



PTCL

FDA grants Breakthrough Therapy Designation to brentuximab vedotin (Adcetris®) for frontline PTCL

 Philippa Redondo | Nov 16, 2018

On 15 November 2018, brentuximab vedotin (Adcetris®), an anti-CD30 monoclonal antibody attached via a protease-cleavable linker to a microtubule-disrupting agent, was granted Breakthrough Therapy Designation by the U.S. Food and Drug Administration (FDA) for the treatment of 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, in combination with CHP (cyclophosphamide, doxorubicin, and prednisone).

The Breakthrough Therapy Designation granted by the FDA was based on the positive results obtained from the randomized, double-blind, placebo-controlled phase III ECHELON-2 trial ([NCT01777152](https://clinicaltrials.gov/ct2/show/study/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 an Independent Review Facility (IRF; HR = 0.71, *P* = 0.0110). In addition, Adcetris® plus CHP led to a superior overall survival compared to standard CHOP chemotherapy (HR = 0.66, *P* = 0.0244) in the treatment of CD30-expressing PTCL.

According to the drug manufacturers, this is the third Breakthrough Therapy Designation granted for Adcetris®, which they say “supports their goal to make this therapy available to patients with newly diagnosed peripheral T-cell lymphomas as soon as possible.”

References

1. BusinessWire: FDA grants Breakthrough Therapy Designation to ADCETRIS® (Brentuximab Vedotin) for frontline peripheral T-Cell lymphomas. 2018 Nov 15. <https://www.businesswire.com/news/home/20181115005173/en/FDA-Grants-Breakthrough-Therapy-Designation-ADCETRIS%C2%AE-Brentuximab>. [Accessed 2018 Nov 16].

© 2018 Scientific Education Support Ltd. This PDF is provided for personal use only. For wider or commercial use, please seek permission from secretariat@scientificeducationsupport.com and attribute the source as: <http://www.lymphomahub.com/medical-information/fda-grants-breakthrough-therapy-designation-to-brentuximab-vedotin-adcetris-for-frontline-ptcl>