AUGUST 2024

SCOS ONCOLOGY DRUG NEWSLETTER

FDA APPROVALS

Tepylute (SH-105)

The FDA has approved **Tepylute (SH-105)**, a ready-to-dilute formulation of an existing treatment for breast and ovarian adenocarcinoma.[1] The original nondilutable agent was approved in the 1950s and has not been updated since, according to Shorla Oncology, manufacturer of Tepylute.[2] The now-approved, ready-to-dilute formulation simplifies the drug reconstitution process, which can improve efficiency and reduce preparation risks for clinicians while increasing satisfaction and safety for patients.[3]

Tepylute is an intravenously administered agent for brain metastasis in patients with breast cancer in its formulation and manufacturing stage. The agent has an estimated commercialization date of Q3 2026. Shorla Oncology has several other agents in its pipeline. These include SH-110, an oral liquid treatment for glioma. SH-110 is currently in clinical development and has an estimated commercialization date of Q2 2026.

SH-201 is a liquid formulation of a treatment for chronic myeloid leukemia, acute lymphoblastic leukemia (ALL), myelodysplastic syndromes, and gastrointestinal tumors. The FDA accepted the new drug application for SH-201 in April 2024 and set a Prescription Drug User Fee Act target action date of November 30, 2024.[4]

Shorla Oncology manufactures Jylamvo, the only approved oral methotrexate solution for adults, and nelarabine, an injection for the treatment of T-cell ALL and T-cell lymphoblastic lymphoma.[2]

Epcoritamab (Epkinly)

The FDA has granted accelerated approval to **epcoritamab (Epkinly)** for the treatment of relapsed/refractory follicular lymphoma after 2 or more lines of therapy. This is the first subcutaneously delivered bispecific antibody to be approved in this intent-to-treat population.[5]

In November 2023, the FDA granted epcoritamab breakthrough drug designation for follicular lymphoma.[6] Epcoritamab is also approved to treat relapsed/refractory third-line diffuse large B-cell lymphoma.

The approval is supported by data from the phase 1/2 EPCORE NHL-1 study (NCT03625037), which were presented at the 2023 American Society of Hematology Annual Meeting.[7] Among 127 patients with follicular lymphoma who were enrolled to receive epcoritamab, the overall response rate (ORR) was 82% (95% CI, 74.1%-88.2%) with a complete response (CR) rate of 60%.[5] The median progression-free survival (PFS) was 15.4 months and the median duration of response (DOR), duration of CR, and overall survival (OS) were not reached by the data cutoff. Further, minimal residual disease (MRD) negativity was associated with improved PFS.[5,7]

Regarding safety, the most common any-grade treatment-emergent adverse events (TEAEs) were cytokine release syndrome (CRS; 66%), injection site reaction (57%), COVID-19 (40%), fatigue (30%), neutropenia (28%), diarrhea (27%), and pyrexia (25%). The most common reason for treatment discontinuation was COVID-19, and TEAEs that led to discontinuation occurred in 19% of patients. No patients discontinued treatment due to CRS. TEAEs resulting in death occurred in 13 patients (10%).

The study's primary end points were dose-limiting toxicities, incidence of adverse events (AEs), ORR, and incidence of CRS events.[8] Secondary end points included number of patients with antilymphoma activity, DOR, changes in lymphoma symptoms, CR rate, duration of CR, PFS, time to CR, PFS, MRD negativity rate, OS, and pharmacokinetics.

Adagrasib (Krazati) with cetuximab (Erbitux)

The FDA has approved the combination of **adagrasib (Krazati)** with **cetuximab (Erbitux)** for the treatment of patients with locally advanced or metastatic colorectal cancer (CRC) harboring a KRAS G12C mutation and who have received prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy.[9]

This approval is supported by findings from the KRYSTAL-1 study (NCT03785249), which showed encouraging clinical activity and manageable safety profiles for adagrasib and cetuximab in patients with metastatic CRC harboring a KRAS G12C mutation. The safety profiles of each drug were consistent with previous reports and with the known safety profiles of each drug individually.

