

# The Medical Letter<sup>®</sup>

## on Drugs and Therapeutics

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Article

### IN THIS ISSUE

Obecabtagene Autoleucel (*Aucatzyl*) – Another CAR-T Cell Immunotherapy for ALL

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**Obecabtagene Autoleucel (*Aucatzyl*) – Another CAR-T Cell Immunotherapy for ALL**

### IN BRIEF

#### Obecabtagene Autoleucel (*Aucatzyl*) – Another CAR-T Cell Immunotherapy for ALL

Obecabtagene autoleucel (*Aucatzyl* – Autolus), a CD19-directed genetically modified autologous T cell immunotherapy, has been approved by the FDA for treatment of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) in adults. The CAR T-cell immunotherapy products tisagenlecleucel (*Kymriah*) and brexucabtagene auto-leucel (*Tecartus*) were approved earlier for the same indication.<sup>1,2</sup>

#### Pronunciation Key

Obecabtagene autoleucel: oh bee kab' ta jeen aw" toe loo' sel  
*Aucatzyl*: aw kat zil

**THE PRODUCT** – *Aucatzyl* is an individualized cellular product prepared from the patient's own T cells, which are genetically modified to express chimeric antigen receptors (CAR) and then infused back into the patient. The T cells are sent to a commercial laboratory, which genetically modifies them using a lentiviral vector to encode an anti-CD19 CAR transgene. *Aucatzyl* is supplied in 3 to 5 patient-specific infusion bags.

**CLINICAL STUDIES** – In a single-arm trial (FELIX) that included 94 patients with relapsed or refractory B-cell ALL with morphologic disease, after a median follow-up of 20.3 months, overall remission was achieved in 77% of patients, complete remission in 55%, and complete remission with incomplete hematologic recovery in 21% who received obecabtagene autoleucel. The median duration of response was 14.1 months.<sup>3</sup>

No trials directly comparing *Aucatzyl* with *Kymriah* or *Tecartus* for treatment of relapsed or refractory B-cell precursor ALL are available.

**ADVERSE EFFECTS** – *Aucatzyl* can cause prolonged cytopenias, severe and fatal infections, hypogammaglobulinemia, and hemophagocytic lymphohistio-

cytosis/macrophage activation syndrome. The label includes a boxed warning about the risks of immune effector cell-associated neurotoxicity syndrome (ICANS), T cell malignancies, and cytokine release syndrome (CRS), a common complication of CAR T-cell immunotherapy that can cause hypotension, pulmonary edema, coagulopathy, multiorgan failure and death, associated with its use. In the FELIX trial, CRS occurred in about 70% of patients and neurologic toxicity occurred in about 23%. Grade 3 or higher CRS occurred in about 2% of patients. Unlike *Kymriah* and *Tecartus*, which are available only through a Risk Evaluation Mitigation Strategy (REMS) program due to risks of CRS and neurologic toxicity, a REMS program is not required with *Aucatzyl*.

**DOSAGE, ADMINISTRATION, AND COST** – Cyclophosphamide and fludarabine lymphodepleting chemotherapy should be administered before infusion of  $410 \times 10^6$  CD19 CAR-positive viable T cells. The CAR T cells are given as a split dose infusion on days 1 and 10. Acetaminophen should be administered about 30 minutes before infusion of *Aucatzyl*. Patients should be monitored at the treatment facility for at least 2 weeks after the infusion and should stay near the treatment facility for at least 4 weeks.

The wholesale acquisition cost (WAC) of *Aucatzyl* is \$525,000. *Tecartus* costs \$462,000 and *Kymriah* costs \$582,000.<sup>4</sup> ■

1. Tisagenlecleucel (*Kymriah*) for ALL. *Med Lett Drugs Ther* 2017; 59:177.
2. In brief: Brexucabtagene autoleucel (*Tecartus*) for acute lymphoblastic leukemia. *Med Lett Drugs Ther* 2023; 65:e105.
3. C Roddie et al. Obecabtagene autoleucel in adults with B-cell acute lymphoblastic leukemia. *N Engl J Med* 2024 November 27 (epub).
4. Approximate WAC. WAC = wholesaler acquisition cost or manufacturer's published price to wholesalers; WAC represents a published catalogue or list price and may not represent an actual transactional price. Source: AnalySource® Monthly. December 5, 2024. Reprinted with permission by First Databank, Inc. All rights reserved. ©2024. [www.fdbhealth.com/policies/drug-pricing-policy](http://www.fdbhealth.com/policies/drug-pricing-policy).

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