LymphomaHub

PTCL

FDA grants approval to brentuximab vedotin (Adcetris®) for frontline PTCL

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On 18 November 2018, brentuximab vedotin (Adcetris®) in combination with CHP chemotherapy (cyclophosphamide, doxorubicin, and prednisone) was granted approval by the U.S. Food and Drug Administration (FDA) for the treatment of adults with previously untreated systemic anaplastic large cell lymphoma or other CD30-expressing peripheral T-cell lymphomas (PTCL), including angioimmunoblastic T-cell lymphoma and PTCL not otherwise specified. This approval comes after brentuximab vedotin was granted Breakthrough Therapy Designation on 16 November 2018.

The approval granted by the FDA was based on the positive results obtained from the multi-center, randomized, double-blind, placebo-controlled phase III ECHELON-2 trial (NCT01777152) assessing Adcetris® in combination with CHP *versus* CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) alone, as a frontline therapy in patients with CD30-expressing PTCL.

The phase III ECHELON-2 study met its primary endpoint, demonstrating a statistically significant improvement in progression-free survival (PFS) of Adcetris® in combination with CHP *versus* CHOP as assessed by a Blinded Independent Central Review facility (BICR, HR = 0.71, 95% CI, 0.54–0.93, $P = 0.011$), corresponding to a 29% reduction in the risk of progression, death, or treatment of residual or progressive disease. In addition, Adcetris® plus CHP led to a superior overall survival compared to standard CHOP chemotherapy (HR = 0.66, 95% CI, 0.46–0.95, $P = 0.024$) in the treatment of CD30-expressing PTCL. The results of the phase III ECHELON-2 study will be presented at the American Society of Hematology (ASH) 2018 Annual Meeting.

According to the drug manufacturers, the FDA, approved Adcetris® via a new review program, Real-Time Oncology Review Pilot Program, which occurred less than two weeks from the date that the complete application was submitted.

References

1. PipelineReview: Seattle Genetics announces FDA approval of ADCETRIS® (Brentuximab Vedotin) in combination with chemotherapy for adults with previously untreated systemic anaplastic large cell lymphoma or other CD30-expressing peripheral T-Cell lymphomas. 2018 Nov 18. https://pipelinereview.com/index.php/2018111869772/Antibodies/Seattle-Genetics-Announces-FDA-Approval-of-ADCETRIS-Brentuximab-Vedotin-in-Combination-with-Chemotherapy-for-Adults-with-Previously-Untreated-Systemic-Anaplastic-Large-Cell-Ly.html. [Accessed 2018 Nov 19].