Most recently, results of the phase 1/2 KRYSTAL-1 trial presented during the 2024 American Association for Cancer Research Annual Meeting and simultaneously published in Cancer Discovery showed that the confirmed objective response rate with the combination per blinded independent central review (BICR) was 34.0%.[10,11] These data come from patients in the phase 1 and 2 cohorts of the KRYSTAL-1trial who were treated with the combination. The data cutoff date was June 30, 2023, and the median follow-up was 11.9 months for the trial. Moreover, the disease control rate (DCR) was 85.1%, and the median DOR was 5.8 months.

The pooled phase 1 and 2 cohorts of the study showed that of the totaled 94 patients, the median age was 57 years (range, 24-75), 53.2% were female, and most patients were White (71.3%), followed by Black or African American (13.8%), Asian (5.3%), or other (9.6%). The majority of patients were non-Hispanic or non-Latino (79.8%), and 48.9% had an ECOG performance status of 1.

Patients received a median number of 3 prior lines of therapy (range, 1-9), 8.5% received 1 prior line of treatment, 36.2% received 2 lines, 30.9% received 3 lines, and 24.5% received 4 lines. A concurrent TP53 mutation was seen in 73.8% of patients, a concurrent PIK3CA mutation in 17.5%, EGFR amplification in 2.5%, and an NTRK fusion in 1.3%.

Additional results from the study showed that the median PFS was 6.9 months (95% CI, 5.7-7.4) and the 6-month PFS rate was 57.7%, and the median OS was 15.9 months (95% CI, 11.8-18.8) with a 6-month OS rate of 87.8%.

Regarding safety, 100% of patients experienced any-grade TRAEs, most of which were grade 2 (63.8%). TRAEs that were most seen included nausea (any-grade, 60.6%; grade 3, 2.1%), vomiting (51.5%; 0%), diarrhea (48.9%; 1.1%), dermatitis acneiform (47.9%; 2.1%), fatigue (42.6%; 1.1%), dry skin (34.0%; 0%), hypomagnesemia (28.7%; 2.1%; grade 4, 1.1%), headache (26.6%; 3.2%), and rash (22.3%; 2.1%).

In 2022, the combination of adagrasib and cetuximab was also granted a breakthrough therapy designation by the FDA for patients with *KRAS* G12C–mutated advanced CRC whose cancer progressed following prior treatment with chemotherapy and anti-VEGF therapy. By February 2024, the FDA accepted a supplemental new drug application for priority review regarding the combination. Both regulatory decisions were based on findings from KRYSTAL-1.

Enrollment in the trial was open to patients with unresectable or metastatic *KRAS* G12C–mutated CRC who had an ECOG performance status of 0 or 1. In both the phase 1 and 2 portions, patients must have had no available treatment with curative intent or refused or were ineligible for standard treatment. In the phase 2 portion, patients could have received prior fluoropyrimidine, irinotecan, oxaliplatin, and a VEGF/VEGFR inhibitor.

First, patients were treated with 600 mg of adagrasib twice per day plus cetuximab at 400 mg/m2 followed by 250 mg/m2 weekly or 500 mg/m2 every 2 weeks (phase 1; n = 32). In the phase 2 portion of the study, adagrasib was given at a dose of 600 mg twice daily plus cetuximab at 500 mg/m2 every 2 weeks.

The primary end points included safety and objective response rate by BICR per RECIST v1.1 criteria, and secondary end points in the phase 1/2 portions were DOR, PFS, and OS, as well as safety in the phase 2 portion alone.

Previous findings were published in The New England Journal of Medicine.[12] Here, adagrasib given with or without cetuximab led to antitumor activity in the heavily pretreated study population. Of the 28 evaluable patients, the ORR was 46% (95% CI, 28%-66%), and the median DOR was 7.6 months (95% CI, 5.7-not estimable). The median PFS with adagrasib was 6.9 months (95% CI, 5.4-8.1).

