Rituxan Hycela™ (rituximab and hyaluronidase human) – New drug approval

- On June 22, 2017, the FDA announced the approval of Genentech's Rituxan Hycela (rituximab and hyaluronidase human) for adult patients with various forms of lymphoma and leukemia.
    - Relapsed or refractory, follicular lymphoma (FL) as a single agent
    - Previously untreated FL in combination with first-line chemotherapy and, in patients achieving a complete or partial response to Rituxan® (rituximab) in combination with chemotherapy, as single-agent maintenance therapy
    - Non-progressing (including stable disease), FL as a single agent after first-line cyclophosphamide, vincristine, and prednisone chemotherapy
    - Previously untreated diffuse large B-cell lymphoma (DLBCL) in combination with cyclophosphamide, doxorubicin, vincristine, prednisone or other anthracycline-based chemotherapy regimens
    - Combination with fludarabine and cyclophosphamide, for the treatment of adults with previously untreated and previously treated chronic lymphocytic leukemia (CLL)

- Rituxan Hycela should only be initiated after patients have received at least one full dose of a Rituxan product by intravenous (IV) infusion. Rituxan Hycela is not indicated for the treatment of non-malignant conditions.

- Rituxan Hycela includes the same monoclonal antibody as Rituxan in combination with hyaluronidase human, an enzyme that helps to deliver rituximab under the skin. Rituxan Hycela is a subcutaneous route of rituximab administration that is administered as a fixed dose, regardless of a patient's body surface area.

- The approval of Rituxan Hycela was based on pharmacokinetic studies demonstrating non-inferiority between Rituxan Hycela and Rituxan, and clinical studies demonstrating comparable efficacy and safety results between Rituxan Hycela vs. Rituxan.

- Similar to Rituxan, Rituxan Hycela carries a boxed warning for severe mucocutaneous reactions, hepatitis B virus reactivation, and progressive multifocal leukoencephalopathy.

- Warnings and precautions of Rituxan Hycela include tumor lysis syndrome, infections, cardiovascular adverse reactions, renal toxicity, bowel obstruction and perforation, immunization, and embryo-fetal toxicity.

- The most common adverse reactions (≥ 20%) with Rituxan Hycela use were:
    - FL: infections, neutropenia, nausea, constipation, cough, and fatigue
    - DLBCL: infections, neutropenia, alopecia, nausea, and anemia
    - CLL: infections, neutropenia, nausea, thrombocytopenia, pyrexia, vomiting, and injection site erythema

- The recommended dosages of Rituxan Hycela (rituximab/hyaluronidase human) are below:
    - FL/DLBCL: 1,400 mg/23,400 units subcutaneously according to recommended schedule
    - CLL: 1,600 mg/26,800 units subcutaneously according to recommended schedule
    - Refer to the Rituxan Hycela drug label for specific dosing schedules.
    - Patients should be premedicated with acetaminophen and an antihistamine before each dose of Rituxan Hycela. Premedication with a glucocorticoid should also be considered.

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- All patients must first receive at least one full dose of Rituxan by IV infusion without experiencing severe adverse reactions before starting treatment with Rituxan Hycela. If patients are not able to receive one full dose by IV infusion, they should continue subsequent cycles with Rituxan by IV infusion and not switch to Rituxan Hycela until a full IV dose is successfully administered.

- Genentech plans to launch Rituxan Hycela within one to two weeks. Rituxan Hycela will be available as 1,400 mg rituximab/23,400 units hyaluronidase human per 11.7 mL (120 mg/2,000 units per mL) and 1,600 mg rituximab/26,800 units hyaluronidase human per 13.4 mL (120 mg/2,000 units per mL) single-dose vials. Rituxan will continue to be available.