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SCOS ONCOLOGY DRUG NEWSLETTER

FDA APPROVALS

Tisotumab vedotin-tftv (Tivdak)

The FDA has granted full approval to **tisotumab vedotin-tftv (Tivdak**) for the treatment of patients with recurrent or metastatic cervical cancer whose disease has progressed on or after chemotherapy.[1]

Results from the phase 3 innovaTV 301 trial (NCT04697628) support this FDA approval and were presented during the European Society for Medical Oncology Congress 2023 in Madrid, Spain. Treatment with tisotumab led to a 30% reduction in the risk of death vs investigator's choice of chemotherapy in the second- or third-line setting among those in the intent-to-treat population.

The median overall survival (OS) was 11.5 months (95% CI, 9.8-14.9) at a median follow-up of 10.8 months (95% CI, 10.3-11.6) with tisotumab compared with 9.5 months (95% CI, 7.9-10.7) with chemotherapy (HR, 0.70; 95% CI, 0.54-0.89; P = .0038). At 12 months, the OS rates observed between the 2 arms were 48.7% and 35.3%, respectively.[2]

With tisotumab vedotin, the median progression-free survival (PFS) was 4.2 months (95% CI, 4.0-4.4) compared with 2.9 months (95% CI, 2.6-3.1) with chemotherapy (HR, 0.67; 95% CI, 0.54-0.82; P < .0001). Furthermore, the PFS rates at 6 months were 30.4% and 18.9%, respectively, with tisotumab vs chemotherapy.

Tisotumab was previously granted accelerated approval from the FDA for the treatment of patients with metastatic cervical cancer in September 2021. In January 2024, the FDA accepted the supplemental

biologics license application (BLA) for tisotumab, which aimed to convert the accelerated approval of the agent to full approval for patients with recurrent or metastatic cervical cancer whose disease has progressed on or after first-line therapy.

Enrollment in the phase 3 innovaTV 301 trial was open to patients who received a diagnosis of recurrent or metastatic cervical cancer and had documented disease progression on or after doublet chemotherapy with or without bevacizumab (Avastin) and an anti–PD-L1 agent if eligible and available, measurable disease per RECIST v1.1 criteria, an ECOG performance status of 0 or 1, and exposure to no more than 2 prior lines of therapy.[3] The study randomly assigned patients 1:1 to receive 2 mg/kg of intravenous tisotumab vedotin every 3 weeks (n = 253) or investigator's choice of chemotherapy (n = 249), which could have included topotecan, vinorelbine, gemcitabine, irinotecan, or pemetrexed. The primary end point was OS, with secondary end points of PFS, overall response rate, and safety.

Trastuzumab-strf (HLX02)

Trastuzumab-strf (HLX02), a trastuzumab (Herceptin, Hercessi) biosimilar, has been granted approval from the FDA as an adjuvant treatment for HER2-

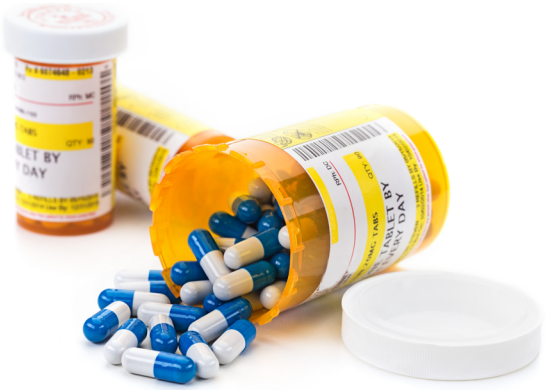
overexpressing breast cancer as well as a treatment for patients with HER2-overexpressing metastatic breast cancer and HER2-overexpressing metastatic gastric or gastroesophageal junction (GEJ) adenocarcinoma.[4]

This approval is supported by findings from a series of head-to-head trials with HLX02, including comparative quality analytical data, findings from a phase 1 pharmacokinetic similarity trial, and findings from a global, multicenter, phase 3 trial (NCT03084237) where HLX02 was shown to be highly similar to reference trastuzumab in regard to quality, safety, and efficacy. These data were submitted by Shanghai Henlius Biotech.

HLX02 is a trastuzumab biosimilar manufactured in China. The agent, developed and manufactured by Shanghai Henlius Biotech, is currently approved in more than 30 countries.

Trastuzumab is an anti-HER2 antibody given in combination with chemotherapy for patients with HER2-positive breast cancer. Although the combination has significantly improved overall survival in these patients and has become the standard of care over the past decade, the cost can limit patient access.

