Ongoing | Cancer Accelerated Approvals

This listing includes accelerated approvals (/drugs/nda-and-bla-approvals/accelerated-approval-program) (AAs) for malignant hematology and oncology indications that have postmarketing requirement(s) for ongoing clinical trial(s) to verify clinical benefit. Please refer to Drugs@FDA (https://www.accessdata.fda.gov/scripts/cder/daf/) for the latest approvals and prescribing information for specific products. Visit the verified (/drugs/resources-information-approved-drugs/verified-clinical-benefit-cancer-accelerated-approvals) and withdrawn (/drugs/resources-information-approved-drugs/withdrawn-cancer-accelerated-approvals) AA indication pages for more information and the Postmarket Requirements and Commitments (https://www.accessdata.fda.gov/scripts/cder/pmc/index.cfm) page for the status of specific requirements.

Indications may remain on this page until FDA updates product labeling or publishes a Federal Register notice regarding a change in status.

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Drug Name	Accelerated Approval (AA) Indication	AA Date	Original Projected Completion	AA Post-Marketing Requirement 1
Tecelra (afamitresgene autoleucel)	Treatment of adults with unresectable or metastatic synovial sarcoma who have received prior chemotherapy, are HLA-A*02:01P, -A*02:02P, -A*02:03P, or -A*02:06P positive and whose tumor expresses the MAGE-A4 antigen as determined by FDA-approved or cleared companion diagnostic devices. (/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-afamitresgene-autoleucel-unresectable-or-metastatic-synovial-sarcoma)	8/2/2024	1: Submit the Final Clinical Study Report, including datasets from ADP-0044-002 Cohorts 2 and 3, to verify and describe the clinical benefit of afamitresgene autoleucel, through more precise estimation of the overall response rate and mature response duration per independent review assessment, in adults with unresectable or metastatic synovial sarcoma who have received prior chemotherapy, are HLA-A*02:01P, -A*02:02P, -A*02:03P, or -A*02:06P positive, and whose tumor expresses the MAGE-A4 tumor antigen as determined by FDA-approved or cleared companion diagnostic devices. Overall response rate and duration of response will be assessed by independent review and all patients will be followed for at least 15 months to assess duration of response.	12/31/2025

Drug Name	Accelerated Approval (AA) Indication	AA Date	Original Projected Completion	AA Post-Marketing Requirement 1
Epkinly (epcoritamab-bysp)	Treatment of adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy (/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-epcoritamab-bysp-relapsed-or-refractory-follicular-lymphoma).	6/26/2024	4657-1: Complete a randomized clinical trial intended to verify and describe the clinical benefit of epcoritamab in patients with relapsed or refractory follicular lymphoma. Patients should be randomized to receive epcoritamab in combination with rituximab and lenalidomide versus rituximab and lenalidomide. The primary endpoint should be PFS, with OS as a secondary endpoint. The trial should enroll a sufficiently representative study population that reflects the racial and ethnic diversity of the U.S. population of patients with follicular lymphoma and allow for interpretation of the results in these populations.	11/30/2027

Drug Name	Accelerated Approval (AA) Indication	AA Date	Original Projected Completion	AA Post-Marketing Requirement 1
Krazati (adagrasib)	In combination with cetuximab for the treatment of adult patients with KRAS G12C mutated locally advanced or metastatic colorectal cancer who have been previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy. (/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-adagrasib-cetuximab-kras-g12c-mutated-colorectal-cancer)	6/21/2024	4650-1: Complete clinical trial, Study 849-010, “A Randomized Phase 3 Study of adagrasib 600 mg twice daily in combination with cetuximab versus chemotherapy in patients with advanced colorectal cancer with KRAS G12C mutation with disease progression on or after first-line therapy.”	9/30/2027

Drug Name	Accelerated Approval (AA) Indication	AA Date	Original Projected Completion	AA Post-Marketing Requirement 1
Augtyro (repotrectinib)	Treatment of adult and pediatric patients 12 years of age and older with solid tumors that have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion, are locally advanced or metastatic where surgical resection is likely results in severe morbidity, and have progressed following treatment or have no satisfactory alternative therapy (/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-repotrectinib-adult-and-pediatric-patients-ntrk-gene-fusion-positive)	6/13/2024	4649-1: Conduct an analysis of patients from ongoing or planned trials to verify and describe the clinical benefit of repotrectinib through more precise estimation of the overall response rate and mature response duration per independent review assessment, in adult and pediatric patients 12 years of age and older with solid tumors with a neurotrophic receptor tyrosine kinase (NTRK) gene fusion who have locally advanced or metastatic disease or would require surgical resection that would result in severe morbidity; and have no satisfactory alternative treatment or that have progressed following treatment. A sufficient number of patients will be evaluated to more precisely characterize response and durability of response for a spectrum of patients with different TKI-naïve and TKI-pretreated tumor types. All responding patients will be followed for at least 12 months from the onset of response or until disease progression whichever comes first.	5/31/2030

