DECEMBER 2024

TACOS ONCOLOGY DRUG NEWSLETTER

The Arizona Clinical Oncology Society

FDA APPROVAL

Nilotinib (Danziten)

The first indication of **nilotinib (Danziten)** tablets that necessitates no mealtime restrictions has been approved by the FDA. The agent is indicated for treating adult patients with newly diagnosed Philadelphia chromosome–positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP); in addition, it is indicated for use by adult patients with Ph+ CML in CP and acute phase (AP) that is resistant to or who were intolerant to prior therapy that included imatinib (Gleevec).[1]

Unlike standard nilotinib (Tasigna) capsules that were approved by the FDA for this patient population in 2007 and in 2010 for patients with newly diagnosed Ph+ CML-CP,2 the nilotinib tablet formulation offers no mealtime restrictions and a lower dose.

Nilotinib tablets are a re-engineered formulation of nilotinib that has improved bioavailability. The tablets have shown improved pharmacokinetics with consistent nilotinib exposure regardless of fasting state or meal type.[1]

According to the prescribing information, patients prescribed standard nilotinib capsules must avoid food for 2 hours before and 1 hour after treatment due to its variable bioavailability, which increases when taken with food.[2] Azurity Pharmaceuticals, the developer of the nilotinib tablet, noted that this increased bioavailability can significantly prolong the QT interval.[1]

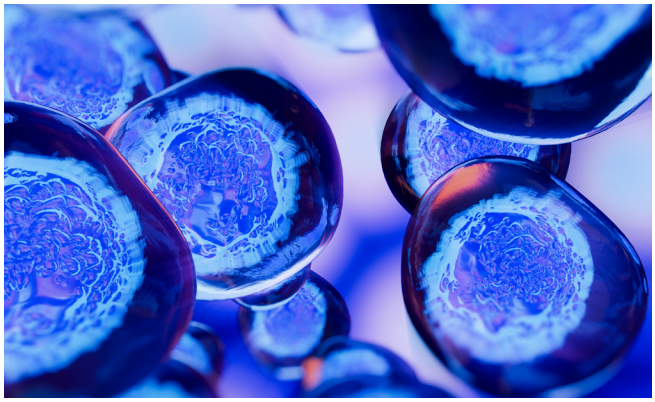
The recommended dose of nilotinib tablets for newly diagnosed adult patients with Ph+ CML-CP is 142 mg orally twice daily. For those with Ph+ CML-CP and CML-AP that is resistant or who are intolerant, the dose is 190 mg orally twice daily.[3]

The starting dose should be reduced in patients with baseline hepatic impairment. Additionally, newly diagnosed adult patients with Ph+ CML-CP who have received nilotinib tablets for at least 3 years and who achieved a sustained molecular response may be eligible for treatment discontinuation, as are those with Ph+ CML-CP that was resistant to or who were intolerant to imatinib and achieved a sustained molecular response.[3]

Obecabtagene autoleucel (obe-cel) (Aucatzyl)

The FDA approved the CD19-directed chimeric antigen receptor (CAR) T-cell therapy **obecabtagene autoleucel (obe-cel; Aucatzyl)** for the treatment of adult patients with relapsed/refractory B-cell precursor acute lymphoblastic leukemia (R/R B-ALL).[4]

Findings from the phase 1b/2 FELIX trial (NCT04404660) support this approval. Data presented during the 2023 American Society of Hematology (ASH) Annual Meeting and Exposition showed that at a median follow-up of 11 months (range, 0.9-30.6 months), treatment with obe-cel



elicited a complete response (CR) or CR with incomplete hematologic recovery (CRi) rate of 77% (n = 95/124) and a CR rate of 57% (n = 71/124).[5]

Additionally, 96% of patients with evaluable measurable residual disease (MRD) status had MRD negativity based on central flow cytometry analysis. As of March 2023, the median duration of response had not yet been reached.

