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NCOA ONCOLOGY DRUG NEWSLETTER

NORTH CAROLINA Oncology Association

FDA APPROVALS

Axicabtagene Ciloleucel (Axi-Cel; Yescarta)

The FDA has approved a manufacturing process change resulting in a shorter manufacturing time for **axicabtagene ciloleucel (axi-cel; Yescarta)**, which is anticipated to reduce turnaround time (TAT) from 16 days to 14 days.[1]

The median TAT is measured from the moment a patient's T cells are collected, also known as leukapheresis, to when the final product is ready for infusion. The manufacturing process, which customizes the patient's cells for a single-use cell therapy, is a crucial step within this time frame.

This manufacturing process change comes as Kite, a Gilead Company, prepares for a significant launch of axi-cel as a second-line treatment for relapsed or refractory large B-cell lymphoma (LBCL). The news follows a recent FDA decision to allow additional patient survival data to be added to the label of the chimeric antigen receptor (CAR) T-cell therapy.[2]

The positive patient survival data show that treatment with axi-cel significantly improved outcomes, reducing the risk of death by 27.4% compared with standard-of-care treatment—a relative 38% improvement in overall survival (OS)—in the pivotal phase 3 ZUMA-7 trial (NCT03391466).

The ZUMA-7 study is an international, phase 3 trial that randomly assigned patients with LBCL who had experienced relapse within a year of first-line chemoimmunotherapy into 2 equal groups.[3] The first group received axi-cel, whereas the other received chemotherapy followed by stem cell transplant if

they responded. The primary end point of the study was event-free survival according to a blinded central review, and key secondary end points were response and OS. Investigators also assessed safety.

With an overall estimated median follow-up of 46.7 months, the primary OS analysis led to a statistically significant improvement with axi-cel vs the standard therapy, even with 57% of patients in the standard-of-care arm subsequently receiving cell therapy off protocol.[2] At 39 months, the OS rates were 55.9% with axi-cel and 46% with standard of care.

Axi-cel is a CD19-directed genetically modified autologous T-cell immunotherapy used to treat a variety of patients and cancer types, including LBCL and follicular lymphoma (FL). Specifically, these indications include adults with LBCL refractory to first-line chemoimmunotherapy or those who have experienced relapse within 12 months; adults with relapsed or refractory LBCL after 2 or more lines of systemic therapy, including diffuse LBCL (DLBCL) not otherwise specified, primary mediastinal LBCL, high-grade BCL, and DLBCL arising from FL; and adults with relapsed or refractory FL (RRFL) following treatment with 2 or more lines of systemic therapy.

The FL indication is approved under accelerated approval due to its response rate. However, continued approval depends on findings from a confirmatory trial proving its clinical benefit. Additionally, axi-cel is not indicated for the treatment of patients with primary central nervous system lymphoma.

"Since the first CAR T-cell therapies were approved more than 5 years ago and the volume of patients treated has grown from hundreds to several thousand patients each year, we have significantly strengthened our knowledge and understanding of cell therapy delivery," David Miklos, MD, PhD, Kite clinical investigator and chief of the blood and marrow transplant and cell therapy program at Stanford University in California, said in a news release. "Time is a critical factor in cell therapy, and it can make the difference between a patient being able to receive CAR T or their cancer progressing to the point where they are no longer strong enough for treatment. Therefore, optimizing steps in the process and ultimately reducing the time to CAR T-cell therapy infusion is paramount."

Erdafitinib (Balversa)

TThe FDA has approved **erdafitinib (Balversa)**, a kinase inhibitor, in patients with locally advanced or metastatic urothelial carcinoma with *FGFR3* genetic alterations who have experienced disease progression on or following at least 1 prior line of treatment. The approval is supported by findings from the phase 3 THOR study (NCT03390504).[4]

Statistically significant improvements in OS, progression-free survival (PFS), and overall response rate (ORR) were observed in the study. The median OS was 12.1 months (95% CI, 10.3-16.4) for patients who received erdafitinib vs 7.8 months (95% CI, 6.5-11.1) in patients who received chemotherapy (HR, 0.64; 95% CI, 0.47-0.88; P = .0050). The median PFS was 5.6 months (95% CI, 4.4-5.7) with erdafitinib vs 2.7 months (95% CI, 1.8-3.7) with chemotherapy (HR, 0.58; 95% CI, 0.44-0.78; P = .0002). The confirmed ORR was 35.3% (95% CI, 27.3%-43.9%) with erdafitinib compared with 8.5% (95% CI, 4.3%-14.6%) with chemotherapy (P = .001).

