

Ukoniq[™] (umbralisib) – Voluntary withdrawal

- On April 15, 2022, <u>TG Therapeutics announced</u> it has voluntarily withdrawn <u>Ukoniq (umbralisib)</u> 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. <u>Gazyva[®] (obinutuzumab)</u>.
 - The updated results from UNITY-CLL showed an increasing imbalance in overall survival in favor of the control arm (Gazyva).



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