In April 2023, the FDA accepted a biologics license application for HLX02 for the adjuvant treatment of patients with HER2-overexpressing breast cancer, HER2-overexpressing metastatic breast cancer, and HER2-overexpressing metastatic gastric or GEJ adenocarcinoma.[5] Data from a randomized, double-blind, phase 3 trial (NCT03084237) served as a part of the basis of this BLA.



The study compared HLX02 with reference trastuzumab across 89 centers in China, the Philippines, Poland, and Ukraine.[6] Patients with HER2-positive recurrent or metastatic breast cancer were eligible and randomly assigned 1:1 to receive HLX02 or European Union (EU)–sourced trastuzumab in combination with intravenous docetaxel. The first dose was 8 mg/kg, followed by 6 mg/kg every 3 weeks for up to 12 months.

The primary end point evaluated in the trial was 24-week overall response rate (ORR). Secondary end points of the study were ORR at weeks 6, 12, 18, and 24; duration of response; disease control rate; clinical benefit rate; progression-free survival; and overall survival.

Of the 649 patients enrolled between November 11, 2016, and July 10, 2019, the 24-week ORR was 71.3% with HLX02 (n = 324) vs 71.4% for patients treated with EU-sourced trastuzumab (n = 325), with a difference of –0.1% (95% CI, –7% to 6.9%). This fell entirely in the predefined equivalence margins.

There were no statistically significant differences in secondary efficacy analyses seen. Additionally, the safety profiles of both agents as well as immunogenicity were comparable.

Tovorafenib (DAY101)

Tovorafenib (DAY101) has been granted accelerated approval by the FDA for the treatment of relapsed or refractory BRAF-altered pediatric low-grade glioma (pLGG), the most common brain tumor diagnosed in children.[7]

The approval is supported by findings from the phase 2 FIREFLY-1 trial (NCT04775485), which evaluated patients aged 6 months to 25 years with relapsed or progressive pLGG and a known activating BRAF alteration. These patients were administered tovorafenib once weekly as monotherapy.[8] Tovorafenib can be administered as a 100-mg immediate-release tablet or 25-mg/mL powder for reconstitution.[9]

Findings from FIREFLY-1 were published in Nature Medicine. The ORR was 67%, which met the study's primary end point. The median duration of response (DOR) was 16.6 months, and the median time to response (TTR) was 3 months.[9]

Regarding safety, the most common treatment-related adverse events (TRAEs) were hair color changes (76%) , increased creatine phosphokinase level (56%), and anemia (49%). TRAEs of grade 3 or higher were reported in 42% of patients, and 9 patients (7%) discontinued study treatment due to TRAEs.[10]

A total of 137 patients were enrolled in FIREFLY-1. Patients were eligible to participate if they had received at least 1 line of systemic therapy, had evidence of radiographic progression, and had at least 1 measurable lesion as defined by Response Assessment in Neuro-Oncology criteria.[9] Patients with additional activating molecular alterations, symptoms of clinical progression in the absence of radiographic progression, or diagnosis of neurofibromatosis type 1 were excluded from the study.

The study's primary end points were ORR, safety, and tolerability. Secondary end points included defining the relationship between pharmacokinetics and efficacy of the agent, visual acuity outcomes, progression-free survival, DOR, TTR, and clinical benefit rate.

The agent was previously granted FDA breakthrough therapy and rare pediatric disease designations. The FDA has also granted orphan drug designation to tovorafenib for the treatment of malignant glioma.[11] Tovorafenib is also being investigated in a phase 1/2 study (NCT04985604) in patients with recurrent or progressive solid tumors and activating RAF alterations.

Lutetium Lu 177 dotatate (177Lu-dotatate; Lutathera)

Lutetium Lu 177 dotatate (177Lu-dotatate; Lutathera) is the first radioactive drug approved for the treatment of patients 12 years or older with somatostatin receptor (SSTR)–positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs).[12] The approval is supported by data from the NETTER-P study (NCT04711135), which evaluated the agent in adolescent patients with locally advanced and inoperable or metastatic SSTR-positive GETP-NETs or pheochromocytoma/paraganglioma.

Data from NETTER-1 (NCT01578239) of 177Lu-dotatate in adult patients also support this approval. NETTER-1 findings supported the original approval of this agent in the adult population in 2018.

In NETTER-P, safety was evaluated in 9 pediatric patients, with 4 patients with GEP-NETs. Primary end points of the study were absorbed radiation doses in target organs and incidence of adverse events following the first treatment cycle. The safety profile of the agent was similar to what was reported in adults.