No synergistic AEs were observed with the combination. However, of the patients treated with adagrasib alone, grade 3 or 4 TRAEs were seen in 34% of patients vs 16% of patients who received adagrasib plus cetuximab. No grade 5 TRAEs were observed.

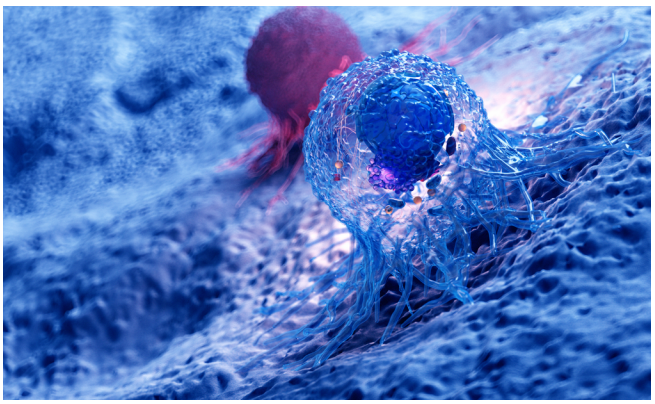
Pembrolizumab (Keytruda) plus chemotherapy

The FDA has approved the combination of **pembrolizumab (Keytruda)** with standard-of-care chemotherapy followed by single-agent pembrolizumab for the treatment of patients with primary advanced or recurrent endometrial cancer.[13]

This approval makes pembrolizumab the first immunotherapy indicated for the frontline treatment of advanced endometrial cancer, regardless of mismatch repair (MMR) status. The application of this combination was granted priority review in February 2024.[14]

The approval is supported by data from the phase 3 NRG-GY018/KEYNOTE-868 study (NCT03914612). Results presented at the 2023 Society of Gynecologic Oncology Annual Meeting and published in The New England Journal of Medicine showed that the Kaplan-Meier estimates of PFS in the MMR-deficient (dMMR) cohort were 74% in the pembrolizumab plus chemotherapy arm compared with 38% in the placebo plus chemotherapy arm (HR, 0.30; 95% CI, 0.19-0.48; *P* = .001), demonstrating a 70% reduction in the relative risk of progression.[15] In the MMR-proficient (pMMR) cohort, the median PFS was 13.1 months with pembrolizumab vs 8.7 months with placebo (HR, 0.54; 95% CI, 0.51-0.71; *P* = .001).

"The main findings were an improvement in the PFS and OS for the addition of pembrolizumab to standard chemotherapy with acceptable toxicity," Matthew Powell, MD, the Ira C. and Judith Gall Distinguished Professor of Obstetrics and Gynecology at Washington University School of Medicine in St. Louis, said.



The safety profile was consistent with the known profiles of pembrolizumab and chemotherapy. Patients treated with pembrolizumab experienced more grade 3 or greater AEs in both the dMMR (63.3% vs 55.1%) and pMMR (47.2% vs 45.3%) cohorts.

"Endometrial cancer is the most common type of gynecological cancer, and frontline treatment options are limited for patients with advanced stage or recurrent disease," Ramez Eskander, MD, principal investigator and gynecologic oncologist, University of California San Diego, Moores Cancer Center, said in a press release.[14] "The use of [pembrolizumab] in this setting has the potential to address a significant unmet need for these patients."

INVESTIGATIONAL NEW DRUG

ZW171

An investigational new drug application for **ZW171** has been cleared by the FDA for the treatment of mesothelin (MSLN)–expressing cancers.[16] ZW171 is a bispecific antibody that works to enable T cell–mediated tumor cell killing. This is achieved by simultaneously binding to the extracellular domain of the MSLN protein on tumor cells and engaging CD3 on T cells.