Grade 3 or higher cytokine release syndrome (CRS) affected 2.4% of patients, and 7.1% had grade 3 or higher immune effector cell–associated neurotoxicity syndrome. Investigators reported that CAR-T expansion was consistent across the phase 1b/2 cohorts and that CAR-T cells were persistent in most responders at the time of follow-up.

The phase 1b/2 study enrolled patients R/R B-ALL. Patients underwent lymphodepletion with 30 mg/m2 of fludarabine for 4 courses and 500 mg/m2 of cyclophosphamide for 2 courses. Additionally, investigators administered obe-cel at a target dose of 410 × 106 CAR-T cells as a split dose on days 1 and 10 as determined via pre-lymphodepletion bone marrow blast burden.

Enrollment was open to patients 18 years and older with R/R B-cell ALL and an ECOG performance status of 0 or 1. Patients were required to have adequate renal, hepatic, pulmonary, and cardiac function and documented CD19 positivity within 1 month before screening. Patients with Philadelphia chromosome–positive ALL were eligible to enroll if they were intolerant to tyrosine kinase inhibitor (TKI) therapy, progressed on 2 lines of TKIs, or progressed on 1 line of therapy including a second-generation TKI.

The primary end point of the study was overall remission rate as assessed by independent review. Secondary end points included duration of remission, MRD-negative remission rate, safety, and CAR-T expansion and persistence.

Asciminib (Scemblix)

The FDA has granted **asciminib (Scemblix)** accelerated approval for the treatment of adult patients with newly diagnosed Philadelphia chromosome–positive chronic myeloid leukemia in chronic phase (Ph+ CML-CP).[6]

Findings from the ASC4FIRST trial (NCT04971226) support this regulatory approval of asciminib in patients with newly diagnosed Ph+ CML-CP. The major molecular response (MMR) rate at 48 weeks, which was the primary end point of the study, was 68% (95% CI, 61%-74%) in the asciminib arm and 49% (95% CI, 42%-56%) in the investigator-selected tyrosine kinase inhibitor (TKI) arm (difference, 19%; 95% CI, 10%-28%; P = .001). Within the imatinib (Gleevec) stratum, the major molecular response (MMR) rate in the asciminib arm was 69% (95% CI, 59%-78%) compared with 40% (95% CI, 31%-50%) in the investigator-selected TKI arm (difference, ≈ 30%; 95% CI, 17%-42%; P = .001).

For safety, the most common adverse events (AEs) observed in more than 20% of patients with newly diagnosed and previously treated Ph+ CML-CP included musculoskeletal pain, rash, fatigue, upper respiratory tract infections, headache, abdominal pain, and diarrhea. The most common laboratory test result abnormalities seen in more than 40% of patients with newly diagnosed Ph+ CML-CP were decreases in calcium level correction and lymphocyte, leukocyte, platelet, and neutrophil counts.

The recommended dosage of asciminib is 80 mg taken orally once daily at approximately the same time of day or 40 mg taken orally twice daily at approximately 12-hour intervals. In 2021, the FDA approved use of asciminib for patients with Ph+ CML-CP who had been treated with 2 or more TKIs.[7]

Asciminib is among the newest available treatments for patients with CML.

ASC4FIRST is a multicenter, randomized, active-controlled, open-label trial. A total of 405 patients were randomly assigned 1:1 to asciminib or to imatinib, nilotinib (Tasigna), dasatinib (Sprycel), or bosutinib (Bosulif).8 A total of 405 adult patients were enrolled across 111 locations.

Secondary end points included MMR at week 96, time to discontinuation of study treatment due to AEs, complete hematologic response, complete cytogenetic response, and duration of MMR. Other secondary end points included time to first MMR, time to treatment failure, failure-free survival, event-free survival, progression-free survival, and overall survival.

