Alliance for Regenerative Medicine Applauds FDA's Elimination of REMS Requirements and Labeling Changes for Autologous CAR-T Cell Therapies

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The Alliance for Regenerative Medicine (ARM), the leading international advocacy organization championing the benefits of engineered cell therapies and genetic medicines, commends the U.S. Food and Drug Administration (FDA) for its decision to eliminate the Risk Evaluation and Mitigation Strategies (REMS) program and reduce other labeling restrictions for autologous CAR-T cell therapies. This evidence-based decision significantly lowers barriers for physicians administering and patients seeking these transformative treatments.

Despite being available in the U.S. market for several years, CAR-T therapies approved to treat several types of blood cancers have been inaccessible to 80% of eligible patients because of complex geographic, financial, and logistical hurdles. The FDA removed the REMS program for six approved CAR-T therapies based on current real-world safety data and clinical experience, reducing the burden on physicians and healthcare systems providing these treatments. The changes should also make it easier for these therapies to be delivered outside of specialized treatment centers closer to where many patients live.

Beyond the removal of the REMS program, the labeling changes alleviate the logistical and financial burden on patients seeking treatment with CAR-T. Patients will only need to stay in proximity to a specialized treatment center for two weeks, as opposed to previously being four weeks, and can drive two weeks after treatment, which is down from eight weeks. These changes are based on data showing that most serious adverse events – including cytokine release syndrome and neurologic toxicities – occur within two weeks of treatment.

"This is a very positive development for patients facing blood cancers and for the broader cell therapy community," said Tim Hunt, Chief Executive Officer of ARM. "Some 80% of eligible patients have been unable to access CAR-T therapies in recent years, partly because of where they live or their ability to navigate complex treatment requirements. The FDA's actions will help more patients access these life-saving treatments and reflect a strong commitment to evolve regulatory standards at the pace of innovation in cell and gene therapy."

ARM and its members have extensively engaged with the Department of Health and Human Services and the FDA on CAR-T class labeling restrictions, bringing an evidence-based perspective based on real-world data generated by respected academic experts.

As the cell and gene therapy sector matures, ARM looks forward to ongoing collaboration with the FDA and other stakeholders to ensure regulatory policies keep pace with innovation while maintaining patient safety and trust.

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About the Alliance for Regenerative Medicine

The Alliance for Regenerative Medicine (ARM) is the leading international advocacy organization championing the benefits of engineered cell therapies and genetic medicines for patients, healthcare systems, and society. As a community, ARM builds the future of medicine by convening the sector, facilitating influential exchanges on policies and practices, and advancing the narrative with data and analysis. We actively engage key stakeholders to enable the development of advanced therapies and to modernize healthcare systems so that patients benefit from durable, potentially curative treatments.