According to preliminary evidence, antitumor activity with engineered T-cell therapy supports the utility of T-cell-targeted therapies in treating patients with MSLN-expressing solid tumors.[16,17] The unique 2+1 format of ZW171 and the incorporation of a novel low-affinity anti-CD3 binder work to better the therapeutic window in patients. This approach helps limit on-target, off-tumor effects and CRS. At the same time, it maintains potent antitumor activity against cancers that express MSLN.

ZW171 was made to target tumors selectively while sparing normal tissues and aims to improve tolerability and antitumor activity against these types of cancers. Through the utilization of Azymetric and EFECT technologies, ZW171 is designed to show better antitumor activity and safety in preclinical models. It is expected that the company will file applications for regulatory consent to initiate clinical studies for ZW171 in countries other than the US during the second half of 2024.[16]

BIOLOGICS LICENSE APPLICATION

Patritumab deruxtecan (HER3-DXd)

The manufacturer of **patritumab deruxtecan (HER3-DXd)** has been issued a complete response letter from the FDA for the agent's biologics license application (BLA), citing issues with third-party manufacturing, but no issues with safety or efficacy have been identified.[18] FDA approval for the agent was sought for those with advanced non–small cell lung cancer (NSCLC) harboring *EGFR* mutations that had been previously treated with 2 or more systemic therapies.

Data from the HERTHENA-Lung01 trial (NCT04619004) presented during the 2023 World Conference on Lung Cancer (WCLC) and published in the Journal of Clinical Oncology support the BLA.[19,20] In those with *EGFR*-mutated NSCLC that had previously progressed despite treatment with an EGFR-targeted tyrosine kinase inhibitor (TKI) and platinum-based chemotherapy, the confirmed ORR among patients treated with a previous EGFR TKI and platinum-based chemotherapy (n = 225) was 29.8% (95% CI, 23.9%-36.2%). This included 1 patient who achieved a CR.

Results showed that the DCR was 73.8% (95% CI, 67.5%-79.4%), the median DOR was 6.4 months (95% CI, 4.9-7.8), the median PFS was 5.5 months (95% CI, 5.1-5.9), and the median OS was 11.9 months (95% CI, 11.2-13.1). Efficacy was observed across patient subgroups, including those who previously received treatment with a third-generation TKI and platinum-based chemotherapy (n = 209). The confirmed ORR in this subgroup was 29.2% (95% CI, 23.1%-35.9%), including 1 CR; the DCR was 72.7% (95% CI, 66.2%-78.6%); the median PFS was 5.5 months (95%

CI, 5.1-6.4); and the median OS was 11.9 months (95% CI, 10.9-13.1).

FAST TRACT DESIGNATION

CT-0525

CT-0525, an ex vivo, gene-modified, autologous chimeric antigen receptor-monocyte (CAR-monocyte) cell therapy, has been granted a fast track designation from the FDA for the treatment of solid tumors that overexpress HER2.[21] An open-label, phase 1 trial (NCT06254807) is now evaluating the safety, tolerability, and manufacturing feasibility of CT-0525 in patients with locally advanced or metastatic solid tumors overexpressing HER2. This study marks the first CAR-monocyte to be evaluated in humans in the solid tumor setting.[22]

In the study of CT-0525, enrollment is open to patients 18 years and older with locally advanced or metastatic solid tumors that overexpress HER2 and whose disease has progressed on standard approved therapies are eligible for enrollment in the study.[23] Other requirements include having at least 1 measurable lesion, an ECOG performance status of 0 or 1 at screening, adequate cardiac function, adequate hepatic function, and an O2 saturation of less than 85%.

Two dose-escalation cohorts will make up the study. In cohort 1, 3 patients will be treated with a single intravenous administration of CT-0525 at a dose of 3 billion CAR-positive cells given on day 1. Cohort 2 will enroll 3 patients who will be given a single IV administration of CT-0525 at 10 billion CAR-positive cells, also on day 1. In May 2024, the first patient with a solid tumor overexpressing HER2 was dosed in the study.

