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TxSCO ONCOLOGY DRUG NEWSLETTER

FDA APPROVAL

Optune Lua

The FDA has granted approval to **Optune Lua** for concurrent use with PD-1/PD-L1 inhibitors or docetaxel in adult patients with metastatic non–small cell lung cancer (NSCLC) whose disease has progressed on or after a platinum-based regimen.[1]

Optune Lua is a portable device that generates alternating electric fields, known as tumor treating fields (TTFields). They are delivered via noninvasive, wearable arrays. TTFields selectively disrupt mitotic processes by exerting physical forces on electrically charged cellular components during cell division, which leads to cancer cell apoptosis.

The regulatory decision was backed by findings from the phase 3 LUNAR trial (NCT02973789).[2] In this study, patients who were treated with Optune Lua in combination with either a PD-1/PD-L1 inhibitor or docetaxel (n = 145) had a median overall survival (OS) of 13.2 months (95% CI, 10.3-15.5).

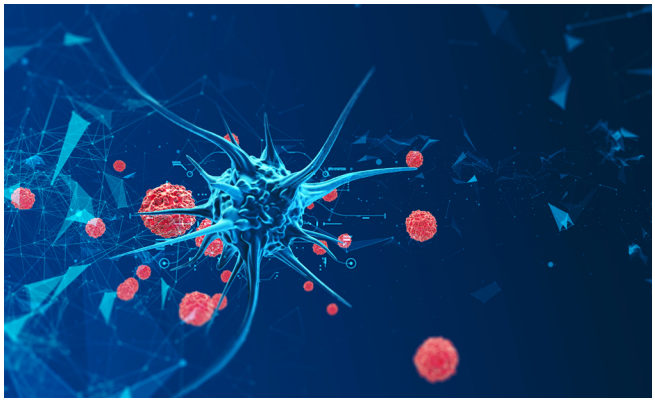
In comparison, patients who were treated with just a PD-1/PD-L1 inhibitor or docetaxel (n = 146) achieved a median OS of 9.9 months (95% CI, 8.2-12.2). The difference between the 2 groups was statistically significant (P = .04).

"There have been a number of important advances in first-line treatment for NSCLC, but this is an aggressive disease, and most patients will develop progression, with limited effective treatment options in second line and beyond," said Ticiana Leal, MD, associate professor and director of the Thoracic Oncology Program at the Winship Cancer Institute of Emory University School of Medicine and primary investigator of the LUNAR study, in a press release.[1]

The results of the pivotal phase 3 LUNAR trial mark the first significant improvement in median OS for this patient population in more than 8 years. This breakthrough represents a major advancement in treatment outcomes.

"The OS results we observed with Optune Lua in the LUNAR study mark the first substantial improvement in more than 8 years in this patient population which, when combined with Optune Lua's lack of systemic toxicity, make this a compelling development for many patients and their physicians who need better treatment options for this advanced disease," added Leal.

The randomized, open-label, phase 3 LUNAR study sought to evaluate Optune Lua in patients at least 22 years of age with metastatic non–small cell lung cancer.[3] Patients must have had disease that progressed on or after platinum-based chemotherapy, and they were allowed to have squamous or nonsquamous histology. Additionally, patients must have had an ECOG performance status of 2 or less. Prior treatment with a platinum-based



regimen was required; however, there was no limit on prior lines of systemic therapy.

This study was conducted across 130 sites in 19 countries and patients were randomized in a 1:1 fashion to receive Optune Lua with the investigator's choice of concurrent standard systemic therapy or systemic therapy alone. Investigator's choice of therapy consisted of nivolumab (Opdivo), pembrolizumab (Keytruda), atezolizumab (Tecentriq), or docetaxel. Further, TTFields were given continuously at 150 kHz to the thoracic region. The target was an average of 18 hours per day of device usage.

The primary end point of the study was OS in the intention-to-treat population. Secondary end points included OS, progression-free survival, overall radiological response rate, quality of life using the EORTC QLQ C30 questionnaire with LC13 addendum, and safety.

