Department of Health and Human Services
Food and Drug Administration (FDA)
Center for Biologics Evaluation and Research (CBER)
Office of Biostatistics and Epidemiology (OBE)
Division of Epidemiology (DE)

ADDENDUM TO PHARMACOVIGILANCE PLAN REVIEW MEMORANDUM

From:	Deborah L. Thompson, MD, MSPH Medical Officer, Analytic Epidemiology Branch (AEB) DE, OBE, CBER, FDA
To:	Anna Kwilas Chair, Review Committee Office of Tissues and Advanced Therapies (OTAT), CBER, FDA
Through:	Manette Niu, MD Acting Branch Chief, AEB DE, OBE, CBER, FDA Meghna Alimchandani, MD Deputy Division Director, DE OBE, CBER, FDA
Subject:	Addendum to Review of Pharmacovigilance Plan
Sponsor:	Celgene Corporation, a Bristol-Myers Squibb Company
Product:	ABECMA® (idecabtagene vicleucel)
BLA Number:	STN 125736/0
Proposed Indication:	ABECMA is a B-cell maturation antigen (BCMA)-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adult patients with multiple myeloma who have received at least three prior therapies.
Submission Date:	July 27, 2020
Action Due Date:	March 26, 2021

1 Objective and Scope

The purpose of this addendum is to review updates to the Risk Evaluation and Mitigation Strategy (REMS) submitted under the original BLA 125736/0 for Abecma® (idecabtagene vicleucel).

2 Updates to Risk Evaluation and Mitigation Strategy (REMS)

The sponsor updated the REMS materials to align with the Boxed Warning and Warnings and Precautions information proposed by the OTAT clinical team, which includes the addition of hemophagocytic lymphohistiocytosis/macrophage activation syndrome (HLH/MAS) and prolonged cytopenia, and to further communicate these risks to healthcare providers. Specifically, the Abecma REMS Training Program was updated to incorporate slides containing the full Boxed Warning and separate slides for the risks of HLH/MAS and prolonged cytopenia. In addition, the sponsor added two questions to the Knowledge Assessment pertaining to the evaluation and management of patients with CRS and HLH/MAS and the risk of prolonged cytopenia.

<u>Reviewer comment:</u> FDA requested that the final REMS materials be aligned with the content and language agreed to in the final label. The goals of the Abecma REMS remain the same: to mitigate the risks of cytokine release syndrome (CRS) and neurologic toxicity (NT) by 1) ensuring hospitals and associated clinics that dispense Abecma are specially certified and have immediate access to tocilizumab, and 2) ensuring that those who prescribe, dispense, or administer Abecma are aware of how to manage the risks of CRS and NT. There are no changes to the REMS program elements to assure safe use (ETASU).

3 DE Conclusions and Recommendations

The sponsor updated the REMS program materials to align with the proposed Boxed Warning and Warnings and Precautions information for HLH/MAS and prolonged cytopenia. The final content of the REMS program materials should align with the package insert. Please see the final version of the REMS Document, REMS materials, and package insert submitted by the sponsor for the final agreed-upon content and language.