Adcetris® (brentuximab vedotin) – New indication

- On November 16, 2018, the FDA announced the approval of Seattle Genetics' Adcetris (brentuximab vedotin), for the treatment of adult patients with previously untreated systemic anaplastic large cell lymphoma (sALCL) or other CD30-expressing peripheral T-cell lymphomas (PTCL), including angioimmunoblastic T-cell lymphoma and PTCL not otherwise specified, in combination with cyclophosphamide, doxorubicin, and prednisone (CHP).

- Adcetris is also approved for adult patients with: (1) previously untreated Stage III or IV classical Hodgkin lymphoma (cHL), in combination with chemotherapy; (2) cHL consolidation; (3) relapsed cHL; (4) relapsed sALCL; and (5) relapsed primary cutaneous anaplastic large cell lymphoma or CD30- expressing mycosis fungoides.

- This is the first FDA approval for treatment of newly diagnosed PTCL and the FDA used the Real-Time Oncology Review (RTOR) pilot program to complete the approval.

    — RTOR allows the FDA to access key data prior to the official submission of a drug application. The FDA approved this indication within two weeks of the completed submission.

- PTCLs are rare, fast-growing non-Hodgkin lymphomas that develop from T-cells. The T-cells often spread quickly throughout the body and are hard to treat. PTCL accounts for approximately 10% of the estimated 74,680 people diagnosed with non-Hodgkin lymphoma in the U.S. in 2018.

- The new indication for Adcetris was based on data from ECHELON-2, a double-blind study in 452 adult patients with previously untreated, CD30-expressing PTCL. Patients received Adcetris plus CHP or CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone). Efficacy was based on progression free survival (PFS). Other efficacy endpoints included overall survival (OS), PFS in patients with sALCL, complete response rate, and overall response rate (ORR).

    — Median PFS was 48.2 months (95% CI: 35.2, not estimable) for Adcetris plus CHP vs. 20.8 months (95% CI: 12.7, 47.6) for CHOP (HR = 0.71; 95% CI: 0.54, 0.93; p = 0.011).
    — Adcetris plus CHP demonstrated superior OS vs. CHOP (HR = 0.66; 95% CI: 0.46, 0.95; p = 0.024).
    — All other key secondary endpoints, including PFS in patients with sALCL (HR = 0.59; 95% CI: 0.42, 0.84; p = 0.003), complete response rate (68% vs. 56%; p = 0.007) and ORR (83% vs. 72%; p = 0.003) were also statistically significant in favor of Adcetris plus CHP.

- Adcetris carries a boxed warning for progressive multifocal leukoencephalopathy.

- The recommended dose of Adcetris for previously untreated sALCL or other CD30-expressing PTCL is an intravenous infusion of 1.8 mg/kg up to a maximum of 180 mg, given in combination with chemotherapy. Adcetris is administered every 3 weeks with each cycle of chemotherapy for 6 to 8 doses.

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- In patients with previously untreated PTCL who are treated with Adcetris plus CHP, granulocyte-colony stimulating factor should be administered beginning with cycle 1.
- Refer to the Adcetris drug label for dosing information for all other indications.
- Refer to individual chemotherapy drug labels for dosing information.