"We now have level 1 evidence showing that erdafitinib improves survival, and it can help extend patients' lives. We certainly are not curing most patients with urothelial cancer, but we are changing the outcomes and patients are living longer because of these targeted therapies that we are able to offer them," Arlene O. Siefker-Radtke, MD, professor of genitourinary medical oncology in the division of cancer medicine at The University of Texas MD Anderson Cancer Center in Houston, told *Targeted Therapies in Oncology*.

The study's primary end point was OS, and secondary end points included PFS, ORR, time until symptom deterioration, duration of response (DOR), incidence of adverse events (AEs), and oral clearance of erdafitinib.[5] Regarding safety, the most common AEs (> 20% of patients) observed included increased phosphate level, nail disorders, and diarrhea.[1]

Erdafitinib is administered as an 8-mg oral dose once daily until disease progression or unacceptable toxicity, and the dose can be increased to 9 mg if tolerated at 14 to 21 days. Erdafitinib is not recommended for patients who are eligible for and have not received treatment with a PD-1 or PD-L1 inhibitor.

INVESTIGATIONAL NEW DRUG

OriCAR-017

The FDA has cleared the investigational new drug (IND) application for **OriCAR-017** for the treatment of patients with relapsed/refractory multiple myeloma (RRMM).[6] This IND approval for OriCAR-017 follows its IND approval from China's National Medical Products Administration in 2023, which was based on findings from the POLARIS study (NCT05016778). All 10 patients in the trial with RRMM responded to the therapy per International Myeloma Working

Group criteria, and the ORR was 100%. The stringent CRR was 80%, and a 100% minimal residual disease negativity rate was detected at day 28. This result was further confirmed at month 3.

Forty percent of patients had extramedullary disease, 50% of patients had received prior CAR T-cell therapies targeting B-cell maturation antigen, 70% had high-risk cytogenetics, 70% had an ECOG performance status of 2, and 80% had International Staging System stage II and III disease. For safety, OriCAR-017 was well tolerated. No immune effector cell–associated neurotoxicity syndrome, cerebellar disorder, or delayed infections were reported.

The single-arm, open-label, dose-escalation study is evaluating the safety, tolerability, cellular kinetics, and initial efficacy of OriCAR-017 among patients with multiple myeloma who have not responded to the standard treatments.[7] The primary end points of the study are dose-limiting toxicities, AEs, and serious AEs. Secondary end points include concentration of CAR T cells, ORR, disease control rate, duration of remission, PFS, and OS.1

HBM9027

An IND application for **HBM9027** has been cleared by the FDA, allowing a first-in-human trial to evaluate the bispecific antibody in patients with advanced solid tumors to commence.[8] HBM9027 is a novel PD-L1 × CD40 bispecific antibody made through Harbour BioMed's proprietary, fully human HCAb-Based Immune Cell Engagers platform. The agent works to activate CD40, which needs PD-L1 cross-linking to show a promising safety profile.

According to the press release, PD-L1 is overexpressed on a variety of solid malignancies. In preclinical studies, HBM9027 has demonstrated cross-linking–dependent specificity on tumors and potent immune modulation activity. The cross-linking–dependent CD40 activation has shown that HBM9027 can overcome the liver and systemic toxicity of traditional anti-CD40 monoclonal antibodies.