Additional data from the phase 3 trial were published in The Lancet Oncology. Among the patients treated with Optune Lua plus an immune checkpoint inhibitor (n = 66), the median OS was 18.5 months (95% CI, 10.6-30.3) vs 10.8 months (95% CI, 8.2-18.4) for patients treated with a checkpoint inhibitor alone (n = 68; HR, 0.63; 95% CI, 0.41-0.96; P = .030). Of the 71 patients treated with Optune Lua in addition to docetaxel, the median OS was 11.1 months (95% CI, 8.2-14.1) vs 8.7 months (95% CI, 6.3-11.3) in the docetaxel-alone arm (HR, 0.81; 95% CI, 0.55-1.19; P = .28).[2]

Regarding safety, 63.1% of the experimental arm experienced device-related adverse effects (AEs), most of which were low grade. One of these AEs was grade 3 skin toxicity, which required a break from treatment, and this occurred in 4% of patients. There were no grade 4 or 5 AEs related to Optune Lua observed in the study, and no device-related AEs leading to death were reported.

"Novocure is committed to extending survival in some of the most aggressive and difficult-to-treat cancers. The approval of Optune Lua brings a new and urgently needed option for people with metastatic NSCLC who have progressed while on or after platinum-based chemotherapy. We are grateful to the patients, caregivers, investigators, and health care providers who supported the clinical trials that led to this approval," added Asaf Danziger, chief executive officer of Novocure, in the press release.[1]

Inavolisib (Itovebi)

The regimen of inavolisib **(Itovebi, previously GDC-0077)**, palbociclib (Ibrance), and fulvestrant has been approved by the FDA for the treatment of patients with hormone receptor-positive, HER2-negative, PIK3CA-mutated breast cancer.[4]

The approval is supported by findings from the phase 3 INAVO120 study (NCT04191499). Initial findings were presented at the 2023 San Antonio Breast Cancer Symposium, and additional data were presented at the 2024 American Society of Clinical Oncology Annual Meeting. With a median follow-up of 21.3 months, the addition of inavolisib to palbociclib and fulvestrant reduced the risk of disease progression or death by 57% (HR, 0.43; 95% CI, 0.32-0.59; P = .0001). The median progression-free survival (PFS) was 15.0 months with inavolisib vs 7.3 months in the placebo plus palbociclib and fulvestrant arm. The 6-month, 12-month, and 18-month PFS rates in the inavolisib arm were 82.9%, 55.9%, and 46.2%, respectively, vs 55.9%, 32.6%, and 21.1% in the placebo arm.[5,6]

An interim analysis of overall survival (OS) showed a reduction in the risk of death of 36% (HR, 0.64; 95% CI, 0.43-0.97; P = .0338). The 6-month, 12-month, and

18-month OS rates were 97.3%, 85.9%, and 73.7%, respectively, with inavolisib vs 89.9%, 74.9%, and 67.5% with placebo. Inavolisib also delivered an overall response rate of 58.4% vs 25.0% with placebo and a clinical benefit rate of 75.2% vs 47.0% with placebo.

"[Inavolisib] is unique…This agent does not just inhibit the target. In certain cells or contexts, it promotes the degradation of the target. You go after the target inhibited, and then you destroy it. The cells have no way to adapt and reactivate the same target because it's destroyed," said Dejan Juric, MD, lead investigator of INAVO120, medicine-hematology and medical oncology at Massachusetts General Hospital Cancer Center, in an interview with Targeted Oncology™.

In the study, 325 patients were randomized to receive inavolisib 9 mg daily (n = 161) or placebo (n = 164). Both groups received palbociclib 125 mg daily on day 1 to 21 of each cycle and fulvestrant 500 mg on day 1 and 15 in cycle 1 followed by once every 4 weeks. In both arms, about two-thirds of patients had an ECOG performance status of 0 and the remainder had 1.

Nearly half of patients in each group had 3 or more organ sites involved, and nearly half had liver involvement, with approximately 40% having lung involvement. Approximately 82% of patients received prior neoadjuvant or adjuvant chemotherapy, and nearly all had received prior neoadjuvant or adjuvant endocrine therapy. A minority of patients had received a prior CDK4/6 inhibitor (1.9% in the inavolisib group and 0.6% in the placebo group).