Drug Name	Accelerated Approval (AA) Indication	AA Date	Original Projected Completion	AA Post-Marketing Requirement 1
Imdelltra (tarlatamab-dlle)	Adult patients with extensive stage small cell lung cancer (ES-SCLC) with disease progression on or after platinum-based chemotherapy (/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-tarlatamab-dlle-extensive-stage-small-cell-lung-cancer)	5/16/2024	4635-1: Conduct a multicenter randomized clinical trial intended to verify and describe the clinical benefit of tarlatamab in patients with ES-SCLC who have had disease progression on or after platinum-based chemotherapy	8/31/2026
Breyanzi (lisocabtagene maraleucel)	Adults patients with relapsed or refractory follicular lymphoma (FL) who have received two or more prior lines of systemic therapy (/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-lisocabtagene-maraleucel-follicular-lymphoma)	5/15/2024	1- Collect and submit the final report, including datasets from the TRANSCEND FL clinical trial (NCT04245839) to verify and describe the clinical benefit of lisocabtagene maraleucel (BREYANZI) in adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy (including an anti-CD20 antibody and an alkylating agent). All partial and complete responders should have completed at least 24 months of follow up starting from the initial objective response.	8/31/2025

Drug Name	Accelerated Approval (AA) Indication	AA Date	Original Projected Completion	AA Post-Marketing Requirement 1
Ojemda (tovorafenib)	Patients 6 months of age and older with relapsed or refractory pediatric low-grade glioma (LGG) harboring a BRAF fusion or rearrangement, or BRAF V600 mutation. (/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-tovorafenib-patients-relapsed-or-refractory-braf-altered-pediatric)	4/23/2024	4608-1: Conduct a multiregional, randomized clinical trial comparing tovorafenib to physician's choice of chemotherapy in pediatric patients with low grade glioma with RAF fusions or rearrangements, or V600 mutations, intended to verify and describe the clinical benefit of tovorafenib through assessment of overall response rate (ORR) as a primary endpoint and progression-free survival (PFS) and duration of response, as determined by blinded independent central review, as key secondary endpoints. Include the protocol-specified ORR and interim PFS analyses in the interim report.	4/30/2032

Drug Name	Accelerated Approval (AA) Indication	AA Date	Original Projected Completion	AA Post-Marketing Requirement 1
Enhertu (fam-trastuzumab deruxtecan-nxki)	Adult patients with unresectable or metastatic HER2-positive (IHC 3+) solid tumors who have received prior systemic treatment and have no satisfactory alternative treatment options. (/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-fam-trastuzumab-deruxtecan-nxki-unresectable-or-metastatic-her2)	4/5/2024	4624-1: Complete Cohort A in Part 2 of the ongoing DESTINY-PanTumor02 trial intended to verify and describe the clinical benefit of Enhertu in adult patients with unresectable or metastatic HER2-positive (IHC3+) solid tumors that have progressed following prior treatment and have no satisfactory alternative treatment options. Include a minimum of 40 patients across all tumor types, other than breast, colorectal, lung, and gastric/GEJ cancer, including a sufficient number of patients with and representation of HER2-positive (IHC3+) tumor types that require additional characterization. In order to characterize response rate and duration of response, patients should be followed for at least 12 months from the onset of response.	6/30/2027

Drug Name	Accelerated Approval (AA) Indication	AA Date	Original Projected Completion	AA Post-Marketing Requirement 1
Iclusig (ponatinib)	Adult patients with newly diagnosed Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) in combination with chemotherapy. (/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-ponatinib-chemotherapy-newly-diagnosed-philadelphia-chromosome)	3/19/2024	4593-1: Complete the randomized trial Ponatinib-3001 (PhALLCON) intended to verify and describe the clinical benefit of ponatinib in adults with newly diagnosed Ph+ acute lymphoblastic leukemia.	06/30/2028
Brukinsa (zanubrutinib)	Adult patients with relapsed or refractory follicular lymphoma (FL), in combination with obinutuzumab, after two or more lines of systemic therapy (/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-zanubrutinib-relapsed-or-refractory-follicular-lymphoma)	3/7/2024	4583-1: Complete a randomized clinical trial that evaluates the clinical benefit of zanubrutinib plus obinutuzumab versus lenalidomide plus rituximab in patients with relapsed or refractory FL. The primary endpoint should be PFS, with secondary endpoints that include ORR and OS. The trial should enroll a sufficiently representative study population that reflects the racial and ethnic diversity of the U.S. population of patients with FL and that allows for interpretation of the results in these populations.	1/31/2029

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1. If multiple PMRs were required, the latest date is reported here. This date represents the original agreed-upon Final Study Report date and does not include any updated deadlines submitted by the Applicant.

2. a b The original AA indication was modified to include an expanded population.

3. The original AA indication was modified to include a restricted population