Ukoniq™ (umbralisib) – Voluntary withdrawal

- On April 15, 2022, TG Therapeutics announced it has voluntarily withdrawn Ukoniq (umbralisib) from sale for the approved indications of treatment of adult patients with marginal zone lymphoma (MZL) who have received at least one prior anti-CD20-based regimen, and treatment of adult patients with follicular lymphoma (FL) who have received at least three prior systemic therapies.

- Ukoniq received accelerated approval for these indications in February 2021 based on overall response rate. Continued approval was contingent upon verification and description of clinical benefit in a confirmatory trial.

- TG Therapeutics' decision to withdraw Ukoniq from sale was primarily based on the withdrawal of the pending Biologics License Application (BLA)/supplemental New Drug Application (sNDA) for the combination of ublituximab and Ukoniq for the treatment of adult patients with chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL).

    - The decision to withdraw the pending applications was based on the recent updated results from the UNITY-CLL study, a Phase 3, randomized controlled clinical trial which compared the combination of ublituximab and Ukoniq vs. Gazyva® (obinutuzumab).
    - The updated results from UNITY-CLL showed an increasing imbalance in overall survival in favor of the control arm (Gazyva).