HBM9027 has been shown to mediate both the PD-1/PD-L1 inhibitory pathway and the CD40 agonistic pathway to reach synergistic antitumor immune responses.[9] Potent in vivo antitumor efficacy and in vivo stability have been observed with the agent along with a long half-life. Overall, these preclinical trials have shown HBM9027 to have a promising safety profile, a unique mechanism of action, and strong antitumor efficacy. A phase 1 study aims to assess the safety, tolerability, pharmacokinetics, and antitumor activity of HBM9027 in patients with advanced solid tumors. The trial will take place in the United States.[8]

BSI-082

The FDA has granted clearance to an IND application for the novel anti-SIRPα monoclonal antibody (mAb) candidate **BSI-082** for the treatment of patients with hematologic and solid tumors.[10] BSI-082 is a best-in-class, highly differentiated, fully human anti-SIRPα antagonistic mAb that shows potential in combination with other therapies and strong binding activity to human SIRPα variants V1, V2, and V8 and is able to cover more than 90% of human populations.

BSI-082 works by binding specifically to SIRPα and SIRPα but does not bind to SIRPα. Once bound, it works by blocking the interaction of SIRPα to CD47, which enables tumor-associated macrophages and dendritic cells to resume their phagocytic activity against tumor cells while avoiding the broad toxicity issue that many CD47-targeting therapies encounter.

In findings from preclinical studies, BSI-082 demonstrated potent in vivo antitumor efficacy when given in combination with mAbs against tumor-associated antigens. According to a poster presented at the American Association for Cancer Research Annual Meeting 2022 in New Orleans, Louisiana, BSI-082 exhibited best-in-class biophysical properties.[11] In addition, the agent showed SIRPα specificity, broad SIRPα variant binding, and superior functional characteristics. These findings support the commencement of IND-enabling studies as well as further manufacturing.

PRIORITY REVIEW

Lisocabtagene Maraleucel (Liso-Cel; Breyanzi)

The FDA has granted priority review to the supplemental biologics license applications (sBLAs) of **lisocabtagene maraleucel (liso-cel; Breyanzi)**, a CAR T-cell therapy, for the treatment of patients with RRFL and mantle cell lymphoma (MCL) after a Bruton tyrosine kinase inhibitor.[12] Japan's Ministry of Health, Labour and Welfare has also accepted the supplemental new drug application of liso-cel for RRFL.

The sBLAs are supported by findings from the TRANSCEND FL (NCT04245839) and TRANSCEND-NHL-001 (NCT02631044) clinical trials, which showed promising CRRs and DOR. The FDA has issued Prescription Drug User Fee Act target action dates of May 23, 2024, for liso-cel in RRFL and May 31, 2024, in R/R MCL.

Updated findings from TRANSCEND FL were presented at the 2023 65th American Society of Hematology Annual Meeting and Exposition in San Diego, California. At 12 months, liso-cel demonstrated a DOR of 89.8% and PFS of 91.3%. At median follow-ups of 16.8 and 17.8 months, the median DOR and PFS were not reached, respectively. The primary end point was ORR.[13] Secondary end points included CRR, DOR, PFS, OS, AEs, and pharmacokinetics. To be eligible, patients with RRFL needed to have received at least 1 prior line of anti-CD20 and alkylating agent therapy as well as 1 prior line of systemic therapy. Patients also needed an ECOG performance status of 0 or 1, adequate organ function, and adequate vascular access for the leukapheresis procedure. Patients with central nervous system (CNS) involvement, history of another primary malignancy, history of active HIV, or history of uncontrolled infection were not eligible for participation.

Updated findings from the phase 1 TRANSCEND-NHL-001 trial were published in December 2023.[14] Investigators reported that at a median follow-up of 16.1 months (range, 0.4-60.5), the ORR was 83.1% (95% CI, 73.3%-90.5%) and the CRR was 72.3% (95% CI, 61.4%-81.6%). The median DOR was 15.7 months (95% CI, 6.2-24.0). The median PFS was 15.3 months (95% CI, 6.6-24.9). The primary end points were treatment-related AEs, dose-limiting toxicities, and ORR.[15] The secondary end points were CRR, DOR, PFS, OS, health-related quality of life, and pharmacokinetics. Patients were required to have an ECOG performance status of 0 or

1, adequate laboratory levels, adequate cardiac function, and adequate vascular access. Patients were not eligible to participate in the trial if they had active CNS involvement, cardiovascular disease, active hepatitis infection, or another active infection.