Nivolumab (Opdivo)

The FDA has approved neoadjuvant nivolumab (Opdivo) plus chemotherapy followed by adjuvant nivolumab in patients with operable stage IIA to IIIB non–small cell lung cancer.[7] This approval is supported by data from the phase 3 CheckMate 77T trial (NCT04025879) presented at the 2024 European Society for Medical Oncology (ESMO) Congress.

Updated data showed that perioperative nivolumab led to a benefit in event-free survival (EFS) vs placebo in this patient population. At a median follow-up of 33.3 months (range, 23.6-52.1), those who received perioperative nivolumab (n = 229) had a median EFS of 40.1 months (95% CI, 33.7-not reached) vs 17.0 (95% CI, 13.6-28.1) in the placebo arm (n = 232; HR, 0.59; 95% CI, 0.45-0.79).[8,9]

At 12 months, the EFS rates across arms were 73% (95% CI, 67%-79%) vs 59% (95% CI, 52%-65%), respectively. The 24-month rates were 65% (95% CI, 58%-71%) vs 44% (95% CI, 38%-51%), respectively.

Patients who achieved a pathologic complete response (pCR) and received nivolumab (n = 58) demonstrated a notable EFS benefit vs those who received placebo (n = 11; HR, 0.59; 95% CI, 0.12-2.91). Similarly, patients in the nivolumab arm who did not achieve a pCR (n = 98) also showed an EFS benefit vs those in the placebo group without a pCR (n = 148; HR, 0.75; 95% CI, 0.51-1.09).

"It is a major step forward for our patients with lung cancer. We are extremely encouraged to see these results," Tina Cascone, MD, PhD, associate professor of Thoracic/Head and Neck Medical Oncology, The University of Texas MD Anderson Cancer Center, and CheckMate 77T investigator, told Targeted Therapies in Oncology in an interview.

Higher rates of pCR and major pathologic response (MPR) in the nivolumab arm were also observed, suggesting better tumor shrinkage than in the placebo arm. Investigators reported that pCR in the nivolumab arm was 25.3% vs 4.7% in the placebo arm. Further, the MPR was 35.4% in the nivolumab arm vs 12.1% in the placebo arm.[10]

Regarding safety, 32% of patients in the nivolumab arm had treatment-related adverse events (AEs) vs 25% in the placebo arm. Both arms experienced a 12% rate of surgery-related AEs.

Selpercatinib (Retevmo)

The FDA has granted traditional approval to **selpercatinib (Retevmo)** for the treatment of adult and pediatric patients 2 years and older with advanced or metastatic medullary thyroid cancer with a RET mutation, as detected by an FDA-approved test, who require systemic therapy.[11]

Findings from the phase 3 LIBRETTO-531 trial (NCT04211337) support this regulatory decision. In the trial, selpercatinib improved progression-free survival (PFS) vs physician's choice of cabozantinib (Cabometyx) or vandetanib (Caprelsa; HR, 0.28; 95% CI, 0.165-0.475; P = .0001). With selpercatinib, the median PFS was not reached (95% CI, not evaluable [NE]-NE) vs 16.8 months (95% CI,12.2-25.1) with cabozantinib or vandetanib. This translated to a 72% reduction in the risk of disease progression or death.

Regarding safety data, toxicities reported in 25% of patients or more consisted of hypertension, edema, dry mouth, fatigue, and diarrhea. Grade 3 or 4 laboratory abnormalities occurring in more than 5% of patients included decreased lymphocytes, neutrophils, and calcium levels, and increased levels of alanine aminotransferase, alkaline phosphatase, blood creatinine, and aspartate aminotransferase.

The trial enrolled patients at least 12 years old with pathologically confirmed, unresectable, locally advanced or metastatic medullary thyroid cancer.[12] Patients were required to have had no prior exposure to kinase inhibitors, have radiologic progressive disease by RECIST 1.1 criteria, and have a prospectively identified pathogenic RET alteration. Enrollment was open to those with an ECOG performance status of 0, 1, or 2; acceptable organ function; and normal electrolyte levels.

