Cell Therapy for Multiple Myeloma

Vaccination with Dendritic Cell/Myeloma Fusion Post-Transplant for Multiple Myeloma

Introduction

The BMT CTN 1401 study was designed as a Phase II, multicenter trial of vaccination with Dendritic Cell (DC)/ myeloma fusions with granulocyte macrophage colony- stimulating factor (GM-CSF) adjuvant plus lenalidomide maintenance therapy versus maintenance therapy alone or with GM-CSF following autologous transplant as part of upfront treatment of multiple myeloma. The primary objective was to compare the proportion of patients alive and in complete response at one year post transplant between patients receiving DC/myeloma vaccine/ GM-CSF with lenalidomide maintenance therapy to those receiving lenalidomide maintenance therapy with or without GM-CSF.

Date Published: 11/08/2023 | Emmes- Cell Therapy for Multiple Myeloma- V:01

Two-hundred and three patients were enrolled and 140 patients underwent transplantation and then were randomized from 14 US institutions.

A collaborative process was established for vaccine manufacturing including tumor cell harvest and cryopreservation, DC generation from leukopheresis collection, and creation and quantification of the DC/tumor fusion vaccine.

This study was funded by Celgene and the NHLBI/NCI. This study utilizes immune therapy in which patient-derived myeloma cells were fused with autologous dendritic cells. Vaccination with DC/myeloma fusion cells following autologous transplant was hypothesized to create an immune response and conversion of patients from a partial response to a complete response.

Outline of challenges and how they were overcome

The major challenge in this study was translating a single center manufacturing approach into a multi-center local manufacturing of the DC/myeloma fusion vaccine.

The study team was able to overcome this challenge by working with the FDA on a well defined training and education process. The lead lab at the Beth Israel Deaconess Medical Centers served as the manufacturing core managed by the study team at Emmes. The study team developed a series of standard operating procedures (SOPs) to facilitate the manufacturing process. Emmes led the management of the SOPs and oversaw compliance with the SOPs.

Very detailed oversight of the institutions by Emmes and the manufacturing core allowed this study to be completed. The study team had frequent communication with the FDA during the entire study.

Trial outcome, highlights and achievements

01

Enrollment was completed a year ahead of schedule.

02

Demonstrated successful site-specific production.

03

While DC/MM fusion vaccination with lenalidomide maintenance after autologous transplant did not result in a significant increase in CR rates at 1-year, the associated measurable anti-MM immune reactivity for which the impact on responseduration is currently being assessed.

04

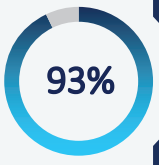
1-year results were presented at the 2021 Transplant and Cellular Therapy meeting.

Key Data

1

Randomization rate was **30%** as pre-specified in the protocol.

Vaccine was successfully generated for **63** out of **68** patients **(93%)**.



2

3

36 of the **68 (52.9%)** evaluable patients on the vaccine arm and **34** of the **68 (50.0%)** of the non-vaccine arms achieved CR/sCR at 1-year post-transplant **(p=0.3)**.

Patients in the vaccine arm demonstrated a significant and persistent expansion of MM-reactive CD8 cells as defined by the percentage of cells expressing IFNgamma upong exposure to autologous tumor lysate.

4

For additional information on Clinical Trial Management, please visit:
www.emmes.com/site-monitoring-and-management

Date Published: 11/08/2023 | Emmes- Cell Therapy for Multiple Myeloma- V:01

Emmes