The application for 177Lu-dotatate was granted priority review and orphan drug designation. The FDA has issued a postmarketing requirement to assess the long-term safety of 177Lu-dotatate in the adolescent population.

The recommended dosage is 7.4 GBq (200 mCi) every 8 weeks for 4 doses. Findings from the primary analysis of NETTER-1 showed that 177Lu-dotatate significantly improved PFS vs high-dose, long-acting octreotide in adult patients with advanced midgut GEP-NETs.[13]

Data from the phase 3 NETTER-2 trial (NCT03972488) were recently presented at the 2024 Gastrointestinal Cancers Symposium in San Francisco, California.[14] In the trial findings, 177Lu-dotatate delivered a median PFS of 22.8 months (95% CI, 19.4-not evaluable) vs 8.5 months (95% CI, 7.7-13.8) with high-dose octreotide (stratified HR, 0.276; 95% CI, 0.182-0.418; P < .0001) among patients with grade 2 and 3 well-differentiated

GEP-NETs, translating to a 72% reduction in the risk of disease progression or death with 177Lu-dotatate vs high-dose octreotide.

In the 177Lu-dotatate arm (n = 151), 47 progression events and 8 deaths occurred. In the high-dose octreotide arm (n = 75), 41 progression events and 5 deaths occurred.

Nogapendekin alfa inbakicept-pmln (N-803; Anktiva)

The FDA has granted approval to **nogapendekin alfa inbakicept-pmln (N-803; Anktiva)** with BCG as a treatment combination for patients with Bacillus Calmette-Guérin (BCG)-unresponsive non–muscle-invasive bladder cancer (NMIBC) carcinoma in situ (CIS) with or without Ta or T1 disease.[15] Positive results from a series of studies of the investigational treatment, including the open-label, single-arm, multicenter, phase 2/3 QUILT-3.032 trial (NCT03022825), support this approval of nogapendekin alfa in patients with BCG-unresponsive NMIBC.[16]

Findings from the QUILT-3.032 study showed improved efficacy and safety with the agent among patients whose disease did not respond to prior therapies. A total of 71% of patients had a complete response (CR) and a median duration of response of 26.6 months.[16] The cystectomy avoidance rate was 91% with nogapendekin alfa, and the 24-month bladder cancer overall survival rate was 100%. Additionally, no serious adverse events (AEs) were reported.

In May 2023, the FDA issued a CR letter (CRL) to ImmunityBio regarding the BLA for nogapendekin alfa for the treatment of patients with BCG-unresponsive NMIBC CIS with or without Ta or T1 disease. The FDA cited insufficient inspection of a third-party manufacturer within the CRL. However, no efficacy or safety issues related to nogapendekin alfa were mentioned. The FDA accepted the BLA resubmission for nogapendekin alfa in October 2023.

Nogapendekin alfa is an IL-15 superagonist that has a mechanism of action resulting in proliferation

of natural killer and T cells. This leads to a secondary boost in immunological response from treatment with BCG or other checkpoint inhibitors for other indications.

QUILT-3.032 included patients with persistent or recurrent CIS within 12 months of undergoing adequate treatment with BCG (cohort A) or papillary recurrent high-grade Ta-T1 disease within 6 months of finishing adequate treatment with BCG. Once enrolled, patients received BCG 50 mg plus 400 µg of intravesical nogapendekin alfa every week for 6 weeks or reinduction for 6 weeks plus maintenance up to a maximum of 3 years.[17]

In cohort A, the primary end point was CR confirmed by biopsy results at 3 or 6 months. In cohort B, the primary end point was disease-free rate at 12 months. Secondary end points of the study included duration of CR, cystectomy avoidance, time to cystectomy, and safety.

Updated findings from the study were presented virtually at the 2022 American Society of Clinical Oncology Annual Meeting in Chicago, Illinois, and showed that the study met its primary end point with a 99% bladder cancer–specific overall survival rate observed at 2 years. There was also a 53% disease-free survival (DFS) rate at 18 months among patients with papillary disease, and 96% showed 24-month bladder cancer–specific progression-free survival.[16]

At 12 months, the DFS rate for patients with papillary disease was 57%, and it was 48% at 24 months.

A total of 95% of patients avoided cystectomy, with the median time to cystectomy among the 4 responders being 12.9 months vs 7.8 months in the 8 nonresponders. This resulted in a 5.1-month delay in cystectomy.