Methotrexate (Jylamvo)

Methotrexate (Jylamvo) has gained expanded approval from the FDA to include the treatment of pediatric acute lymphoblastic leukemia (ALL), making it the only oral methotrexate solution available for adult and pediatric patients.[9] The expanded approval also includes treatment of pediatric patients with polyarticular juvenile idiopathic arthritis.

In November 2022, the FDA approved this oral methotrexate solution for the treatment of adult patients with ALL, mycosis fungoides, relapsed/refractory non-Hodgkin lymphoma, rheumatoid arthritis, and severe psoriasis.[9,10] This formulation offers advantages over traditional methotrexate formulations; these include room temperature stability for 3 months after opening.[9]

Zolbetuximab-clzb (Vyloy)

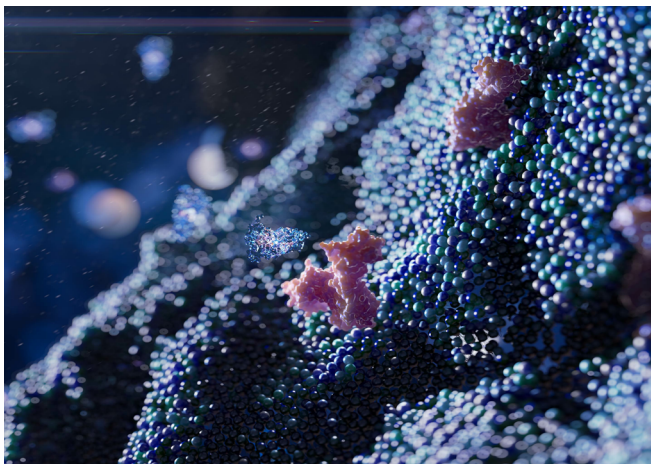
The FDA has approved **zolbetuximab-clzb (Vyloy)** for the first-line treatment of patients with locally advanced unresectable or metastatic, HER2-negative, claudin 18.2 (CLDN18.2)–positive gastric/gastroesophageal junction (GEJ) cancer. It is used in combination with fluoropyrimidine- and platinum-containing chemotherapy. This is the first CLDN18.2-targeted therapy approval for this patient population.[11]

The approval follows a complete response letter issued in January 2024 after third-party manufacturing deficiencies were identified during the inspection of the facility before licensing. However, the FDA did not raise any concerns related to the clinical data of zolbetuximab and did not request any additional studies to support the biologics license application.

The approval is supported by data from the phase 3 SPOTLIGHT (NCT03504397) and GLOW (NCT03653507) studies.[12,13] In SPOTLIGHT, zolbetuximab-clzb was combined with mFOLFOX6 (modified fluorouracil, leucovorin, and oxaliplatin) and led to a median progression-free survival (PFS) by independent review committee of 10.61 months (95% CI, 8.90-12.48 months) vs 8.67 months (95% CI, 8.21-10.28 months) with placebo/mFOLFOX6. This finding represented a 25% reduction in the risk of disease progression or death (HR, 0.751; 95% CI, 0.589-0.942; P = .0066).[12]

The international, double-blind, placebo-controlled SPOTLIGHT trial enrolled patients with previously untreated, locally advanced, unresectable or metastatic gastric/GEJ adenocarcinoma and CLDN18.2 positivity.12 To be eligible for enrollment, patients had to have moderate to strong CLDN18 staining in at least 75% of tumor cells, HER2-negative disease, and an ECOG performance status of 0 or 1. Patients were randomly assigned 1:1 to receive the combination of zolbetuximab-clzb and mFOLFOX6 (n = 283) or placebo and mFOLFOX6 (n = 282).

In GLOW, zolbetuximab was combined with CAPOX (capecitabine and oxaliplatin).[13] At a median



follow-up of 12.62 months in the experimental arm and 12.09 months in the comparator arm, the median PFS was 8.21 months (95% CI, 7.46-8.84 months) for the experimental arm compared with 6.8 months (95% CI, 6.14-8.08 months) for the comparator arm (HR, 0.687; 95% CI, 0.544-0.866; P = .0007). The 12-month PFS with zolbetuximab-clzb/CAPOX was 35% vs 19% with placebo/CAPOX, and the 24-month PFS was 14% vs 7%, respectively.

