Riabni™ (rituximab-arrx) – New biosimilar approval

- On December 17, 2020, Amgen announced the FDA approval of Riabni (rituximab-arrx), a biosimilar to Genentech/Biogen's Rituxan® (rituximab).
    - Riabni is the third FDA-approved biosimilar to Rituxan.
    - Teva/Celltrion's Truxima® (rituximab-abbs) was the first biosimilar to Rituxan and launched in November 2019.
    - Pfizer's Ruxience™ (rituximab-pvvr), the second biosimilar to Rituxan, launched in January 2020.

- Riabni, Ruxience, Truxima and Rituxan share the following indications:
    - Treatment of adult patients with Non-Hodgkin's lymphoma (NHL):
        - 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 (CVP) chemotherapy
        - Previously untreated diffuse large B-cell, CD20-positive NHL in combination with (cyclophosphamide, doxorubicin, vincristine, and prednisone) (CHOP) or other anthracycline-based chemotherapy regimens
    - Previously untreated and previously treated CD20-positive chronic lymphocytic leukemia (CLL) in combination with fludarabine and cyclophosphamide.
    - Granulomatosis with polyangiitis (GPA) (Wegener's Granulomatosis) and microscopic polyangiitis (MPA) in adult patients in combination with glucocorticoids.

- In addition, Rituxan and Truxima are also indicated for the treatment of adult patients with rheumatoid arthritis. And, Rituxan is approved for the treatment of pemphigus vulgaris.

- Riabni has been approved as a biosimilar, ***not*** as an interchangeable product.
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- The approval of Riabni is based on a review of analytical, non-clinical, pharmacokinetic and clinical data confirming that Riabni is highly similar to Rituxan.

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

- Other warning and precautions of Riabni include tumor lysis syndrome, infections, cardiovascular adverse reactions, renal toxicity, bowel obstruction and perforation, immunization, embryo-fetal toxicity, and concomitant use with other biologic agents and disease modifying anti-rheumatic drugs in GPA and MPA.

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

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

- The most common adverse reactions (≥ 15%) with Riabni use in GPA and MPA were infections, nausea, diarrhea, headache, muscle spasms, anemia, and peripheral edema. Another important adverse reaction was infusion-related reactions.

- The recommended dose of Riabni is given by intravenous infusion and varies by indication:

Indication	Dose	Duration
Relapsed or refractory, low-grade or follicular, CD20-positive, B-cell NHL	375 mg/m^2	Once weekly for 4 or 8 doses
Retreatment for relapsed or refractory, low-grade or follicular, CD20-positive, B-cell NHL		Once weekly for 4 doses
Retreatment for relapsed or refractory, low-grade or follicular, CD20-positive, B-cell NHL		Administer on day 1 of each cycle of chemotherapy, for up to 8 doses
Non-progressing, low-grade, CD20-positive, B-cell NHL, after first-line CVP chemotherapy		Following completion of 6 to 8 cycles of CVP chemotherapy, administer once weekly for 4 doses at 6-month intervals for a maximum of 16 doses
Diffuse large B-cell NHL		Administer on day 1 of each cycle of chemotherapy for up to 8 infusions
CLL	375 mg/m^2 the day prior to the initiation of FC chemotherapy, then 500 mg/m^2 on day 1 of cycles 2-6 (every 28 days)	--
Active GPA/MPA	375 mg/m^2	Once weekly for 4 weeks

    - Refer to the Riabni drug label for further dosing recommendations, glucocorticoid dosing and maintenance treatment for GPA/MPA.

- Amgen plans to launch Riabni in January 2021. Riabni will be available as 100 mg/10 mL and 500 mg/50 mL solution in single-dose vials.