Adcetris® (brentuximab vedotin) – New indication

- On November 9, 2017, Seattle Genetics announced the FDA approval of Adcetris (brentuximab vedotin) for the treatment of adult patients with primary cutaneous anaplastic large cell lymphoma (pcALCL) or CD30-expressing mycosis fungoides (MF) who have received prior systemic therapy.

- Adcetris is also approved for the treatment of:

    - Adult patients with classical Hodgkin lymphoma (cHL) at high risk of relapse or progression as post-autologous hematopoietic stem cell transplantation (auto-HSCT) consolidation.
    - Adult patients with cHL after failure of auto-HSCT or after failure of ≥ 2 prior multi-agent chemotherapy regimens in patients who are not auto-HSCT candidates.
    - Adult patients with systemic ALCL after failure of ≥ 1 prior multi-agent chemotherapy regimen.

- MF and pcALCL are the most common subtypes of cutaneous T-cell lymphoma (CTCL), a category of non-Hodgkin lymphoma that primarily involves the skin.

    - CTCL typically presents as red, scaly patches or thickened plaques of skin that often mimic eczema or chronic dermatitis. Progression from limited skin involvement may be accompanied by skin tumor formation, ulceration, and exfoliation. Advanced stages are defined by involvement of lymph nodes, peripheral blood and internal organs.
    - CTCL represents approximately 4% of non-Hodgkin lymphoma, or an estimated 2,800 patients.

- Adcetris' new indication was approved based on the ALCANZA trial, which involved 131 patients with pcALCL. ALCANZA was designed to compare Adcetris monotherapy to physician's choice of methotrexate or bexarotene. The primary endpoint was the proportion of patients achieving an objective response rate that lasted at least 4 months (ORR4).

    - In the trial, the Adcetris treatment arm achieved a statistically significant improvement in ORR4 vs. the control arm (56.3% vs. 12.5%, $p < 0.001$).
    - Supportive trials included two single-arm trials. Out of 73 patients with MF from these pooled supportive trials, 34% achieved ORR4. Among those with CD30-expression, 31% achieved ORR4.

- Adcetris carries a boxed warning regarding the risk of progressive multifocal leukoencephalopathy.

- In pcALCL or CD30-expressing MF, the recommended dosage of Adcetris is 1.8 mg/kg (up to a maximum of 180 mg) given intravenously every 3 weeks until a maximum of 16 cycles, disease progression, or unacceptable toxicity.

    - For the recommended dosages, frequencies, and durations of Adcetris in other FDA-approved indications, please refer to the drug label.