GLOW was a global, multicenter, double-blind, randomized study. In the experimental arm, zolbetuximab-clzb was administered at a loading dose for cycle 1 on day 1 followed by a lower dose during subsequent cycles given every 3 weeks.[13] Patients in the experimental arm also received CAPOX until disease progression was confirmed or 8 treatments were completed. For the CAPOX regimen, oxaliplatin was administered on day 1 of each cycle, and capecitabine was given on days 1 through 14. Chemotherapy was continued at the investigator's discretion or until the patient met the discontinuation criteria. Patients in the comparator arm were given matching placebo and CAPOX.

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 (mNSCLC) whose disease has progressed on or after a platinum-based regimen.[14]

Optune Lua is a portable device that generates alternating electric fields known as tumor treating fields (TTFields). These 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).[15,16] In this study, 145 patients who received Optune Lua in combination with either a PD-1/PD-L1 inhibitor or docetaxel had a median overall survival (OS) of 13.2 months (95% CI, 10.3-15.5 months).

In comparison, 146 patients who were treated with only a PD-1/PD-L1 inhibitor or docetaxel achieved a median OS of 9.9 months (95% CI, 8.2-12.2 months). 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," Ticiana Leal, MD, said in a press release. Leal is an associate professor and director of the Thoracic Oncology Program at the Winship Cancer Institute of Emory University School of Medicine in Atlanta, Georgia, and the primary investigator of the LUNAR study.[14]

"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," Leal said, "which, when combined with Optune Lua's lack of systemic toxicity, makes this a compelling development for many patients and their clinicians who need better treatment options for this advanced disease."

The randomized, open-label, phase 3 LUNAR study sought to evaluate Optune Lua in patients 22 years or older with mNSCLC.[16] Criteria for participants included disease that progressed on or after platinum-based chemotherapy and that had squamous or nonsquamous histology and 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 randomly assigned 1:1 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 daily 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 European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire C30 with the LC13 addendum, and safety.

Additional data from the phase 3 trial were published in The Lancet Oncology. Among 66 patients treated with Optune Lua plus an immune checkpoint inhibitor (ICI), the median OS was 18.5 months (95% CI, 10.6-30.3 months) vs 10.8 months (95% CI, 8.2-18.4 months) for 68 patients treated with an ICI alone (HR, 0.63; 95% CI, 0.41-0.96; P = .030). Of 71 patients treated with Optune Lua in addition to docetaxel, the median OS was 11.1 months (95% CI, 8.2-14.1 months) vs 8.7 months (95% CI, 6.3-11.3 months) in the docetaxel-alone arm (HR, 0.81; 95% CI, 0.55-1.19; P = .28).[15]

In terms of safety, 63.1% of patients in the experimental arm experienced device-related adverse effects (AEs), most of which were low grade.[14] One of these AEs was grade 3 skin toxicity that required a break from treatment; this occurred in 4% of patients. Additionally, there were no grade 4/5 AEs related to Optune Lua observed in the study, and no device-related AEs leading to death were reported.

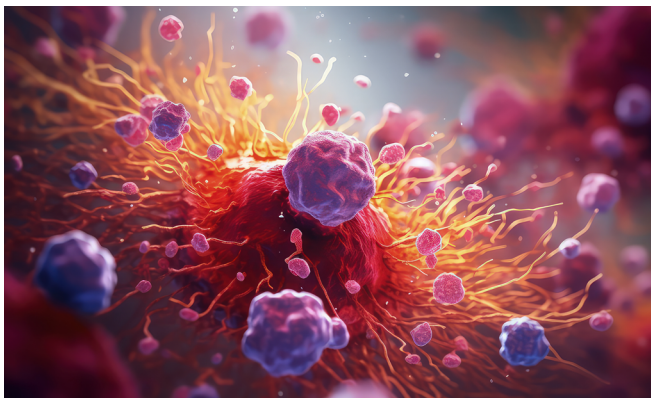
Inavolisib (Itovebi)/Palbociclib (Ibrance)/Fulvestrant