Trastuzumab Deruxtecan (T-Dxd; Enhertu)

Trastuzumab deruxtecan (T-Dxd; Enhertu) has been granted priority review by the FDA for the treatment of patients with unresectable or metastatic HER2-positive tumors who have received prior treatment or who have no suitable treatment options available.[16] If approved, it would be the first tumor-agnostic HER2-directed therapy and antibody-drug conjugate. The Prescription Drug User Fee Act target action date is in the second quarter of 2024.

The application is based on findings from the phase 2 DESTINY-PanTumor02 study (NCT04482309). Primary results were published in the Journal of Clinical Oncology and presented at the European Society for Medical Oncology Congress 2023 in Madrid, Spain. Among 267 patients with endometrial, cervical, ovarian, bladder, biliary tract, pancreatic, and other tumors, the ORR was 37.1% (n = 99; 95% CI, 31.3%-43.2%) at a median follow-up of 12.75 months.[17] Responses were observed across all tumor cohorts, and the median DOR was 11.3 months (95% CI, 9.6-17.8). The median PFS was 6.9 months (95% CI, 5.6-8.0), and the median OS was 13.4 months (95% CI, 11.9-15.5).

SUPERVISORY REVIEW

ProSense System

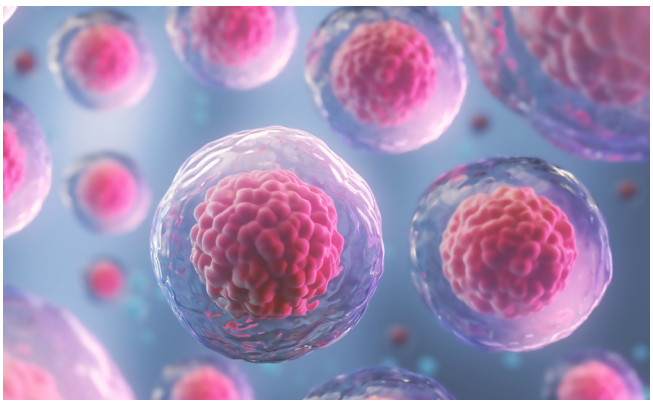
Following its initial rejection, the **ProSense System**—a minimally invasive approach for the treatment of patients with

early-stage, low-risk breast cancer—will undergo a detailed FDA review under 21 Code of Federal Regulations 10.75. If the 5-year data from the Ice3 trial (NCT02200705) confirm ProSense's safety and efficacy, it could become a valuable tool for treating patients with early-stage breast cancer.[18]

The ProSense System is a cryoablation technology that works by destroying tumors through freezing. It is an alternative approach to surgical tumor removal among patients with early-stage breast cancer, using liquid nitrogen's chilling power, creating precise lethal zones, and minimizing damage to surrounding healthy tissue. ProSense offers a minimally invasive option for treating patients with various tumors, including those in the breast, kidney, lung, and liver. By the end of February 2024, the company plans to expedite data monitoring and analysis to submit the final 5-year data set from the ICE3 trial to the FDA by April 2024.

The FDA has requested that the company submit an analysis of the ICE3 results and how they compare with findings from the LUMINA study (NCT01791829), a study sponsored by the Ontario Clinical Oncology Group in Canada, which assessed the risk of recurrence among patients with low-risk luminal A breast cancer. Those included in this study were treated with lumpectomy surgery and adjuvant hormone therapy. IceCure Medical was invited to submit real-world data from the use of ProSense across the globe by the FDA.

