Phase I Study Data Update of PHE885, a Fully Human BCMA-Directed CAR-T Cell Therapy Manufactured Using the T-Charge™ Platform for Patients With Relapsed/Refractory Multiple Myeloma

Adam S. Sperling, Sarah Nikiforov, Ben Derman, Omar Nadeem, Clifton Mo, Jacob Laubach, Kenneth Anderson, Alejandro Alonzo, So-Yeon Im, Shuntaro Ikegawa, Do Prabhala, Diego Hernandez Rodriguez, Heather Daley, Kit L. Shaw, Yohi Anihara, Yifang Li, David S. Quinn, David Pearson, Anniesha Hack, Louise Treenor, Dexis Bu, Jennifer Matsuzaki, Lawrence Rispoli, Marc Credi, Jerome Rita, Andzej Jakubowiski, Serene De Vita, Nikhil Munshi

BACKGROUND

CAR-T Cells and PHE885

- BCMA-directed CAR-T cells are an emerging therapeutic option for the treatment of multiple myeloma.
- PHE885 is a fully human CAR-T cell therapy that targets the BCMA receptor.

Study Design

- Phase I study designed to evaluate safety, tolerability, and preliminary antitumor activity.
- Dose-escalation phase followed by an expansion phase.

Methods

- Eligibility criteria:
  - Patients with MM to date of trial registration.
  - BCMA-directed treatment (ipilimumab and lenalidomide) required.
  - Anti-CD20 monoclonal antibodies, alemtuzumab.

- Treatment:
  - Patients received PHE885 at 5×10^5 cells.
  - Treatment phase 3 ± 14 days.

- Outcome measures:
  - Clinical responses (CR, VGPR, PR).
  - Duration of response.
  - Safety profile.

Results

- Baseline characteristics of patients:
  - Median age: 64 years (range: 37-79).
  - Induction chemotherapy: 21/27 (78%).
  - Median number of prior regimens: 4 (range: 2-10).

- Clinical responses:
  - VGPR: 1 (25%), PR: 7 (54%), SD: 9 (69%), PD: 1 (4%).
  - ORR: 8 (38%).

- T-Charge™ Process Preserves T-Cell Stemness in Final Product

- Cell phenotype of CD4 and CD8 subsets in leukapheresis and PHE885 final product measured by flow cytometry.

- PHE885 Seemed Robust to Cellular Expansion in All Patients

- Cellular kinetics of PHE885 were measured and evaluated by polyclonal reactivity.

- Clinical responses occur rapidly and deepen over time.

- Long-term persistence data is not yet available for the 10×10^6 cells.

- Maximum persistence of at least 12 months was observed at doses 1×10^6 and 5×10^6.

- PHE885 is manufactured using the novel T-Charge™ platform.

- Treatment and follow-up phase

- 2 years

- Up to 18 years

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Disclosures

The authors declare no conflicts of interest.