

STATEMENT ON A NONPROPRIETARY NAME ADOPTED BY THE USAN COUNCIL

USAN (LM-239)

PRULACABTAGENE LEUCEL

PRONUNCIATION

proo" la kab' ta jeen loo' sel

THERAPEUTIC CLAIM

Antineoplastic; Treatment of Non-Hodgkin lymphoma or other B cell malignancies; Treatment of Autoimmune diseases

DESCRIPTION

Drug Product (ADI-001), is composed of healthy donor-derived $\gamma\delta$ T cells enriched for the V δ 1 $\gamma\delta$ T cell subset. In addition, ADI-001 is demonstrated to be viable, as assessed by viable dye exclusion, and are depleted of residual $\alpha\beta$ T cells. ADI-001 contains cells that express a chimeric antigen receptor (CAR) targeting CD20 (MS4A1), a surface antigen found on non-malignant and malignant B cells. The CAR is introduced via a gamma-retroviral vector (AR3751) during the manufacture of the cellular ADI-001 Drug Substance. Additionally, for information only, approximately 97.9% of ADI-001 cells, on average, are routinely defined by multiparametric flow cytometry to identify and enumerate monocytes, B cells, natural killer (NK) cells and other V δ 1- cells including V δ 2 $\gamma\delta$ and V δ 1-V δ 2- $\gamma\delta$ T cells.

ADI-001 is a sterile suspension for injection and is packaged in 6 mL vials (with a nominal extractable volume of 5 mL) with a rigid body made of a cyclo-olefin co-polymer and a stopper comprised of a thermoplastic elastomer. ADI-001 is stored in liquid nitrogen vapor phase ($\leq -120^{\circ}\text{C}$). ADI-001 is a translucent to opaque cell suspension that is colorless to slightly yellow and practically free of foreign particulates. ADI-001 is comprised of the ADI-001 Drug Substance formulated to target $3.0\text{E}7$ viable cells/mL. $\gamma\delta$ T cells are an attractive candidate for allogeneic CAR T cell therapy for a number of reasons:

- 1) they combine innate and adaptive mechanisms to recognize and kill malignant cells,
- 2) their prevalence in both hematological and solid tumors is associated with clinical benefit, and
- 3) they do not initiate graft-versus-host-disease (GvHD).

TRADEMARKS

None

SPONSOR

Adicet Therapeutics Inc

DESIGNATION CODE

ADI-001

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WHO NUMBER

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