EU Panel Recommends Approval of Zykadia as First-line Treatment for ALK-Positive NSCLC

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Zykadia (ceritinib) was recommended for approval in Europe by the EMA's Committee for Medicinal Products for Human Use (CHMP) as first-line treatment for patients with advanced non-small cell lung cancer (NSCLC) whose tumors are ALK-positive.

Marketed by Novartis, Zykadia is currently approved in the European Union to treat patients with the same disease, but who were previously treated with Xalkori (crizotinib).

"Novartis is committed to bringing targeted treatment options to more patients living with lung cancer who may benefit from them," Bruno Strigini, CEO of Novartis Oncology, said in a press release. "Today, we've taken an important step towards fulfilling that commitment with the potential approval of Zykadia as a first-line treatment option for those in the EU diagnosed with ALK-positive advanced NSCLC."

The European Commission (EC) will review the label expansion application. A final decision is expected within two months. Although the EC will take into consideration the CHMP's approval recommendation during the review process, this does not ensure approval of the the label expansion.

The CHMP recommendation was based on results from the Phase 3 ASCEND-4 study (NCT01828099), which assessed the safety and effectiveness of Zykadia vs. standard chemotherapy: Alimta (pemetrexed) plus Platinol (cisplatin) or Alimta plus Paraplatin (carboplatin), in previously untreated patients.

The trial was conducted at 134 medical centers in 28 countries, and included a total of 376 patients with stage 3B or 4 ALK-positive NSCLC.

According to the trial results, patients treated with first-line Zykadia presented a 45 percent reduction in the risk of disease progression compared to patients treated with standard first-line platinum-based chemotherapy followed by Alimta maintenance therapy.

Patients treated with Zykadia had a median progression-free survival (PFS) rate of 16.6 months, which was more than double the 8.1 months median PFS seen in patients receiving chemotherapy.

Zykadia's beneficial effects on PFS rates were observed in patients with or without brain metastasis, demonstrating the drug's high intracranial efficacy. Patients receiving Zykadia without brain metastasis had a median PFS of 26.3 months vs. 8.3 months in chemotherapy-treated patients.

Among those with brain metastasis, median PFS was 10.7 months and 6.7 months in the Zykadia and chemotherapy arms, respectively.

In February, the U.S. Food and Drug Administration (FDA) granted breakthrough therapy status to Zykadia as first-line therapy of ALK-positive NSCLC patients with brain metastasis. Also supported by the positive results from the ASCEND-4 trial, this designation is expected to expedite the development and review of Zykadia to treat this serious and life-threatening medical condition. The application for first-line use of Zykadia is now under priority review by the FDA.