Looking at pharmacokinetic data, there were no systemic levels of N-803 and activity was confined to the bladder. Moreover, there was no incidence of grade 4/5 treatment-related serious AEs, immune-related AEs, or TRAEs observed among any patients in the study. Two patients had grade 3 TRAEs, including urinary tract infection and arthralgia. The most common grade 1/2 AEs were dysuria (22%), pollakiuria (19%), hematuria (18%), fatigue (16%), and urgency (12%), and all other AEs were seen at 7% or less.

Alectinib (Alecensa)

The FDA has granted approval to **alectinib (Alecensa)** as an adjuvant treatment following tumor resection for the treatment of patients with ALK-positive non–small cell lung cancer (NSCLC) whose tumors are at least 4 cm or node positive as detected by an FDA-approved test.[18] Findings from the phase 3 ALINA trial (NCT03456076) support this regulatory decision, as alectinib reduced the risk of disease recurrence or death by 76% vs platinum-based chemotherapy in patients with completely resected stage IB to IIIA ALK-positive NSCLC (HR, 0.24; 95% CI, 0.13-0.43; P < .0001).

At a median follow-up of 27.8 months for alectinib and 28.4 months for chemotherapy, the median disease-free survival (DFS) among the 116 patients in the alectinib arm was not yet reached. This was compared with 44.4 months (95% CI, 27.8-not evaluable) for patients in the chemotherapy arm (n = 115).[19]

The randomized, active-controlled, multicenter, open-label ALINA study sought to assess the efficacy and safety of adjuvant alectinib vs platinum-based chemotherapy in patients with resected stage IB to IIIA ALK-positive NSCLC. Patients were randomly assigned 1:1 to receive 600 mg of alectinib twice per day for 2 years or platinum-based chemotherapy every 3 weeks for 4 cycles. Chemotherapy regimens consisted of cisplatin plus pemetrexed, cisplatin plus vinorelbine, or cisplatin plus gemcitabine.

Enrollment was open to patients with an ECOG performance status of 0 to 1 who were eligible for platinum-based chemotherapy. Additional requirements included patients with adequate end-organ function and no prior systemic cancer therapy. The primary end point was investigator-assessed DFS, and key secondary end points were central nervous system DFS, overall survival, and safety.

Ciltacabtagene autoleucel (cilta-cel; Carvykti)

The FDA has approved **ciltacabtagene autoleucel (cilta-cel; Carvykti)**, a chimeric antigen receptor (CAR) T-cell therapy, for relapsed/refractory (R/R) multiple myeloma that has been treated with at least 1 prior line of therapy, including a proteasome inhibitor (PI) and immunomodulatory drug (IMiD) agent, and is refractory to lenalidomide.[20]

The approval is supported by data from the phase 3 CARTITUDE-4 study (NCT04181827) that were originally presented at the 2023 American Society of Clinical Oncology Annual Meeting in Chicago, Illinois, and published in The New England Journal of Medicine. At a median follow-up of 15.9 months (range, 0.1-27.3), the median PFS was not reached in the cilta-cel arm vs 11.8 months in the standard-of-care arm (HR, 0.26; 95% CI, 0.18-0.38; P < .001). PFS at 12 months was 75.9% (95% CI, 69.4%-81.1%) and 48.6% (95% CI, 41.5%-55.3%) in the cilta-cel vs standard-of-care arms, respectively.[21]

Cilta-cel was approved in February 2022 for patients with R/R multiple myeloma who had received at least 4 prior lines of therapy, including a PI, IMiD, and anti-CD38 antibody.[22] In March 2024, the FDA's Oncologic Drugs Advisory Committee met to discuss

data from CARTITUDE-4. The committee unanimously agreed that despite the safety risks, the benefits of cilta-cel outweigh the risks in this earlier line of treatment.[23]

"We saw cilta-cel significantly reduce the risk of disease progression or death vs standard of care by 74%. Cilta-cel led to significantly higher rates of response and default response compared with standard of care," Binod Dhakal, MD, MS, associate professor of medicine in the Division of Hematology and Oncology at the Medical College of Wisconsin in Milwaukee, said in an interview with Targeted Therapies in Oncology. "These results suggest cilta-cel is highly effective and provides superior efficacy responses compared with standard of care in the study."