The regimen of inavolisib (Itovebi; 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.[17]

The approval is supported by findings from the phase 3 INAVO120 study (NCT04191499). Initial findings were presented at the San Antonio Breast Cancer Symposium 2023 held in Texas, and additional data were presented at the 2024 American Society of Clinical Oncology Annual Meeting held in Chicago, Illinois. 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 months with inavolisib vs 7.3 months in the arm given placebo plus palbociclib and fulvestrant. The 6-, 12-, and 18-month PFS rates in the inavolisib arm were 82.9%, 55.9%, and 46.2%, respectively; in the placebo arm, they were 55.9%, 32.6%, and 21.1%.[18,19]

An interim analysis of overall survival (OS) showed a 36% reduction in the risk of death (HR, 0.64; 95% CI, 0.43-0.97; P = .0338). The 6-, 12-, and 18-month OS rates with inavolisib were 97.3%, 85.9%, and 73.7%, respectively; in the placebo arm, they were 89.9%, 74.9%, and 67.5%. Inavolisib also delivered an overall response rate of 58.4% vs 25% with placebo and a clinical benefit rate of 75.2% vs 47%, respectively.

"[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 is destroyed," said Dejan Juric, MD, lead investigator of INAVO120 and associate physician in medicine-hematology and medical oncology at Massachusetts General Hospital Cancer Center in Boston, in an interview with Targeted Therapies in Oncology.



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

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

CHANGES IN LABELED INDICATIONS

Avapritinib (Ayvakit)

Patients receiving **avapritinib (Ayvakit)** should avoid coadministration of contraceptives containing ethinyl estradiol; this combination may increase exposure of ethinyl estradiol20 and lead to increased risk of associated adverse events. If use of an effective nonhormonal contraceptive or an effective hormonal contraceptive without estrogen is intolerable or the patient is unable to use for other reasons, a formulation containing 20 µg or less of ethinyl estradiol may be used unless a higher dose is necessary.

When receiving avapritinib, female patients should use effective contraception during and 6 weeks after the final dose. Clinicians should be made aware of all medications (both prescription and over the counter), herbal supplements, and vitamins being used by the patient; avapritinib may affect the intended use of these other agents, or the other products may affect the use of avapritinib.

Trastuzumab-pkrb (Herzuma)

Updated results of clinical trials are extensive regarding treatment with **trastuzumab-pkrb (Herzuma)**; please refer to the prescribing information.[21]

Postmarketing updates noted that trastuzumab-pkrb can cause fetal harm if given to a female patient while pregnant. Adverse events reported were cases of oligohydramnios and of oligohydramnios sequence that were manifested as pulmonary hypoplasia, skeletal abnormalities, and neonatal death. Patients must be informed of these risks. Female patients receiving trastuzumab-pkrb should be monitored for oligohydramnios while pregnant or within 7 months before conception. If oligohydramnios occurs, appropriate fetal/neonatal testing should be performed for gestational age consistent with community standards of care.

These reports included findings in patients taking trastuzumab-pkrb alone or in combination with other agents. In most cases reported, the amniotic fluid index increased after trastuzumab was stopped. Oligohydramnios recurred with resumption of trastuzumab-pkrb therapy after the amniotic fluid index improved.

Denosumab-bbdz (Jubbonti)

Patients who have pre-existing hypocalcemia must rectify this condition before starting treatment with **denosumab-bbdz (Jubbonti)**.[22] Use of denosumab-bbdz may also cause fetal harm in woman who are pregnant while receiving treatment; a pregnancy test should be given prior to treatment initiation.

