Brukinsa® (zanubrutinib) – New formulation approval

- On June 10, 2025, the FDA approved BeOne Medicines' Brukinsa (zanubrutinib) tablets, for the treatment of adult patients with:
    - Mantle cell lymphoma who have received at least one prior therapy
    - Waldenström's macroglobulinemia
    - Relapsed or refractory marginal zone lymphoma who have received at least one anti–CD20-based regimen
    - Chronic lymphocytic leukemia or small lymphocytic lymphoma
    - Relapsed or refractory follicular lymphoma, in combination with obinutuzumab, after two or more lines of systemic therapy.
- Brukinsa tablets are a new formulation of zanubrutinib. Brukinsa is also available as an oral capsule.
- The tablet formulation will be available as an 160 mg strength. The capsule is available as an 80 mg strength.
- The recommended dosage of Brukinsa for monotherapy or in combination with obinutuzumab is 160 mg taken orally twice daily or 320 mg taken orally once daily until disease progression or unacceptable toxicity.
    - The tablets can be split in half as prescribed by the healthcare provider.
- BeOne Medicines' launch plans for Brukinsa tablets are pending.