Brukinsa® (zanubrutinib) – New indication

- On September 15, 2021, BeiGene announced the FDA approval of Brukinsa (zanubrutinib), for the treatment of adult patients with relapsed or refractory marginal zone lymphoma (MZL) who have received at least one anti-CD20-based regimen.
    - 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.
- Brukinsa is also approved for:
    - Treatment of adult patients with mantle cell lymphoma who have received at least one prior therapy
    - Treatment of adult patients with Waldenström's macroglobulinemia.
- The approval of Brukinsa for its new indication was based on an open-label, single-arm study in 66 patients with MZL who received at least one prior anti-CD20-based therapy. Brukinsa was given orally at a dosage of 160 mg twice daily until disease progression or unacceptable toxicity. The efficacy was also assessed in a separate open-label, single-arm study in 20 patients with previously treated MZL. Brukinsa was given orally at dosages of 160 mg twice daily or 320 mg once daily. Efficacy was based on overall response rate (ORR) and duration of response (DOR).
    - In the first study, the ORR was 56% (95% CI: 43, 68). The median DOR was not estimable (NE) (95% CI: NE, NE).
    - In the second study, the ORR was 80% (95% CI: 56, 94). The median DOR was NE (95% CI: 8.4, NE).
- The recommended dosage of Brukinsa for all its indications is 160 mg taken orally twice daily or 320 mg taken orally once daily until disease progression or unacceptable toxicity.