STATEMENT ON A NONPROPRIETARY NAME ADOPTED BY THE USAN COUNCIL

USAN (MN-69) **Formerly (HI-45)**	LIFILEUCEL
PRONUNCIATION	lif” i loo’ sel
THERAPEUTIC CLAIM	Cellular immunotherapy for treatment of cancer

DESCRIPTION

Autologous tumor-infiltrating lymphocytes (TIL) derived from the patient's own tumor.

Cellular identity: Tumor-infiltrating lymphocytes (TIL)

Culture conditions: The process for manufacturing lifileucel begins at the clinical site with the excision of tumors of ≥ 1 cm from metastatic sites, including lymph nodes. Tumor tissue is placed in media and shipped by overnight courier to the GMP centralized manufacturing site, in cooled (2-8°C) temperature-monitored containers. Next, in the pre rapid expansion protocol (pre-REP) step, small fragments of patient tumor are cultured with human recombinant interleukin 2 (IL-2) in a small scale culture for 11 days to generate ≥ 5 million TIL. TIL numbers are expanded using the rapid expansion protocol (REP), in which the pre-REP TIL are cultured for an additional 11 days in the presence of feeder cells (irradiated allogeneic mononuclear cells from normal donors), IL-2, and the OKT3 anti-CD3 antibody (for T-cell stimulation). The culture is then harvested and the cells washed, concentrated, and suspended in a final transport media and cryopreserved (≤ -150°C). The product is shipped by courier to the treatment site in temperature-monitored containers.

Human culture expanded activated autologous T cells for cell-based immunotherapy. The cell substance is a heterogeneous mixture consisting of CD4+ and CD8+ tumor-infiltrating lymphocytes (TIL), derived from isolated metastatic tumor biopsy of patients with solid tumors, and cultured in the presence of feeder cells (irradiated allogeneic mononuclear cells from healthy donors) and human recombinant interleukin 2 (IL-2)/OKT3 anti-CD3 antibody (muromonab-CD3 (59)(29)) for T-cell activation. (Source: INN PL118)

TRADEMARK	AMTAGVI
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