Truxima® (rituximab-abbs) – New and expanded indications

- On May 23, 2019, the FDA approved Teva and Celltrion's Truxima (rituximab-abbs), for the treatment of adult patients with previously untreated diffuse large B-cell, CD20-positive non-Hodgkin's lymphoma (NHL) in combination with (cyclophosphamide, doxorubicin, vincristine, and prednisone) (CHOP) or other anthracycline-based chemotherapy regimens; and with previously untreated and previously treated CD20-positive chronic lymphocytic leukemia (CLL) in combination with fludarabine and cyclophosphamide (FC).

- Previously, Truxima was approved for the following:

    - Relapsed or refractory, low grade or follicular, CD20-positive B-cell NHL as a single agent
    - Previously untreated follicular, CD20-positive, B-cell NHL in combination with first line chemotherapy and, in patients achieving a complete or partial response to a rituximab product in combination with chemotherapy, as single-agent maintenance therapy
    - Non-progressing (including stable disease), low-grade, CD20-positive, B-cell NHL as a single agent after first-line cyclophosphamide, vincristine, and prednisone chemotherapy.

- Truxima is a biosimilar to Genentech and Biogen's Rituxan® (rituximab).

    - Rituxan is also approved for the treatment of adult patients with rheumatoid arthritis, granulomatosis with polyangiitis (Wegener's granulomatosis) and microscopic polyangiitis, and pemphigus vulgaris.

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

- The most common adverse reactions (≥ 25%) with Truxima use in NHL were infusion-related reactions, fever, lymphopenia, chills, infection and asthenia.

- The most common adverse reactions (≥ 25%) with Truxima use in CLL were infusion-related reactions and neutropenia.

- The recommended dose of Truxima in the expanded NHL indication is 375 mg/m^2 as an intravenous infusion on day 1 of each cycle of chemotherapy, for up to 8 infusions.

- The recommended dose of Truxima for CLL is 375 mg/m^2 the day prior to the initiation of FC chemotherapy, then 500 mg/m^2 on day 1 of cycles 2 to 6 (every 28 days).

- Consult the Truxima drug label for dosing information for all other indications.

- Consult the Rituxan drug label for dosing information for the additional indications.

- Teva and Celltrion's launch plans for Truxima are pending.