FDA Approves Lunsumio for Treatment of Follicular Lymphoma

Mosunetuzumab is the first bispecific antibody, a type of immunotherapy, approved to treat non-Hodgkin lymphoma.

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The U.S. Food and Drug Administration (FDA) on December 22 granted approval of mosunetuzumab (Lunsumio) for the treatment of adults with advanced follicular lymphoma. This is the first bispecific antibody, a type of immunotherapy, approved to treat any type of non-Hodgkin lymphoma. The drug is approved to treat patients whose follicular lymphoma has returned or worsened despite at least two earlier treatments.

“This new treatment has the potential to help patients with this hard-to-treat cancer achieve remission,” says [Leukemia & Lymphoma Society] LLS Chief Scientific Officer Dr. Lee Greenberger. “Mosunetuzumab is an ‘off the shelf’ treatment, meaning it can be started more quickly than individualized immunotherapies, and it doesn’t require patients to live near, or travel to, specialized treatment centers.”

LLS support contributed directly to this approval, with grants and scholar awards to several researchers working on this important immunotherapy. To date, LLS has invested more than $100 million in immunotherapy, including as one of the earliest supporters of CAR T-therapy, which today is a mainstay in the treatment of certain difficult to treat leukemias, non-Hodgkin lymphomas and multiple myeloma.

While CAR T and many other treatments work on one target, bispecific antibodies work by attaching to the surface of cancer cells and also to the body’s immune T cells. This dual targeting “handcuffs” the cells together to engage the T cells to eliminate the cancer. In the case of mosunetuzumab, the drug attaches to the surface of B cells, which are highly expressed on follicular lymphoma and other forms of B-cell cancers, mainly non-Hodgkin lymphomas.

FDA designated mosunetuzumab for Priority Review, which is reserved for medications that may provide significant improvements in safety and effectiveness over current therapies. Mosunetuzumab study results reported earlier in December at the American Society of Hematology by Dr. Nancy Bartlett and colleagues (abstract no. 610) showed that 80% of 90 study participants with relapsed/refractory follicular lymphoma responded to a fixed duration of mosunetuzumab (up to 17 doses every 3 weeks) and 60% demonstrated a complete response (no

tumor detected). In comparison, a complete response rate of 14% has been demonstrated in historical controls.

Responses were also durable, with 48% of the patients still in remission 24 months after therapy was started. As is typical with this type of immunotherapy, cytokine release syndrome (CRS) did occur, although almost all cases were low grade, short lasting (median of 3 days) and all cases resolved. No late-onset or chronic toxicities were observed.

This important new treatment option is a great way to cap an exciting 2022 and open up another year that is sure to bring more exciting advances.

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