aGvHD

Abatacept granted breakthrough therapy designation for the prevention of acute GvHD

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Abatacept has been granted breakthrough therapy designation by the U.S. Food & Drug Administration (FDA) for the prevention of acute graft-*versus*-host disease (GvHD) in patients who have had hematopoietic stem cell transplantation (HSCT) from unrelated donors.[1]

Acute GvHD is a potentially life-threatening complication affecting up to 40% of patients who undergo HSCT from unrelated donors, there are currently no approved preventative therapies. Abatacept blocks donor T-cell activation by binding to and inhibiting proteins that are involved in co-stimulation, which results in stopping donor T cells from attacking the recipient's healthy cells.[2]

Breakthrough therapy designation was based on a phase II trial assessing abatacept plus standard GvHD prophylaxis in patients with hematologic malignancies treated with HSCT from unrelated donors. Leslie Kean, lead study investigator and the director of the stem cell transplantation program at Dana-Farber/Boston Children's Cancer and Blood Disorders Center, Boston, US said "A therapy that lowers the risk [for] GvHD in unrelated stem cell transplants would potentially allow more patients to receive a transplant, which typically is the last option to treat hematologic cancers, after other therapies have been used unsuccessfully." [1]

Abatacept is currently approved in the US for the treatment of certain arthritic conditions in both adults and children. [1]

References

1. Healio. FDA NEWS FDA grants Orencia breakthrough therapy designation to prevent acute GVHD. 2019 Dec 4. https://www.healio.com/hematology-oncology/bone-marrow-transplantation/news/online/%7B80f232f9-af14-46fd-83fb-7689d7c62efe%7D/fda-grants-orencia-breakthrough-therapy-designation-to-prevent-acute-gvhd. Published; December 4 2019, [Accessed December 5 2019]

2. Bristol-Myers Squibb Press Release. Bristol-Myers Squibb Announces U.S. FDA Breakthrough Therapy Designation for ORENCIA® (abatacept) to Help Prevent Acute Graft-Versus-Host Disease, a Potentially Life-Threatening Complication After Stem Cell Transplant. 2019 Dec 4. https://news.bms.com/press-release/rd-news/bristol-myers-squibb-announces-us-fda-breakthrough-therapy-designation-orencia. Published; December 4 2019, [Accessed December 5 2019]