The treatment of cancer patients with autologous T cells expressing a chimeric antigen receptor (CAR) is one of the most promising adoptive cellular therapy approaches. Reproducible manufacturing of high-quality, clinical-grade CAR-T cell products is required for the wide utilization of such technology. The manufacturing process established at Kite Pharma to support phase I/II clinical trials utilizing KTE-C19 in hematological malignancies aimed to improve productivity, maximize manufacturing success rate and minimize timing between leukapheresis collection and KTE-C19 administration at bedside. The manufacturing process initiates with the enrolled subjects undergoing to leukapheresis procedure to target collection of mononuclear cells (MNCs). After collection, leukapheresis material is shipped to the central manufacturing site and processed. T cells are activated, transduced with a gamma retroviral vector that encodes the CAR gene and further expanded for 3 to 5 days to achieve the target dose of 2 x 10^6 CAR positive T cells/kg body weight (minimum of 1 x 10^6). Final KTE-C19 product is washed, formulated, cryopreserved and tested for identity, potency, and safety. After acceptance criteria were met, the KTE-C19 was shipped to the clinical site using a validated cryoshipper.

The manufacturing process has been able to successfully generate KTE-C19 products for patients enrolled in Kite sponsored trials allowing a rapid turnaround from patient leukapheresis collection to product administration.