Augtyro™ (repotrectinib) – New indication

- On June 13, 2024, Bristol Myers Squibb announced the FDA approval of Augtyro (repotrectinib), for the treatment of adult and pediatric patients 12 years of age and older with solid tumors that: have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion, are locally advanced or metastatic or where surgical resection is likely to result in severe morbidity, and have progressed following treatment or have no satisfactory alternative therapy.
    - This indication is approved under accelerated approval based on overall response rate (ORR) and duration of response (DOR). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).
- Augtyro is also approved for the for the treatment of adult patients with locally advanced or metastatic ROS1-positive non-small cell lung cancer (NSCLC).
- The approval of Augtyro for the new indication was based on TRIDENT-1, a single-arm, open-label, multi-cohort study in 88 adult patients with locally advanced or metastatic NTRK gene fusion-positive solid tumors who had either received a prior tyrosine kinase inhibitor (TKI) treatment or were TKI-naïve. The major outcome measures were ORR and DOR.
    - Among TKI-naïve patients, the ORR was 58% (95% CI: 41, 73). The median DOR was not evaluable (NE) (95% CI: NE, NE).
    - Among TKI-pretreated patients, the ORR was 50 (95% CI: 35, 65). The median DOR was 9.9 months (95% CI: 7.4, 13.0).
- The recommended dosage of Augtyro for adult and pediatric patients 12 years of age and older is 160 mg taken orally once daily with or without food for 14 days, with the dose then increased to 160 mg twice daily and continued until disease progression or unacceptable toxicity.
    - Patients should be selected for the treatment of solid tumors with Augtyro based on the presence of NTRK1/2/3 rearrangements in tumor specimens. An FDA-approved test to detect NTRK1/2/3 rearrangements for selecting patients for treatment with Augtyro is not currently available. In patients with secretory breast cancer or mammary analogue secretory cancer, treatment should be considered without confirmation of NTRK rearrangements in tumor specimens.