LymphomaHub

DLBCL

FDA grants polatuzumab vedotin priority review for the treatment of relapsed/refractory DLBCL

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On 19 February 2019, the US Food and Drug Administration (FDA) accepted a Biologics License Application (BLA) and granted priority review to polatuzumab vedotin, a first-in-class anti-CD79b antibody-drug conjugate, in combination with bendamustine and rituximab, for the treatment of patients with relapsed/refractory (R/R) diffuse large B cell lymphoma (DLBCL). This comes after polatuzumab vedotin received Breakthrough Therapy Designation from the FDA and Priority Medicine (PRIME) designation by the European Medicines Agency (EMA) in 2017.

The BLA for polatuzumab vedotin was based on data from the global, randomized phase Ib/II GO29365 study, which is assessing the tolerability, safety and activity of polatuzumab vedotin in combination with bendamustin and rituximab (BR), versus BR alone in patients with pre-treated R/R DLBCL. The results from this trial showed that polatuzumab vedotin in combination with BR improved median progression-free survival compared to BR alone (7.6 months *vs* 2.0 months). Furthermore, infection and transfusion rates were similar between the treatment arms. However, patients receiving polatuzumab vedotin in combination with BR had a higher rate of grade 3–4 cytopenias compared to patients receiving BR alone.

According to the drug manufacturers, polatuzumab vedotin treatment regimens could provide an “important new option to patients with this aggressive disease”, with this therapy demonstrating “improved clinical outcomes including survival in some people with relapsed or refractory diffuse large B-cell lymphoma” in a clinical trial setting.

References

1. GlobeNewswire. FDA grants priority review to Roche’s polatuzumab vedotin in previously treated aggressive lymphoma. https://globenewswire.com/news-release/2019/02/19/1733913/0/en/FDA-grants-Priority-Review-to-Roche-s-polatuzumab-vedotin-in-previously-treated-aggressive-lymphoma.html [Accessed 2019 Feb 19]