Once enrolled, patients were randomly assigned in a 2:1 fashion and treated with 160 mg of selpercatinib twice daily, or physician's choice of cabozantinib once a day at 140 mg or vandetanib at 300 mg once daily. Treatment was given until progressive disease, intolerable toxicity, withdrawn consent, or death.

The primary end point was progression-free survival (PFS) by RECIST 1.1 criteria and blinded independent central review (BICR). Secondary end points were treatment failure-free survival by BICR and investigator, investigator-assessed PFS, overall survival by BICR and investigator assessment, and safety.

In May 2020, the FDA granted accelerated approval of selpercatinib for adult and pediatric patients 12 years and older with advanced or metastatic RET-positive medullary thyroid cancer who require systemic treatment.[13] The agent then received another accelerated approval in May 2024 for the treatment of pediatric patients 2 years and older with advanced or metastatic medullary thyroid cancer harboring a RET mutation who require systemic treatment. This approval also included those with advanced or metastatic thyroid cancer harboring a RET gene fusion who needed systemic therapy and are refractory to radioactive iodine, as well as select patients with locally advanced or metastatic solid tumors and a RET gene fusion.[14]

In June 2024, the FDA granted traditional approval to selpercatinib for the treatment of adult and pediatric patients 2 years and older with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine refractory.[15]

Osimertinib (Tagrisso)

The FDA has approved **osimertinib (Tagrisso)** for adults with locally advanced, unresectable stage III EGFR-mutated non–small cell lung cancer. This approval applies to patients whose disease has not progressed during or after concurrent or sequential platinum-based chemoradiation, and it is indicated for tumors with specific EGFR mutations (exon 19 deletions or exon 21 L858R mutations), identified through an FDA-approved test.[16]

The decision was based on the results of the phase 3 LAURA trial (NCT03521154), which demonstrated statistically significant improvements in progression-free survival (PFS). Data presented at the 2024 American Society of Clinical Oncology Annual Meeting showed that patients receiving osimertinib achieved a median PFS at 39.1 months (95% CI, 31.5-not calculable) vs 5.6 months (95% CI, 3.7-7.4) with placebo. The 12-month PFS rate was 74% with osimertinib vs 22% with placebo, and the 24-month PFS rates were 65% vs 13%, respectively.[17]

Overall survival data were not mature at the time of analysis; however, investigators observed no trend toward a detriment.

Regarding safety, the most common adverse events observed in at least 20% of patients included lymphopenia, leukopenia, interstitial lung disease/pneumonitis, thrombocytopenia, neutropenia, rash, diarrhea, nail toxicity, musculoskeletal pain, cough, and COVID-19 infection.

"It is an exciting time for patients with lung cancer because of the availability of targeted and immunotherapy treatment options. We are seeing improvement in patients with NSCLC. Overall, patients with lung cancer are living better and living longer, and that is thanks to the amazing therapeutic advances that have been made in the past few years," Suresh S. Ramalingam, MD, FACP, FASCO, associate vice president for cancer of Woodruff Health Sciences Center and executive director of Winship Cancer Institute of Emory University, previously told *Targeted Therapies in Oncology*, in an interview.

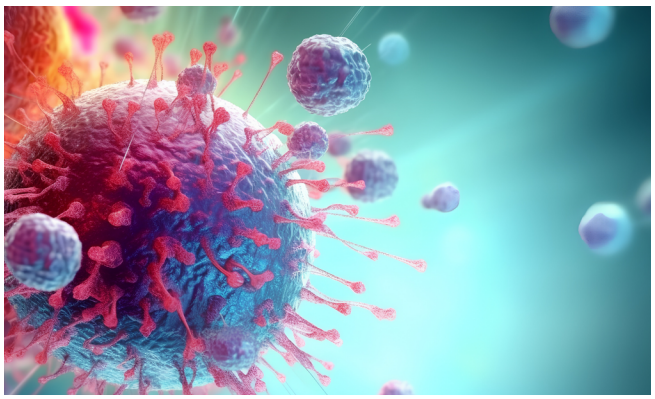
Isatuximab (Sarclisa)

