**CART-Cells Agents and the Post-Marketing Reported Patients Adverse Events Cases**

**Ollie Anum, B.S., PharmD BenV Health Ministry Center & Research- Patient Advocacy**

**Abstract**

**Background**: The United States, Food and Drugs Administration (FDA) has strongly supported innovation in Development of Gene Therapy, including CART-cells. The FDA Adverse Events Reporting System (FAERS) have shown annually that over million adverse-event and medication-error reporting are associated with drugs or biological products used to manage a condition or a disease. Since 1968 to February 6, 2020, FDA has 19, 184,658-total cases; 10,700,950-serious cases excluding death; 1,861,988-death cases and 10,226,913-total expedited cases. These reports are used by FDA to monitor the safety of drugs and biological products. However, FDA indicated that these reports are valuable source of information, but this surveillance-system cannot rule out the potential submission of incomplete, inaccurate, untimely, unverified information, duplicate reporting, concomitant medications and underlying-disease. Also, the incidence and prevalence cannot be determined from the reporting-system alone because of potential under or over reporting of events. The FDA indicated that FAERS-data do not represent all known safety information for a reported drug and should be interpreted in the context of other available information when making drug related or treatment decision.

**Hypothesis:** To determine the risk and benefits of CART-cells Post-Marketing Patient-Safety

**Methods:** Of the over million adverse-event and medication-error submitted to FDA annually, on drugs or biological products, a search on two CART-cells agents (i.e., tisagenlecleucel, axicabtagene-ciloleucel) was done at FDA.gov website. Data-analysis from 2017 to February 6, 2020 is stratified based on age, sex and report-source

**Results:** Of these reports;845-total cases, 796-serious cases including deaths, 170-death cases were from tisagenlecleucel and 1094-total cases, 1,023-serious cases including deaths, 131-death cases were from axicabtagene-ciloleucel. Some reported cases are Cytokines Release Syndrome (CRS) (433), pyrexia (314) for tisagenlecleucel and CRS (725), pyrexia (227) for axicabtagene-ciloleucel. The odd-ratio of the CART-cells agents Post-Marketing for CRS and Death outcomes are 0.54 and 1.83 respectively.

**Conclusion**: Reporters are encouraged to submit complete-detail and accurate adverse events that is used to monitor or improve safety awareness of the CART-cells agents and there is no report on Replication-Competent-Virus.