Monjuvi® (tafasitamab-cxix) – New drug approval

- On January 31, 2020, Morphosys and Incyte announced the FDA approval of Monjuvi (tafasitamab-cxix), in combination with Revlimid® (lenalidomide) for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from low grade lymphoma, and who are not eligible for autologous stem cell transplant (ASCT).
    - This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).
- DLBCL is the most common type of non-Hodgkin lymphoma in adults worldwide, characterized by rapidly growing masses of malignant B-cells in the lymph nodes, spleen, liver, bone marrow or other organs. It is an aggressive disease with about one in three patients not responding to initial therapy or relapsing thereafter.
    - In the U.S. each year approximately 10,000 patients are diagnosed with relapsed or refractory DLBCL who are not eligible for ASCT.
- Monjuvi is a Fc-modified monoclonal antibody that binds to CD19 antigen expressed on the surface of pre-B and mature B lymphocytes and on several B-cell malignancies, including DLBCL.
- The efficacy of Monjuvi in combination with Revlimid followed by Monjuvi as monotherapy was evaluated in L-MIND, an open label, single arm study. A total of 71 patients with relapsed or refractory DLBCL and not candidates for high dose chemotherapy followed by ASCT were enrolled. Efficacy was established based on best overall response rate (ORR) and duration of response (DOR).
    - The best ORR was 55% (95% CI: 43%, 67%).
    - The media DOR was 21.7 months (95% CI: 0, 24).
- Warnings and precautions for Monjuvi include infusion-related reactions, myelosuppression, infections, and embryo-fetal toxicity.
- The most common adverse reactions (≥ 20%) with Monjuvi use were neutropenia, fatigue, anemia, diarrhea, thrombocytopenia, cough, pyrexia, peripheral edema, respiratory tract infection, and decreased appetite.
- The recommended dose of Monjuvi is 12 mg/kg based on actual body weight administered as an intravenous infusion according to the dosing schedule below. Administer Monjuvi in combination with Revlimid 25 mg for a maximum of 12 cycles, then continue Monjuvi as monotherapy until disease progression or unacceptable toxicity.

Cycle*	Dosing schedule
Cycle 1	Days 1, 4, 8, 15, and 22
Cycles 2 and 3	Days 1, 8, 15 and 22
Cycle 4 and beyond	Days 1 and 15
* Each treatment cycle is 28-days	

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- — Administer pre-medications 30 minutes to 2 hours prior to starting Monjuvi infusion to minimize infusion-related reactions. Pre-medications may include acetaminophen, histamine H_1 receptor antagonists, histamine H_2 receptor antagonists, and/or glucocorticosteroids.
- — Refer to the Revlimid prescribing information for additional dosage recommendations.

- Morphosys and Incyte plan to launch Monjuvi shortly. Monjuvi will be available as a 200 mg lyophilized powder for reconstitution in a single-dose vial.