Interim data from the ICE3 breast cancer study support the FDA's decision to reevaluate the ProSense system. ICE3, the largest controlled, multilocation trial evaluating liquid nitrogen–based cryoablation, is assessing ProSense in malignant breast tumors that are small, low risk, and early stage.[19] The trial followed 82 patients with breast cancer for 5 years, with a total of 194 patients eligible for cryoablation across 19 hospitals in the United States. As of July 2022, the recurrence-free survival rate was 96.91% and 188 of the 194 eligible patients did not have a cancer recurrence. The procedure was 100% safe, no significant divide-related adverse events or complications were reported, and no scarring or change to the shape or size of the breast was observed.



BIOLOGICS LICENSE APPLICATION

Daratumumab (Darzalex)

The sBLA for a **daratumumab (Darzalex)**-based regimen for the treatment of patients with newly diagnosed multiple myeloma has been submitted to the FDA, according to a press release from Johnson & Johnson.[20] The application is based on findings from the phase 3 Perseus study (NCT03710603). The regimen is comprised of daratumumab combined with bortezomib (Velcade), lenalidomide (Revlimid), and dexamethasone (D-VRd) induction and consolidation treatment, autologous stem cell transplant, and lenalidomide maintenance therapy.

Findings from the study were presented at the 2023 65th American Society of Hematology Annual Meeting and Exposition in San Diego, California, and showed that the study met its primary end point of PFS.[21] At a median follow-up of 47.5 months, the 4-year PFS was 84.3% with the D-VRd regimen compared with 67.7% with VRd alone. D-VRd reduced the risk of disease progression or death by 58% (HR, 0.42; 95% CI, 0.30-0.59; P = .0001).

D-VRd demonstrated a complete response (CR) or better rate of 87.9% vs 70.1% with VRd (P = .0001). These improvements were seen across sex, age, race, disease type, disease stage, and ECOG performance status subgroups. The stringent CR and CRRs were 69.3% and 18.6% with D-VRd, respectively, vs 44.6% and 25.4% with VRd. In all, 64% of patients in the D-VRd arm who entered the maintenance phase were able to discontinue treatment after achieving a CR or better and 2-year sustained minimal residual disease negativity.[20]

Obecabtagene Autoleucel (Obe-Cel; AUTO1)

The FDA accepted the biologics license application (BLA) submission for **obecabtagene autoleucel (obe-**

cel; AUTO1), a CD19-directed CAR T-cell therapy, in relapsed/refractory B-cell acute lymphoblastic leukemia, according to Autolus Therapeutics.[22] A Prescription Drug User Fee Act target action date of November 16, 2024, has been issued.

The review timeline is standard and consistent with recently approved CAR T-cell therapies, and the FDA has not announced any advisory committee meetings pertaining to this application so far. The submission and acceptance are based on findings from the phase 2 FELIX study (NCT04404660) presented at the American Society of Clinical Oncology (ASCO) Annual Meeting in June 2023 in Chicago, Illinois, and the 65th American Society of Hematology (ASH) Annual Meeting and Exposition in December 2023 in San Diego, California.

At the ASCO meeting, investigators presented frontline data showing that obe-cel delivered a 76% CR rate or CR with incomplete count (CRi) rate.[23] Updated findings presented at the ASH meeting showed that the CR/CRi rate was 77% (95 of 124 patients) and the CR rate specifically was 57% (71 of 124 patients).[24] Among evaluable patients, 96% achieved minimal residual disease–negative status by central flow cytometry analysis. As of March 2023, the median DOR had not yet been reached.

ORPHAN DRUG DESIGNATION

PTX-252

An orphan drug designation has been granted by the FDA to **PTX-252** for the treatment of patients with acute myeloid leukemia (AML), according to Hyloris Pharmaceuticals.[25] PTX-252 is a novel molecular drug that aims to improve responsiveness and increase sensitivity of cancer cells to chemotherapy with a molecular entity derived from an established molecule.

