FDA approves augtyro for NTRK-positive advanced solid tumors

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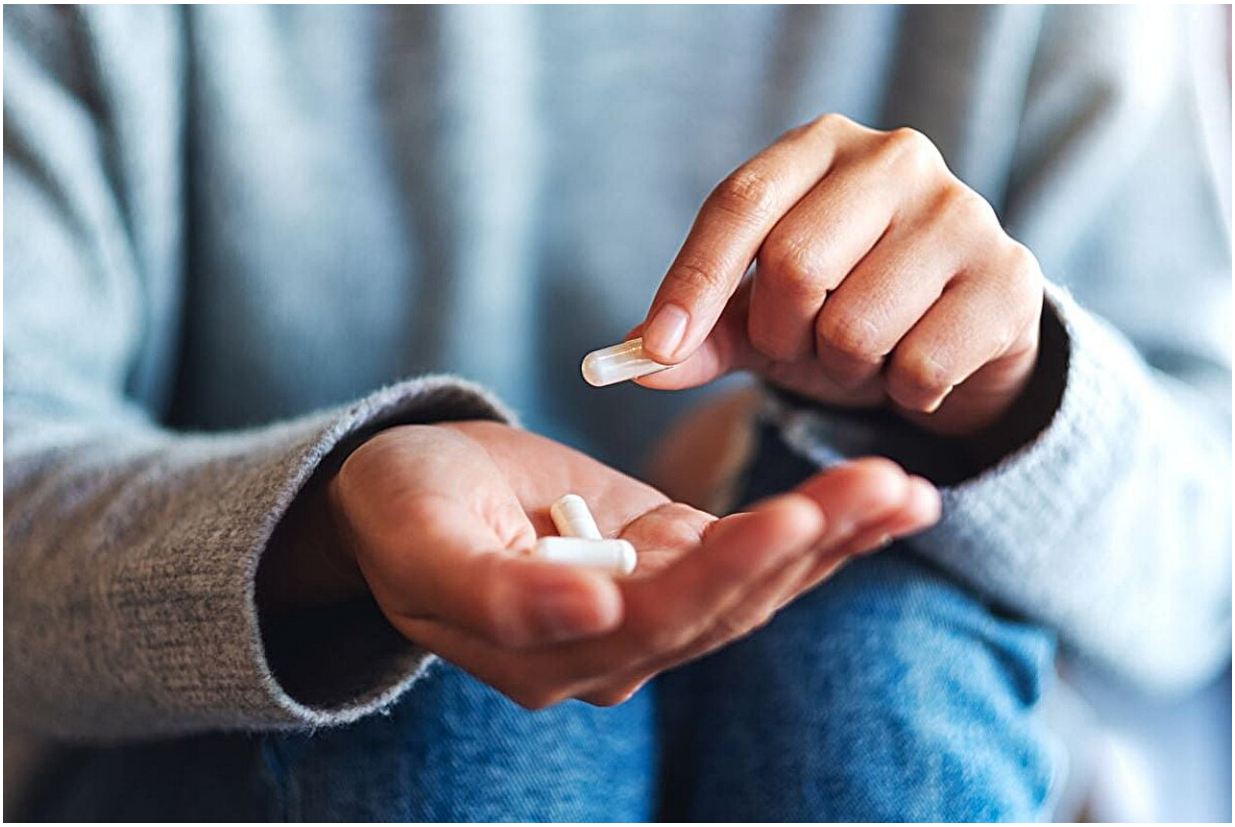

The U.S. Food and Drug Administration has approved Augtyro (repotrectinib), a next-generation tyrosine kinase inhibitor (TKI), for the treatment of patients with neurotrophic tyrosine receptor kinase

(*NTRK*)-positive locally advanced or metastatic solid tumors.

Augtyro is approved for adult and pediatric patients (aged 12 years and older) with solid tumors that have an *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.

The approval was based on the TRIDENT-1, phase 1/2 trial, which included both TKI-naive and TKI-pretreated patients (40 and 48 individuals, respectively), collectively representing 15 different types of solid tumor cancer. During a median follow-up of 17.8 months, 58 percent of TKI-naive patients had a confirmed objective response rate (cORR), of whom 43 percent experienced partial responses and 15 percent had complete responses. Among the TKI-naive responding patients, 83 percent were still in response at one year, and the median duration of response (mDOR) was not yet reached. During a median follow-up of 20.1 months, 50 percent of TKI-pretreated patients had a cORR, all of whom experienced partial responses and none of whom achieved complete responses. At one year, 42 percent of TKI-pretreated responding patients were still in response at one year and the mDOR was 9.9 months. Among the participants with measurable central nervous system metastases at baseline, intracranial response was seen in two of two TKI-naive patients and in three of three TKI-pretreated patients.

"NTRK fusion-positive tumors can present challenges in the clinical setting, which is why it is important that we have additional treatment options for these patients," TRIDENT-1 global trial lead Alexander Drilon, M.D., from Memorial Sloan Kettering Cancer Center in New York City, said in a statement. "The FDA approval of repotrectinib adds an important tool to our toolbox, offering oncologists a next-generation TKI that can be used across a broad range of *NTRK* fusion-positive solid tumors for both TKI-naïve and TKI-pretreated patients."

Approval of Augtyro was granted to Bristol Myers Squibb.