Isatuximab (Sarclisa) plus bortezomib (Velcade), lenalidomide (Revlimid), and dexamethasone (VRd; isa-VRd) is now an FDA-approved combination for the treatment of patients with transplant-ineligible, newly diagnosed multiple myeloma. This is the first anti-CD38 therapy plus VRd available for this patient population.[18]

In May 2024, the supplemental biologics license application of isatuximab for this indication was granted priority review, identifying the treatment as a significant improvement compared with those currently available.[19]

The approval is supported by data from the phase 3 IMROZ study (NCT03319667).[20,21] At a median follow-up of 59.7 months, patients treated with isa-VRd (n = 265) followed by isatuximab plus lenalidomide/dexamethasone experienced a median progression-free survival (PFS) that was not reached (NR) vs 54.34 months (95% CI, 45.207-NR) in patients treated with VRd alone (HR, 0.596; 98.5% CI, 0.406-0.876; log-rank P = .0005). This met the primary end point of the study. The 60-month PFS rate was 63.2% in the investigational group vs 45.2% in the control arm. This PFS benefit was seen across most subgroups, including some difficult-to-treat populations with negative prognostic factors.[21]

"IMROZ is the first global, phase 3 study of an anti-CD38 monoclonal antibody in combination with VRd in patients with transplant-ineligible myeloma. In this presentation, we [showed] that the IMROZ regimen led to a statistically significant improvement in PFS; deep response rates with statistically



significant improvements in complete response [CR] and minimal residual disease [MRD]-negative CR, sustained in MRD negativity; and a safety profile consistent with that of each agent," lead study author Thierry Facon, MD, professor of hematology in the Department of Hematology at Lille University Hospital, France, stated in a presentation of the data.

Although overall survival (OS) data were immature at data cutoff, an interim OS analysis showed a positive trend for isa-VRd (HR, 0.776; 95% CI, 0.407-1.48). The 5-year OS rates were 72.3% and 66.3% for patients treated with isa-VRd vs VRd, respectively. Further, the overall response rate was 91.3% for isa-VRd and 92.3% for VRd, with a CR or better rate of 74.7% for isa-VRd and 64.1% for VRd (P = .01). The very good partial response or better rate was 89.1% and 82.9% for isa-VRd and VRd, respectively.[20]

Amivantamab (Rybrevant)

Amivantamab (Rybrevant) and carboplatin/pemetrexed chemotherapy is now an FDA-approved combination for the treatment of locally advanced or metastatic non–small cell lung cancer harboring EGFR exon 19 deletions or exon 21 L858R substitution mutations that has progressed following an EGFR tyrosine kinase inhibitor.[22]

The MARIPOSA-2 trial (NCT04988295) data support this approval. In the trial, 657 patients who experienced disease progression on or after treatment with osimertinib (Tagrisso) were randomly assigned 1:2:2 to receive amivantamab plus chemotherapy, chemotherapy, or amivantamab as part of another combination regimen.

The primary end point was progression-free survival (PFS) assessed by blinded independent central review. The median PFS was 6.3 months (95% CI, 5.6-8.4) with amivantamab and chemotherapy vs 4.2 months (95% CI, 4.0-4.4) in the chemotherapy-alone arm (HR, 0.48; 95% CI, 0.36-0.64; P = .0001). The overall response rate, a key secondary end point, was 53% (95% CI, 44%-62%) in the amivantamab/chemotherapy arm vs 29% (95% CI, 23%-35%) in the chemotherapy arm (P = .0001).

Regarding overall survival (OS), there was no significant difference between the 2 arms, with a stratified OS and an HR of 0.73 (95% CI, 0.54-0.99; P = .039).