Pleco Therapeutics worked with Hyloris Pharmaceuticals for the development of PTX-252. Appointed in September 2023, Henno Welgemoed, MD, chief medical officer of Pleco Therapeutics, will lead the development of PTX-252 in AML. The agent will undergo evaluation in a phase 2 study that plans to launch in 2024.[26] Welgemoed is overseeing the development of PTX-062 for the treatment of patients with lung cancer, PTX-142 for treating patients with pancreatic cancer, and PTX-081 in other cancers. Currently, all these agents are undergoing candidate selection or being evaluated in preclinical studies.[27]

CLINICAL TRIAL CLEARANCE

NK010

The FDA has granted clearance for a clinical trial of **NK010** for the treatment of specific cancer types, particularly those that are resistant to established therapies, according to NK CellTech.[28] The first indication selected for investigation in the clinical trial is ovarian cancer. NK010 is a novel nongenetically modified natural killer (NK) cell therapy. This is the first nongenetically modified NK cell therapy that comes from allogeneic peripheral blood mononuclear cells (PBMCs) from China to be approved for clinical trials by the FDA.

The therapy uses nongenetically modified NK cells extracted from healthy donor PBMCs and demonstrates a comprehensive antitumor profile through broad spectrum activity by expressing activation receptors that enable potent targeting of diverse tumor types and enhanced potency. The high purity of NK010 ensures a concentrated arsenal of cytotoxic NK cells. In preclinical trials, NK010 demonstrated remarkable tumor-suppressing prowess against ovarian cancer, liver cancer, and other solid tumors. The agent also showed strong tumor growth inhibition on acute myeloid leukemia.[29]

NK010 shows the potential to treat multiple other types of diseases, including nontumor diseases.

Furthermore, its high purity and effectiveness make it an ideal starting point for the company's next-generation synthetic NK cell drugs.[28] The agent also represents a promising advancement in the landscape of NK cell–based immunotherapy. Ongoing trials will further evaluate its potential impact on cancer treatment and explore its use in nontumor settings. A phase 1 clinical trial will evaluate NK010 in patients with a variety of cancer types, focusing first on patients with ovarian cancer.

CHANGES IN LABELED INDICATIONS

Blinatumomab (Blincyto)

There are new warnings associated with blinatumomab including cytokine release syndrome (CRS) and neurological toxicities, such as immune effector cell-associated neurotoxicity syndrome, which is a fatal and severe AE. The incidence of this AE was 7.5% in clinical trials, and it can be concurrent with CRS or can take place post CRS; it can also occur without CRS. Patients are advised to refrain from hazardous occupations such as operating heavy or dangerous machinery while taking blinatumomab.[30]

Nilotinib Hydrochloride Monohydrate (Tasigna)

Musculoskeletal and connective tissue disorders, such as osteonecrosis, are associated with the use of nilotinib hydrochloride monohydrate.[31]

Tepotinib Hydrochloride (Tepmetko)

An update to the percentage of patients who have experienced AEs while taking tepotinib hydrochloride has been issued. Two percent of patients experienced interstitial lung disease/pneumonitis and 5 patients discontinued use of tepotinib hydrochloride because of it. Eighteen percent of patients experienced hepatotoxicity, and grade 3 alanine aminotransferase and aspartate aminotransferase increase occurred in 4.7%; this caused 4 patients to discontinue use of tepotinib hydrochloride. The median starting time of this grade 3 AE was 47 days (range 1 to 262).[32]

A new section related to pancreatic toxicity has been added. There were patients (13%) taking tepotinib who experienced increased levels (grade 3 and 4) of amylase and lipase (in 5% and 1.2% of patients, respectively).

It is recommended to monitor amylase and lipase levels throughout treatment and, based on severity of the treatment, sometimes they should be withheld, reduced, or discontinued. Patients should inform their doctor if they have any known pancreatic issues. Patients should be informed prior to treatment that laboratory tests will be administered to monitor pancreatic function and they should contact their health care provider immediately if symptoms relating to the pancreas should occur—upper stomach pain that occurs when eating or spreads to the back, vomiting, nausea, and/or weight loss. There are further extensive changes regarding pancreatic toxicity. Please refer to the label for more information.

Additions to common AEs when taking tepotinib hydrochloride now include loss of appetite, rash, and changes in certain blood tests.

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