CHANGES IN LABELED INDICATIONS

Trastuzumab (Herceptin)

Due to **trastuzumab's (Herceptin)** estimated long washout period, after discontinuing trastuzumab, patients who receive anthracycline could be at higher risk for cardiac dysfunction. Patients should be advised to avoid anthracycline-based therapy for up to 7 months after discontinuing trastuzumab.[24]

The use of trastuzumab during pregnancy has been associated with cases of oligohydramnios and oligohydramnios sequence, as reported in post-marketing data and published literature.[25] Fetuses exposed to trastuzumab in utero have shown manifestations such as pulmonary hypoplasia, skeletal abnormalities, and neonatal death. Oligohydramnios improved in most cases after trastuzumab was discontinued, but in instances where treatment resumed after improvement, oligohydramnios reappeared.[24]

Herceptin was given to 386 patients aged 65 and older (253 in adjuvant treatment and 133 in metastatic breast cancer treatment). Older patients had a higher risk of heart problems compared with younger patients in both metastatic and adjuvant settings, as seen in studies H0648g, H0649g, NSABP B31 (NCT00004067), and NCCTG N9831(NCT00005970).

(Extensive changes; please refer to label for complete information)

Trametinib (Mekinist)

Updates to the AEs associated with the use of **trametinib (Mekinist)** include peripheral neuropathy, which occurred in 2.5% of patients in the COMBI-AD Study (NCT01682083) and 9% in the BRF117019 study (NCT01763164).[26]

Ixazomib citrate (Ninlaro)

An immune system disorder, angioedema, has been observed in those receiving **ixazomib citrate (Ninlaro)**. Another AE associated with receiving ixazomib citrate is swelling, and patients should inform their clinician if they are experiencing swelling in the neck, face, legs, hands, ankles, or feet, or if weight gain is experienced due to swelling.[27]

Tovorafenib (Ojemda)

No dosage adjustment is necessary for patients with mild hepatic impairment (defined as bilirubin ≤ upper limit of normal (ULN) and aspartate aminotransferase (AST) > ULN, or bilirubin > 1x to 1.5x ULN with any AST) receiving **tovorafenib (Ojemda)**. Tovorafenib has not been studied in patients with moderate to severe hepatic impairment (bilirubin > 1.5 to 3x ULN with any AST, or bilirubin > 3x ULN with any AST). AEs can be reported using the following contact information: Day One Biopharmaceuticals at 1-855-329-1246 as well as the FDA at 800-FDA-1088.[28]

The ingredients for tovorafenib now include an orange film coating, of which contains hypromellose, polyethylene glycol 8000, titanium dioxide, ferric oxide yellow, and ferric oxide orange.

Mercaptopurine (Purinethol, Purixan)

Intrahepatic cholestasis of pregnancy (ICP) has been reported in those with inflammatory bowel disease who received **mercaptopurine (Purinethol, Purixan)** during pregnancy, and women who are pregnant should discontinue use if ICP develops.[29]

Thioguanine (Tabloid)

In postmarketing reports, women treated with other drugs similar to **thioguanine (Tabloid)** for inflammatory bowel disease have experienced ICP. Thioguanine is not intended for use in treating inflammatory bowel disease. If a pregnant woman develops ICP while using thioguanine, treatment should be discontinued. If AEs occur contact Waylis Therapeutics LLC Toll-Free at 1-888-514-4727 or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.[30]

Azacitidine (Vidaza)

Cutaneous vasculitis had been added as a postmarketing experience among those receiving **azacitidine (Vidaza).**[31]

