Farydak® (panobinostat) – Voluntary withdrawal

- On November 30, 2021, Secura Bio announced, based on discussions with the FDA, that they have submitted for the withdrawal of the approval of Farydak (panobinostat), for use in combination with bortezomib and dexamethasone, for the treatment of patients with multiple myeloma who have received at least two prior regimens, including bortezomib and an immunomodulatory agent.

- Farydak received accelerated approval for this indication in February 2015. The accelerated approval was based on progression-free survival and consistent with FDA regulations, required further adequate and well-controlled clinical studies to verify and describe the product's clinical benefit.

- In its withdrawal submission, Secura Bio noted that, as previously discussed with FDA, it was not feasible for the company to complete the required post-approval clinical studies as designed as part of the accelerated approval process. Because those studies were required to verify and describe the clinical benefit of the drug product, the clinical benefit of Farydak has not been confirmed under the specific constraints of the accelerated approval process.