Adcetris® (brentuximab vedotin) – New indication

- On March 20, 2018, the FDA announced the approval of Seattle Genetics' Adcetris (brentuximab vedotin) for the treatment of adult patients with previously untreated Stage III or IV classical Hodgkin lymphoma (cHL), in combination with chemotherapy.

- Adcetris is also approved in adult patients for the following:

    - Treatment of cHL at high risk of relapse or progression as post-autologous hematopoietic stem cell transplantation (auto-HSCT) consolidation.
    - Treatment of cHL after failure of auto-HSCT or after failure of at least two prior multi-agent chemotherapy regimens in patients who are not auto-HSCT candidates.
    - Treatment of systemic anaplastic large cell lymphoma (sALCL) after failure of at least one prior multi-agent chemotherapy regimen.
    - Treatment of primary cutaneous anaplastic large cell lymphoma or CD30-expressing mycosis fungoides who have received prior systemic therapy.

- According to the American Cancer Society, approximately 8,500 cases of Hodgkin lymphoma will be diagnosed in the U.S. during 2018 and more than 1,000 will die from the disease. Approximately half of all newly diagnosed Hodgkin lymphoma patients have Stage III/IV disease.

- The efficacy of Adcetris in combination with chemotherapy for the treatment of previously untreated Stage III/IV cHL was based on a clinical study of 1,334 patients randomized to Adcetris plus chemotherapy [doxorubicin, vinblastine, and dacarbazine (AVD)] or a chemotherapy-only regimen (AVD plus bleomycin, also known as ABVD).

    - The main endpoint was modified progression-free survival (PFS), defined as progression, death, or receipt of additional anticancer therapy for patients who are not in a complete response (CR) after completing frontline therapy.
    - After patients received an average of six 28-day cycles of treatment, the Adcetris group was 23% less likely to experience the main endpoint vs. those receiving chemotherapy alone (HR = 0.77 [95% CI: 0.60, 0.98]; p = 0.035).
    - There were 117 (18%) patients in the Adcetris group who experienced disease progression, death, or began new therapy vs. 146 (22%) patients in the chemotherapy-alone group.
    - At the time of the modified PFS analysis, an interim overall survival analysis did not demonstrate a significant difference. The CR rate at the end of the randomized regimen was 73% in the Adcetris arm vs. 70% in the chemotherapy-alone arm.

- Adcetris carries a boxed warning for progressive multifocal leukoencephalopathy.

- The recommended dose of Adcetris for previously untreated stage III/IV cHL is an intravenous infusion of 1.2 mg/kg up to a maximum of 120 mg, given in combination with chemotherapy. Adcetris is administered every 2 weeks until a maximum of 12 doses, disease progression, or unacceptable toxicity.

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- In patients with previously untreated stage III/IV cHL who are treated with Adcetris plus AVD, granulocyte-colony stimulating factor should be administered beginning with cycle 1.
- Refer to the Adcetris drug label for dosing information for all other indications.