REFERENCES

1. Shorla Oncology announces FDA approval for Tepylute, a novel formulation to treat breast and ovarian cancer. News release. Shorla Oncology. June 28, 2024. Accessed June 28, 2024. https://bit.ly/45Rdtko
2. Shorla Oncology announces FDA filing acceptance of new drug application for novel formulation to treat breast and ovarian cancer. News release. Shorla Oncology. January 9, 2024. Accessed April 25, 2024. http://tinyurl.com/59ksrpnj
3. Pipeline. Shorla Oncology. Accessed April 25, 2024. https://shorlaoncology.com/pipeline/sh-201/
4. Shorla Oncology announces FDA filing acceptance of new drug application to treat certain forms of leukemia and other cancers. News release. Shorla Oncology. April 8, 2024. Accessed April 25, 2024. https://tinyurl.com/dbrczpjw
5. FDA grants accelerated approval to epcoritamab-bysp for relapsed or refractory follicular lymphoma. News release. FDA. June 26, 2024. Accessed June 27, 2024. https://tinyurl.com/dtu92zjh
6. Genmab announces positive regulatory updates for epcoritamab (Epkinly/Tepkinly) for the treatment of relapsed/refractory follicular lymphoma. News release. Genmab. November 27, 2023. Accessed November 27, 2023. https://tinyurl.com/5mprp34d
7. Linton K, Jurczak W, Lugtenburg P, et al. Epcoritamab SC monotherapy leads to deep and durable responses in patients with relapsed or refractory follicular lymphoma: first data disclosure from the Epcore NHL-1 follicular lymphoma dose-expansion cohort. Blood. 2023;142(suppl 1):1655. doi:10.1182/blood-2023-179887
8. First-in-human (FIH) trial in patients with relapsed, progressive or refractory B-cell lymphoma (EPCORE NHL-1). ClinicalTrials.gov. Updated April 5, 2024. Accessed April 25, 2024. https://clinicaltrials.gov/study/NCT03625037
9. FDA grants accelerated approval to adagrasib with cetuximab for KRAS G12C-mutated colorectal cancer. News release. FDA. June 21, 2024. Accessed June 21, 2024. https://tinyurl.com/3dezap8f
10. Kopetz S, Uboha NV, Klempner SJ, et al. KRYSTAL-1: pooled phase 1/2 efficacy and safety of adagrasib (MRTX849) in combination with cetuximab in patients with metastatic colorectal cancer (CRC) harboring a KRAS G12C mutation. Presented at: 2024 AACR Annual Meeting; April 5-10, 2024; San Diego, CA. Abstract CT013.

11. Yaeger R, Uboha NV, Pelster MS, et al. Efficacy and safety of adagrasib plus cetuximab in patients with KRAS G12C-mutated metastatic colorectal cancer. Cancer Discov. Published April 8, 2024. doi:10.1158/2159-8290.CD-24-0217

12. Yaeger R, Weiss J, Pelster MS, et al. Adagrasib with or without cetuximab in colorectal cancer with mutated KRAS G12C. N Engl J Med. 2023;388(1):44-54. doi:10.1056/NEJMoa2212419

13. FDA approves pembrolizumab with chemotherapy for primary advanced or recurrent endometrial carcinoma. News release. FDA. June 17, 2024. Accessed June 17, 2024. https://tinyurl.com/47p6cwy2

14. FDA grants priority review to Merck's application for Keytruda (pembrolizumab) plus chemotherapy as treatment for primary advanced or recurrent endometrial carcinoma. News release. Merck. February 20, 2024. Accessed April 23, 2024. http://tinyurl.com/yc2v3n3r

15. Eskander RN, Sill MW, Beffa L, et al. Pembrolizumab plus chemotherapy in advanced endometrial cancer. N Engl J Med. 2023;388(23):2159-2170. doi:10.1056/NEJMoa2302312

16. Zymeworks announces FDA clearance of investigational new drug application for ZW171, a novel 2+1 T-cell targeting bispecific antibody for mesothelin-expressing cancers. News release. Zymeworks Inc. June 17, 2024. Accessed June 18, 2024. https://tinyurl.com/5ae6rr6c