In the cilta-cel vs standard-of-care arms, 84.6% and 67.3% of patients had an overall response, 73.1% and 21.8% had a complete response or better, and 60.6% and 15.6% had an absence of minimal residual disease. Overall survival data are not fully mature but continue to strengthen.[23]

Regarding safety, 39 patients and 46 patients across both arms died (HR, 0.78; 95% CI, 0.5-1.2), and most patients experienced a grade 3 or 4 adverse event during treatment. Among 176 patients treated with cilta-cel, 134 (76.1%) had cytokine release syndrome (CRS), 1.1% of which was grade 3 or 4. No grade 5 CRS was observed.

Also in this group, 8 (4.5%) patients had immune effector cell–associated neurotoxicity syndrome, which was all grade 1 or 2. Furthermore, 1 patient had movement and neurocognitive symptoms deemed grade 1, 16 patients (9.1%) had cranial nerve palsy (grade 2, 8.0%; grade 3, 1.1%), and 5 patients (2.8%) had peripheral neuropathy that was related to CAR T-cell therapy (grade 1 or 2, 2.3%; grade 3, 0.6%).[23]

CHANGES IN LABELED INDICATIONS

Ropeginterferon alfa-2b-njft (Besremi)

Patients with a history of transplantation and receiving immunosuppressant agents are newly included among the list of patients that **ropeginterferon alfa-2b-njft (Besremi)** is contraindicated with.[24]

Female patients should receive a pregnancy test prior to starting ropeginterferon alfa-2b-njft treatment. The risk summary of ropeginterferon alfa-2b-njft now includes an abortifacient effect reported in cynomolgus monkeys receiving the agent.

(Extensive updates; please refer to label for complete information.)

Fluoroestradiol F-18 (Cerianna)

Medications that attach to the estrogen receptor (ER) might interfere with **fluoroestradiol F-18 (Cerianna)** binding, potentially lowering the identification of ER-positive lesions.

Before using fluoroestradiol F-18, stop ER-binding medications like selective estrogen receptor modulators and selective estrogen receptor degraders for a minimum of 5 biological half-lives (for example, elacestrant (Orserdu) for 11 days, tamoxifen (Nolvadex, Soltamox) for 8 weeks, and fulvestrant (Faslodex) for 28 weeks).[25]

Ibrutinib (Imbruvica)

Drug-induced liver injury (DILI), including severe cases potentially leading to fatalities, has been reported in patients using Bruton tyrosine kinase inhibitors like ibrutinib.[26]

Monitor levels of bilirubin and transaminases before starting ibrutinib and regularly during treatment. If abnormal liver test results emerge after starting ibrutinib, increase the frequency of monitoring for liver test abnormalities and signs of liver damage. If DILI is suspected, stop using ibrutinib. Once DILI is confirmed, cease ibrutinib treatment.

Patients should be informed of the liver effects when using ibrutinib and should contact their clinician if they experience dark urine, abdominal discomfort or pain, or jaundice while on ibrutinib treatment.

Osimertinib mesylate (Tagrisso)

New clinical trial experiences have been reported for those using **osimertinib mesylate (Tagrisso)**. Erythema dyschromicum perstans has been identified as an AE after approval of osimertinib mesylate. As these reactions are reported voluntarily from a population of unknown size, it's not always feasible to accurately determine how often they occur or establish a definite link to drug exposure.[27]

(Extensive updates on AEs in trials (FLAURA [NCT02296125]; FLAURA2 [NCT04035486]; AURA3 [NCT02151981]) evaluating osimertinib mesylate; please refer to label for complete information.)

Tisotumab vedotin-tftv (Tivdak)

An update of AEs observed in patients receiving **tisotumab vedotin-tftv (Tivdak)** include peripheral neuropathy (5%), paresthesia (3.8%), and motor neuropathy (2.4%). Of the patients who experienced peripheral neuropathy, there were 18% that had complete resolution and 21% that had partial improvement. However, for patients with cervical cancer, peripheral neuropathy resulted in the discontinuation of the agent for 7% of patients.[28]

Hemorrhage was also observed in 51% of patients with cervical cancer and the most common hemorrhage AE was epistaxis, which occurred in 33% of patients.

(Extensive changes regarding observed AEs; please refer to label for complete information.)

Animal studies have shown that tisotumab vedotin-tftv can impair female fertility.

Patients should be informed of the eye exam with an eye care provider prior to treatment initiation and before each of the 9 cycles. Patients should be informed of the ocular signs/symptoms reviewed in these exams. For complete eye care regimen during treatment with tisotumab vedotin-tftv, please refer to the label.)

Additions to the most common AEs with tisotumab vedotin-tftv treatment now include numbness or tingling of hands or feet, eye issues that include conjunctival disorders, fluctuations in liver blood tests, and hemorrhaging

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