Brukinsa® (zanubrutinib) – New indication

- On March 7, 2024, BeiGene announced the FDA approval of Brukinsa (zanubrutinib), for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL), in combination with obinutuzumab, after two or more lines of systemic therapy.
    - This indication is approved under accelerated approval based on response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.
- Brukinsa is also approved for the treatment of mantle cell lymphoma, Waldenström's macroglobulinemia, marginal zone lymphoma, and chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma.
- The approval of Brukinsa for the new indication was based on ROSEWOOD, an open-label, randomized study in 217 adult patients with relapsed or refractory FL after at least 2 prior systemic treatments. Patients were randomized to receive either Brukinsa until disease progression or unacceptable toxicity plus obinutuzumab, or obinutuzumab alone. Efficacy was based on overall response rate (ORR) and duration of response (DOR).
    - The ORR was 69% for Brukinsa + obinutuzumab vs. 46% with obinutuzumab alone (risk difference 22.7, 95% CI: 9.0, 36.5; p = 0.0012).
    - The median DOR was not estimable (95% CI: 25.3, not estimable) for Brukinsa + obinutuzumab vs. 14.0 months (95% CI: 9.2, 25.1) for obinutuzumab alone.
- The recommended dosage of Brukinsa for all indications is 160 mg taken orally twice daily or 320 mg taken orally once daily until disease progression or unacceptable toxicity.