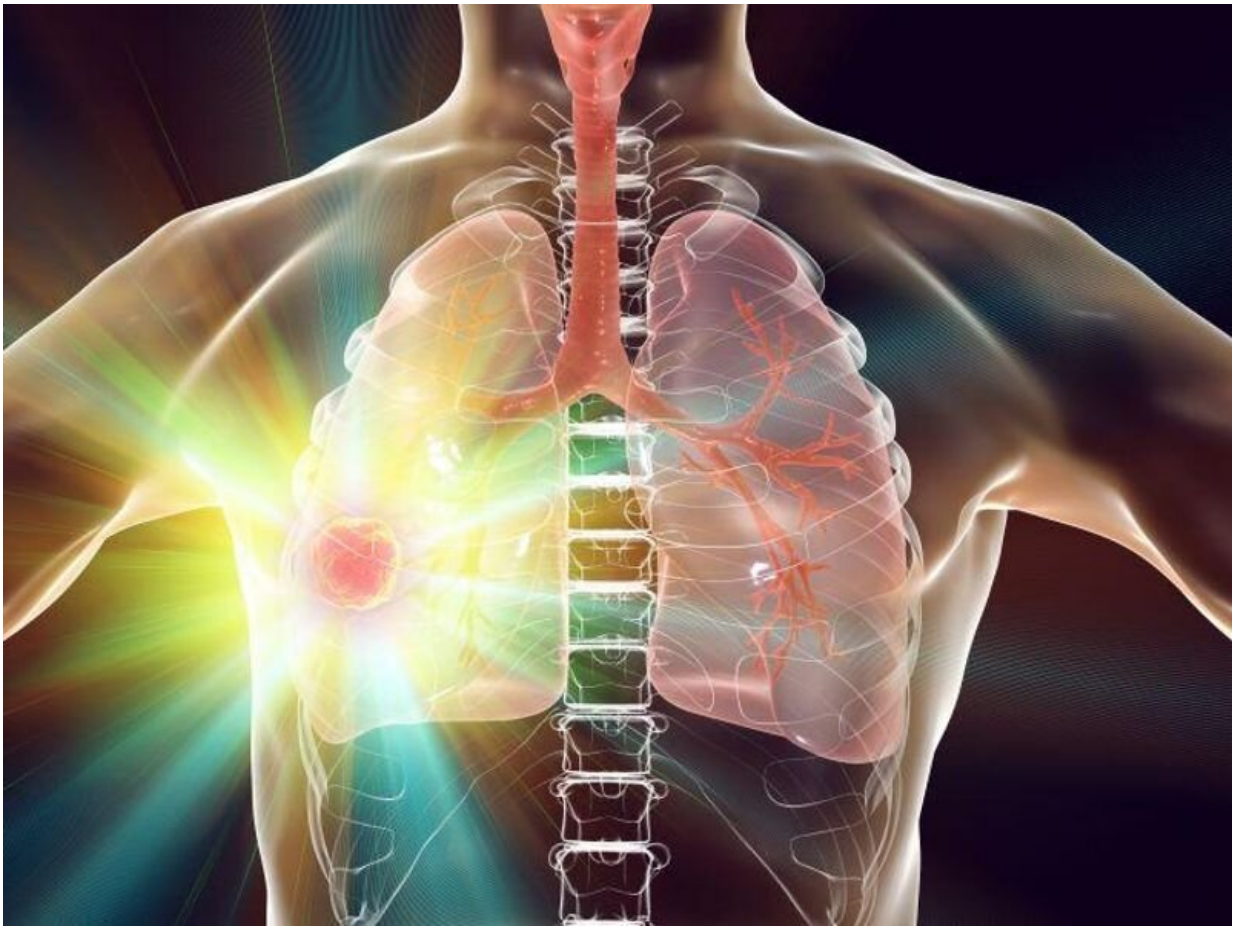
FDA approves drug combo for metastatic non-small cell lung cancer

November 16 2022, by Lori Solomon



The U.S. Food and Drug Administration approved the combination of

tremelimumab (Imjudo) plus durvalumab (Imfinzi) and platinum-based chemotherapy for adult patients with metastatic non-small cell lung cancer with no sensitizing epidermal growth factor receptor mutation or anaplastic lymphoma kinase genomic tumor aberrations.

Both tremelimumab and durvalumab are administered as an intravenous infusion. For patients weighing 30 kg or more, the recommended tremelimumab dose is 75 mg every three weeks with durvalumab 1,500 mg and platinum-based chemotherapy for four cycles, then durvalumab 1,500 mg with maintenance chemotherapy every four weeks. A fifth tremelimumab dose (75 mg) should be given at week 16.

The approval was based on the randomized POSEIDON trial (675 patients). Statistically significant and clinically meaningful improvement in overall survival was seen with tremelimumab plus durvalumab and platinum-based chemotherapy versus platinum-based chemotherapy alone (hazard ratio, 0.77). Median overall survival was 14 months with tremelimumab plus durvalumab and 11.7 months for platinum-based chemotherapy alone. Median progression-free survival was 6.2 months and 4.8 months, respectively (hazard ratio, 0.72). The overall response rate was 39 percent with the drug combination versus 24 percent with chemotherapy alone, with median duration of responses of 9.5 and 5.1 months, respectively.

Nausea, fatigue, decreased appetite, musculoskeletal pain, rash, and diarrhea were the most common adverse reactions reported, while grade 3 or 4 laboratory abnormalities included neutropenia, anemia, leukopenia, lymphocytopenia, lipase increase, hyponatremia, and thrombocytopenia.

The approval was granted to AstraZeneca.

More information: More Information