Istodax® (romidepsin) – Indication withdrawal

- On August 2, 2021, Bristol-Myers Squibb (BMS) announced that the company plans to voluntarily withdraw the indication for Istodax (romidepsin) as monotherapy for the treatment of peripheral T-cell lymphoma (PTCL) in adult patients who have received at least one prior therapy.
    - Celgene, a wholly subsidiary of BMS, received FDA approval of this indication in 2011 through the accelerated approval pathway.
- The accelerated approval was based upon results from two clinical studies, assessing the effect of Istodax on the surrogate endpoint of overall response rate. BMS conducted a subsequent confirmatory phase 3 study evaluating Istodax plus cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP) vs. CHOP in first line PTCL patients, but the trial did not meet the primary efficacy endpoint of progression free survival.
- Patients who are being treated with Istodax for PTCL should consult with their healthcare provider.
- Istodax is still approved for the treatment of cutaneous T-cell lymphoma in adult patients who have received at least one prior systemic therapy.
- Refer to the Istodax drug label for information regarding this indication and Istodax's other FDA approved indication.