17. Pipeline. Zymeworks Inc. Accessed June 18, 2024. https://www.zymeworks.com/pipeline/

18. Patritumab deruxtecan BLA submission receives complete response letter from FDA due to inspection findings at third-party manufacturer. News release. Merck. June 26, 2024. Accessed June 27, 2024. https://tinyurl.com/3yycw5f6

19. 19. Yu HA, Goto Y, Hayashi H, et al. Patritumab deruxtecan (HER3-DXd) in EGFR-mutated NSCLC following EGFR TKI and platinum-based chemotherapy: HERTHENA-Lung01. Presented at: 2023 World Conference on Lung Cancer; September 9-12, 2023; Singapore.

20. Yu HA, Goto Y, Hayashi H, et al. HERTHENA-Lung01, a phase II trial of patritumab deruxtecan (HER3-DXd) in epidermal growth factor receptor–mutated non–small-cell lung cancer after epidermal growth factor receptor tyrosine kinase inhibitor therapy and platinum-based chemotherapy. J Clin Oncol. 2023;41(35):5363-5375. doi:10.1200/JCO.23.01476

21. Carisma Therapeutics granted FDA fast track designation for CT-0525 for the treatment of HER2-overexpressing solid tumors. News release. Carisma Therapeutics Inc. June 25, 2024. Accessed June 25, 2024. https://tinyurl.com/38awj695

22. Carisma Therapeutics announces first patient dosed in phase 1 clinical trial of CT-0525, a novel HER2-targeting CAR-monocyte. News release. Carisma Therapeutics Inc. May 16, 2024. Accessed June 25, 2024. https://tinyurl.com/3m886ycz

23. CAR-monocytes for the treatment of HER2 overexpressing solid tumors. ClinicalTrial.gov. Updated April 11, 2024. Accessed May 19, 2024. https://classic.clinicaltrials.gov/ct2/show/NCT06254807

24. Trastuzumab. Prescribing information. Genentech, Inc; 2024. Accessed July 22, 2024. https://www.accessdata.fda.gov/scripts/cder/safetylabelingchanges/index.cfm?event=searchdetail.page&DrugNameID=85

25. Gougis P, Grandal B, Jochum F, et al. Treatments during pregnancy targeting ERBB2 and outcomes of pregnant individuals and newborns. JAMA network open. 2023;6(10): e2339934-e2339934. doi.org/10.1001/jamanetworkopen.2023.39934

26. Trametinib. Prescribing information. Novartis Pharmaceuticals; 2024. Accessed July 22, 2024. https://www.accessdata.fda.gov/scripts/cder/safetylabelingchanges/index.cfm?event=searchdetail.page&DrugNameID=865

27. Ixazomib. Prescribing information. Takeda; 2024. Accessed July 22, 2024. https://www.accessdata.fda.gov/scripts/cder/safetylabelingchanges/index.cfm?event=searchdetail.page&DrugNameID=570

28. Tovorafenib. Prescribing information. HUYA Bioscience International; 2024. Accessed July 22, 2024. https://www.accessdata.fda.gov/scripts/cder/safetylabelingchanges/index.cfm?event=searchdetail.page&DrugNameID=2987

29. Mercaptopurine. Prescribing information. Teva Pharmaceuticals; 2024. Accessed July 22, 2024. https://www.accessdata.fda.gov/scripts/cder/safetylabelingchanges/index.cfm?event=searchdetail.page&DrugNameID=1587

30. Thioguanine. Prescribing information. Aspen Pharmacare; 2024. Accessed July 22, 2024. https://www.accessdata.fda.gov/scripts/cder/safetylabelingchanges/index.cfm?event=searchdetail.page&DrugNameID=1588

31. Azacitidine. Prescribing information. Celgene Corporation; 2024. Accessed July 22, 2024. https://www.accessdata.fda.gov/scripts/cder/safetylabelingchanges/index.cfm?event=searchdetail.page&DrugNameID=358