloma.
- LLS is also supporting a T-cell immunotherapy project for myeloma at Baylor College of Medicine.
- LLS-supported researchers at Dana-Farber Cancer Institute are experimenting with different ways to prevent pre-myeloma conditions from progressing.

Overall, LLS is currently supporting more than 20 multiple myeloma projects. Approximately 10 percent of LLS's research budget is focused on multiple myeloma therapies.

Background on Multiple Myeloma

Multiple myeloma is one of the three main types of blood cancers -- diseases that affect the bone marrow, blood cells and lymph nodes. There are hundreds of subtypes of blood cancers, and currently more than 1.1 million people are living with a blood cancer in the U.S. While multiple myeloma is not as prevalent as some other blood cancers,

such as lymphoma and leukemia, the urgency to find better treatment options for the disease is reflected in the surge of new therapies for multiple myeloma either recently approved or in the pipeline.

Prior to 2003, the prognosis for a patient diagnosed with multiple myeloma was very grim, as the standard therapies were largely ineffective. People diagnosed with multiple myeloma rarely lived beyond three years.

However, in 2003, the FDA approved bortezomib (Velcade®), a new therapy for myeloma, advanced with LLS support. This marked the first new effective treatment for myeloma patients and more than tripled survival rates for some patients. Other promising therapies followed, including lenalidomide (Revlimid), an oral therapy, and thalidomide (Thalomid ®), approved within a month of each other in 2006, giving myeloma patients even more options and more hope, extending lives and improving quality of life.

Source:

The Leukemia & Lymphoma Society
