GvHDHub

aGvHD

CD3/CD7-IT receives Fast Track designation from the FDA for the treatment of steroid-refractory acute graft-versus-host disease (SR-aGvHD)

Paola Frisone | Oct 22, 2019

On the 14th of October 2019, the U.S. Food & Drug Administration (FDA) granted Fast Track designation to CD3/CD7-IT, for the treatment of SR-aGvHD in patients following allogeneic stem cell transplantation (allo-SCT).[1] CD3/CD7-IT received Orphan Drug Designation in the US for the treatment of graft-*vs*-host disease (GvHD) in 2013.[2]

CD3/CD7-IT is designed to reset the body's immune system in life-threatening T cell–mediated conditions and consists of combination of two antibodies (directed against T-cell antigens CD3 and CD7) both conjugated to an immunotoxin. CD3/CD7-IT has demonstrated *in vivo* depletion of mature T cells and NK cells with minimal treatment-related side effects, in preclinical and early phase studies.[1]

The FDA approval is based on a phase I/II study that showed that one week of CD3/CD7-IT treatment triggered a strong clinical response and doubled the six-month overall survival rate in SR-aGVHD patients.[3]

A US Phase III trial involving patients with SR-aGVHD following allo-SCT will soon begin.

References

1. Yahoo. Xenikos receives FDA Fast Track designation for T-Guard(R) for treating steroid-refractory acute graft-versus-host disease. Weblink [Accessed 22 Oct 2019]
2. Xenikos. T-Guard® Receives Orphan Drug Designation for Treatment of Graft versus Host Disease (GVHD) in the US https://www.xenikos.com/t-guard-receives-orphan-drug-designation-for-treatment-of-graft-versus-host-disease-gvhd-in-the-us/ [Accessed 22 Oct 2019]
3. Groth C. *et al.*, Phase I/II Trial of a Combination of Anti-CD3/CD7 Immunotoxins for Steroid-Refractory Acute Graft-versus-Host Disease. Biol Blood Marrow Transplant. 2019 Apr;25(4):712-719. DOI: 10.1016/j.bbmt.2018.10.020

© 2019 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: <https://gvhdhub.com/medical-information/cd3-cd7-it-receives-fast-track-designation-from-the-fda-for-the-treatment-of-steroid-refractory-acute-graft-versus-host-disease-sr-agvhd>