



FOR IMMEDIATE RELEASE

American Society for Blood and Marrow Transplantation Announces Consensus Grading of CART Toxicities

CHICAGO, IL – January 30, 2019 – [The American Society for Blood and Marrow Transplantation](#) (ASBMT), a professional society dedicated to advancing the science and clinical care for patients who require blood and marrow transplants, today [released a paper](#) on chimeric antigen receptor (CAR) T cell therapy that proposes a new consensus grading scale for toxicities to be applied across clinical trials, academic research and commercial product development. CAR T cell therapy is considered one of the most promising new treatments for patients battling relapsed and refractory leukemia, lymphoma and other forms of cancer.

Currently, there are two commercially available treatments that use CAR T cell therapy in the United States and Europe – Yescarta (Kite/Gilead) and Kymriah (Novartis). These therapies treat patients by modifying their white blood cells (T cells) to better recognize and fight cancer cells. Several other therapies that reprogram and activate T cells in a similar way are also currently in clinical development. In some cases, CAR T cell therapy can lead to side effects: cytokine release syndrome (CRS) and neurological toxicity (now referred to as Immune effector Cell Associated Neurotoxicity Syndrome, or ICANS).

The assessment and grading of CRS and ICANS have varied considerably across clinical trials, academic studies, and commercial products, which has made it difficult to compare the safety and measure toxicity across all of these settings. This also has hindered the ability of researchers to develop the best strategies to manage these toxicities.

To solve this problem, the ASBMT supported three meetings in the summer and fall of 2018, where experts from all areas of the field gathered to develop a single definition and grading system for CRS and neurotoxicity. Participants included stakeholders from multiple major CAR T centers, commercial product industry representatives, the Center for International Blood and Marrow Transplant Research, the American Society of Hematology, the National Cancer Institute, and others.

According to the resulting paper released today, titled, “ASBMT Consensus Grading for Cytokine Release Syndrome and Neurological Toxicity Associated with Immune Effector Cells,” the meeting resulted in “new definitions and grading for CRS and neurotoxicity that are objective, easy to use, and ultimately more accurately categorize the severity of these toxicities.”

“Without a unified grading system in CAR T cell therapy, there have even been doctors at the same treatment center using different products in the same types of patients and reporting toxicities differently,” said Stephan Grupp, MD PhD, Section Chief of the Children’s Hospital of Philadelphia’s Cell

Therapy and Transplant Section, and one of the authors of the paper. “This has resulted in inconsistent assessments that prevent full understanding of the toxicity burden and hinder advancement of these therapies. Having entered the era of commercially available CAR T therapy products, it is crucial that data are reported in the same way. With the release of this ASBMT report, I believe stakeholders will see the added value of implementing a consistent grading system.”

“The response has been overwhelmingly positive both from the academic medical community as well as the industry all over the world including North America, Europe, and Asia,” noted paper co-author Dr. Sattva Neelapu, professor in the Department of Lymphoma/Myeloma at the University of Texas MD Anderson Cancer Center. “Everyone is eager to implement this new grading system at their hospitals, as well as in prospective clinical trials. I have talked to investigators at some of the major academic centers in the U.S., and all of them plan to switch to this new grading system soon.”

“I am incredibly proud of the work ASBMT and the authors have done highlighting the importance of a unified grading system in CAR-T cell therapy,” noted ASBMT President, Dr. John DiPersio MD, PhD. “This work furthers our advancement of the field of cellular transplantation and, more importantly, helps us give better care to our patients.”

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About the American Society for Blood and Marrow Transplantation

The American Society for Blood and Marrow Transplantation (ASBMT) is a professional society of more than 2,200 individuals from over 45 countries. The Society is dedicated to advancing the science and clinical care for patients who require blood and marrow transplants for blood cancers and other deadly diseases.