Zydelig® (idelalisib) – Indication withdrawals

- On January 14, 2022, Gilead Sciences announced the voluntary withdrawal of the Zydelig (idelalisib) indications for the treatment of patients with relapsed follicular B-cell non-Hodgkin lymphoma (FL) who have received at least two prior systemic therapies and treatment of patients with relapsed small lymphocytic lymphoma (SLL) who have received at least two prior systemic therapies.
    - These indications received accelerated approval in 2014 and continued approval was contingent upon confirmatory studies providing evidence supporting clinical benefit in FL and SLL.
- As the treatment landscape for FL and SLL has evolved, enrollment into the confirmatory study has been an ongoing challenge. As a result, Gilead formally notified the FDA of its decision to voluntarily withdraw these indications in the U.S. market.
- This decision does not affect the other approved indication for Zydelig, in combination with rituximab, for the treatment of patients with relapsed chronic lymphocytic leukemia for whom rituximab alone would be considered appropriate therapy due to other co-morbidities.
- Gilead will work with the FDA to complete the withdrawal of the FL and SLL indications and with healthcare professionals to support those currently being treated with Zydelig.
- People receiving Zydelig for relapsed FL or SLL should discuss their treatment options with their healthcare provider.