Adcetris® (brentuximab vedotin) – New indication

- On November 10, 2022, Seagen announced the FDA approval of Adcetris (brentuximab vedotin), for the treatment of pediatric patients 2 years and older with previously untreated high risk classical Hodgkin lymphoma (cHL), in combination with doxorubicin, vincristine, etoposide, prednisone, and cyclophosphamide.

- Adcetris is also approved for adult patients for previously untreated stage III or IV 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, in combination with chemotherapy; relapsed sALCL; relapsed primary cutaneous anaplastic large cell lymphoma or CD30-expressing mycosis fungoides.

- The approval of Adcetris for the new indication was based on AHOD1331, a randomized, open-label, active-controlled study in 600 pediatric patients (2 to < 22 years of age) with previously untreated high risk cHL. Patients were randomized to Adcetris + doxorubicin [A], vincristine [V], etoposide [E], prednisone [P], cyclophosphamide [C] (ADCETRIS + AVEPC) or to A+ bleomycin [B]+V+E+P+C (ABVE-PC). Efficacy was established based on event-free-survival (EFS), defined as the time from randomization to the earliest of disease progression or relapse, second malignancy, or death due to any cause.

    — Patients had a 59% reduction in the risk of disease progression or relapse, second cancer or death (hazard ratio 0.41; 95% CI: 0.25, 0.67; p = 0.0002).

- Adcetris carries a boxed warning for progressive multifocal leukoencephalopathy.

- The recommended dose of Adcetris for the treatment of pediatric patients with previously untreated high risk cHL is 1.8 mg/kg intravenously up to a maximum of 180 mg in combination with chemotherapy. Adcetris should be administered every 3 weeks with each cycle of chemotherapy for a maximum of 5 doses.

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