Treatment is not recommended for patients who are hypersensitive to components within denosumab-

bbdz; hypersensitivity reactions have included anaphylaxis, facial swelling, and urticaria.

The most commonly reported adverse events associated with denosumab-bbdz by those with postmenopausal osteoporosis include back pain, pain in extremity, musculoskeletal pain, hypercholesterolemia, and cystitis.

Regarding pediatric use, efficacy and safety are not yet established with denosumab-bbdz. For trial data, please refer to the prescribing information.

Mitotane (Lysodren)

Dyspnea and QT prolongation (an abnormal delay in the heart's electrical system) have been added as adverse events associated with **mitotane (Lysodren)** treatment.[23]

Oxaliplatin

Serious and fatal hypersensitivity adverse events (AEs) associated with use of **oxaliplatin** and other platinum-based drugs have been added as a new warning.[24] AEs including anaphylaxis can occur within minutes of administration and during any cycle of oxaliplatin use. Clinicians should permanently discontinue oxaliplatin treatment immediately if hypersensitivity AEs occur and proceed with management of these effects. Other updated warnings associated with oxaliplatin treatment are extensive and include the following AEs:

- hypersensitivity reactions;
- peripheral sensory neuropathy;
- severe myelosuppression;
- reversible posterior leukoencephalopathy syndrome;
- pulmonary toxicity;
- hepatotoxicity;
- QT-interval prolongation and ventricular arrhythmias;
- rhabdomyolysis; and
- hemorrhage.

Please refer to the prescribing information.

Mercaptopurine (Purixan)

Pellagra and erythema nodosum have been added as adverse events (AEs)associated with **mercaptopurine (Purixan)** treatment noted during postmarketing experience.[25] The dose of mercaptopurine may need to be adjusted if given with methotrexate simultaneously. The mechanism of the interaction is not fully defined; however, increased mercaptopurine exposure with concomitant methotrexate use may lead to increased risk of AEs associated with mercaptopurine treatment.

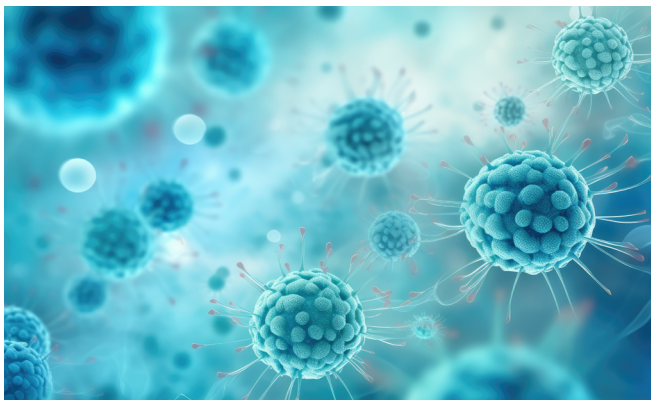
Isatuximab-irfc (Sarclisa)

Isatuximab-irfc (Sarclisa) binds to CD38 on red blood cells, which can cause a false-positive result in the indirect antiglobulin (Coombs) test.[26] Patients should be advised that this interference may continue for up to 6 months following the last dose of isatuximab-irfc. For clinical data regarding this warning, please consult the prescribing information.

Filgrastim-sndz (Zarxio)

Use of **filgrastim-sndz (Zarxio)** is approved by the FDA to improve survival in pediatric patients acutely exposed to myelosuppressive radiation doses.[27] Due to ethical and practical constraints, human efficacy studies for this specific use were not possible. Thus, this approval is based upon the results of animal studies and clinical data supporting its use for other approved indications.

Patients receiving filgrastim-sndz for acute radiation exposure should be informed that its effectiveness was not tested in humans and that regular blood tests every 3 days will be needed to monitor white blood cell counts during treatment.



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