At the 2024 European Society for Medical Oncology (ESMO) Congress, longer-term follow-up results from MARIPOSA-2 were presented. Patients assigned amivantamab plus chemotherapy had a median OS of 17.7 months (95% CI, 16.0-22.4) compared with 15.3 months (95% CI, 13.7-16.8) in patients assigned chemotherapy alone. OS was 50% for the amivantamab plus chemotherapy group vs 40% in the chemotherapy-alone group.[23]

"Indeed, amivantamab's multitargeted mechanism of action and immune cell–directed activity, combined with chemotherapy's nonspecific antitumor effects, likely contribute to this observed durability," Sanjay Popat, MBBS, PhD, BSc, FRCP, consultant medical oncologist at The Royal Marsden NHS Foundation Trust and professor of thoracic oncology at the Institute of Cancer Research in London, said during the presentation of the data.

Adverse events occurring in 20% or more of patients were rash, infusion-related reactions, fatigue, nail toxicity, nausea, constipation, edema, stomatitis, decreased appetite, musculoskeletal pain, vomiting, and COVID-19 infection.[22]

On August 20, 2024, the FDA approved the combination of amivantamab and lazertinib (Lazcluze) for the first-line treatment of EGFR-mutated non–small cell lung cancer with exon 19 deletions or exon 21 L858R substitution mutations.[24]

ODAC UPDATES

Esophageal and Gastric Cancers

- In an 11-to-1 vote, the FDA's Oncologic Drugs Advisory Committee (ODAC) concluded that the risk-benefit assessment is unfavorable for using checkpoint inhibitors (CPIs) in patients with metastatic or unresectable esophageal squamous cell carcinoma with PD-L1 expression less than 1.[25]

- In a 2-to-10 vote, the ODAC voted that the risk-benefit assessment is not favorable for the use of CPIs in first-line advanced HER2-negative gastric and gastroesophageal junction adenocarcinoma in patients with PD-L1 expression less than 1.

- The ODAC discussed data supporting the current approvals of nivolumab (Opdivo) with chemotherapy or ipilimumab (Yervoy) and pembrolizumab (Keytruda) plus chemotherapy, as well as the application of tislelizumab-jsgr (Tevimbra) plus chemotherapy, for esophageal and gastric Committee members emphasized that the current data do not support the use of CPIs in patients with PD-L1 expression less than 1. They expressed concerns about the risks of immune-mediated adverse events and the statistical significance and sample sizes in the studies.

CHANGES IN LABELED INDICATIONS

Cabazitaxel (Jevtana)

Neutropenia resulting in death has been reported for those receiving **cabazitaxel (Jevtana)**. Patients' blood cell count should be monitored frequently. Cabazitaxel injection should not be given to patients with neutrophil counts of 500 cells/mm^3 or lower. It is recommended to use granulocyte-colony stimulating factor (G-CSF) for primary prophylaxis in high-risk patients, and it should also be considered for all patients receiving a 25 mg/m^2 dose.[26]

Extensive additions and/or revisions regarding trial experience including the TROPIC (NCT00417079), PROSELICA (NCT01308580), and CARD (NCT0248569) trials have been made; please refer to label for complete information.

In animal studies, intravenous administration of cabazitaxel to pregnant rats during organ development resulted in embryonic and fetal death at doses lower than the maximum recommended human dose (about 0.06 times the peak concentration in patients). Males with female partners of reproductive potential are advised to use effective contraception during treatment and for 4 months after the last dose of cabazitaxel injection.

In an animal study on milk excretion, cabazitaxel-related radioactivity was found in the stomachs of nursing pups within 2 hours after a single intravenous dose of 0.08 mg/kg given to lactating rats, which is about 0.02 times the peak concentration in humans. The radioactivity was still detectable 24 hours later, with an estimated 1.5% of the dose received by the mother appearing in her milk.

Cabazitaxel injection can lead to serious adverse events, including a low white blood cell count, which is common during treatment and can result in severe infections that may be fatal; men aged 65 and older may be at higher risk. Before starting treatment, inform your health care provider about all medical conditions, especially if you have a history of pelvic radiation, gastrointestinal issues, are pregnant or planning to become pregnant, or if you are a male with a female partner capable of becoming pregnant. Effective contraception is advised during treatment and for 4 months afterward.

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