Adcetris® (brentuximab vedotin) – New indication

- On February 12, 2025, Pfizer announced the FDA approval of Adcetris (brentuximab vedotin), in combination with lenalidomide and a rituximab product, **for the treatment of adult patients with relapsed or refractory large B-cell lymphoma (LBCL), including diffuse large B-cell lymphoma (DLBCL) NOS, DLBCL arising from indolent lymphoma, or high-grade B-cell lymphoma (HGBL), after two or more lines of systemic therapy who are not eligible for auto-hematopoietic stem-cell transplantation (HSCT) or chimeric antigen receptor (CAR) T-cell therapy**.

- Adcetris is also approved for the treatment of:

    - Previously untreated stage III or IV classical Hodgkin lymphoma (cHL), in combination with chemotherapy.
    - Previously untreated high risk cHL, in combination with chemotherapy
    - cHL consolidation
    - Relapsed cHL
    - Previously untreated systemic anaplastic large cell lymphoma (sALCL) or other CD30-expressing peripheral T-cell lymphomas (PTCL), in combination with chemotherapy
    - Relapsed sALCL
    - Relapsed primary cutaneous anaplastic large cell lymphoma (pcALCL) or CD30-expressing mycosis fungoides.

- The approval of Adcetris for the new indication was based on ECHELON-3, a randomized, double-blind, placebo-controlled study in 230 patients 18 years of age and older with relapsed or refractory LBCL. Patients were randomized to receive Adcetris plus lenalidomide and a rituximab product or to receive placebo plus lenalidomide and a rituximab product until disease progression or unacceptable toxicity. The major efficacy outcome was overall survival (OS). Additional efficacy outcome measures included progression free survival (PFS) and objective response rate (ORR).

    - Median OS was 13.8 months and 8.5 months in the Adcetris and placebo arms, respectively (hazard ratio [HR] 0.63, 95% CI: 0.45, 0.89; p = 0.0085).
    - Median PFS was 4.2 months and 2.6 months in the Adcetris and placebo arms, respectively (HR 0.53, 95% CI: 0.38, 0.73; p < 0.0001).
    - The ORR was 64.3% (95% CI: 54.7, 73.1) and 41.5% (95% CI: 32.5, 51.0) in the Adcetris and placebo arms, respectively (p = 0.0006).

- Adcetris carries a boxed warning for progressive multifocal leukoencephalopathy.

- The recommended dose of Adcetris for the treatment of LBCL is **1.2 mg/kg intravenously up to a maximum of 120 mg** in combination with lenalidomide and rituximab. Adcetris should be **administered every 3 weeks** until disease progression, or unacceptable toxicity.

    - Refer to the Adcetris drug label for dosing for all its other indications.