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the verified (/drugs/resources-information-approved-drugs/verified-clinical-benefit-cancer-accelerated-approvals) and withdrawn (/drugs/resources-information-approved-drugs/withdrawn-cancer-accelerated-approvals) AA indication pages for more information and the Postmarket Requirements and Commitments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.

Search:

Show 10 entries

Drug Name	Accelerated Approval (AA) Indication	AA Date	Original Projected Completion	AA Post-Marketing Requirement 1
Amtagvi (lifileucel)	Adult patients with unresectable or metastatic melanoma previously treated with a PD-1 blocking antibody, and if BRAF V600 mutation positive, a BRAF inhibitor with or without a MEK inhibitor. (/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-lifileucel-unresectable-or-metastatic-melanoma)	2/16/2024	1: Complete the Phase 3, multiregional, multicenter, randomized, open-label controlled trial (IOV-MEL-301) in patients with previously untreated unresectable or metastatic melanoma. Patients will be randomized to lifileucel (LN-144) regimen in combination with pembrolizumab or to pembrolizumab monotherapy. The dual primary endpoints will be ORR and PFS, with OS as the key secondary endpoint.	03/31/2031

Drug Name	Accelerated Approval (AA) Indication	AA Date	Original Projected Completion	AA Post-Marketing Requirement 1
Jaypirca (pirtobrutinib)	Adults with CLL or small lymphocytic lymphoma (SLL) who have received at least two prior lines of therapy, including a BTK inhibitor and a BCL-2 inhibitor (/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-pirtobrutinib-chronic-lymphocytic-leukemia-and-small-lymphocytic)	12/1/2023	4557-1: Complete a randomized trial in patients with relapsed or refractory CLL or SLL. Patients should be randomized to receive pirtobrutinib or an investigator's choice arm of idelalisib plus rituximab or bendamustine plus rituximab. The primary endpoint should be progression-free survival, with secondary endpoints that include response rate and overall survival. The trial should include sufficient representation of racial and ethnic minorities to adequately reflect the U.S. patient population with CLL or SLL and allow for interpretation of the results in these patient populations.	6/30/2024

Drug Name	Accelerated Approval (AA) Indication	AA Date	Original Projected Completion	AA Post-Marketing Requirement 1
Elrexfio (elranatamab-bcmm)	Adults with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody. (/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-elranatamab-bcmm-multiple-myeloma)	8/14/2023	4476-1: Complete a randomized clinical trial in patients with relapsed or refractory multiple myeloma. Patients should be randomized to receive an elranatamab-based regimen compared to standard therapy for relapsed or refractory multiple myeloma. The primary endpoint should be progression-free survival and secondary endpoints should include overall survival and overall response rate. The trial should enroll sufficient numbers of older patients (ages 65-74 years and 75 years and above) to enable an evaluation of elranatamab in a study population that reflects the age of the U.S. population of patients with multiple myeloma.	9/30/2026

Drug Name	Accelerated Approval (AA) Indication	AA Date	Original Projected Completion	AA Post-Marketing Requirement 1
Talvey (talquetamab-tgvs)	Adults with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody (/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-talquetamab-tgvs-relapsed-or-refractory-multiple-myeloma)	8/9/2023	4473-1: Conduct a randomized clinical trial that evaluates the clinical efficacy and safety of talquetamab in patients with relapsed or refractory multiple myeloma. Patients should be randomized to receive a talquetamab-based regimen compared to standard therapy for relapsed or refractory multiple myeloma. The primary endpoint should be progression-free survival and secondary endpoints should include overall survival and overall response rate. The trial should enroll sufficient numbers of racial and ethnic minority patients and older patients (ages 65-74 years and 75 years and above) to enable an evaluation of talquetamab in a study population that reflects the U.S. population of patients with multiple myeloma.	12/31/2026

Drug Name	Accelerated Approval (AA) Indication	AA Date	Original Projected Completion	AA Post-Marketing Requirement 1
Columvi (glofitamab-gxbm)	Relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified or large B-cell lymphoma arising from follicular lymphoma, after two or more lines of systemic therapy (/drugs/drug-approvals-and-databases/fda-grants-accelerated-approval-glofitamab-gxbm-selected-relapsed-or-refractory-large-b-cell)	6/15/2023	4464-1 Complete a randomized clinical trial that evaluates the clinical benefit of glofitamab in patients with diffuse large B-cell lymphoma. The trial should compare glofitamab in combination with gemcitabine and oxaliplatin (GemOx) to rituximab in combination with GemOx for patients with relapsed or refractory diffuse large B-cell lymphoma. The primary endpoint should be overall survival with secondary endpoints that include progression-free survival and response rate.	9/30/2024
Epkinly (epcoritamab-bysp)	Adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from indolent lymphoma, and high-grade B-cell lymphoma after two or more lines of systemic therapy. (/drugs/drug-approvals-and-databases/fda-grants-accelerated-approval-epcoritamab-bysp-relapsed-or-refractory-diffuse-large-b-cell)	5/19/2023	4435-1: Complete a randomized clinical trial in patients with relapsed or refractory large B-cell lymphoma. The trial should compare epcoritamab monotherapy to an investigator's choice of standard therapies for patients with relapsed or refractory large B-cell lymphoma. The primary endpoint should be OS with secondary endpoints that include PFS and response rate.	6/30/2025

Drug Name	Accelerated Approval (AA) Indication	AA Date	Original Projected Completion	AA Post-Marketing Requirement 1
Zynyz (retifanlimab-dlwr)	Adult patients with metastatic or recurrent locally advanced Merkel cell carcinoma (MCC). (/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-retifanlimab-dlwr-metastatic-or-recurrent-locally-advanced-merkel)	3/22/2023	4412-1: Conduct a multicenter clinical trial intended to confirm the clinical benefit of retifanlimab-dlwr in patients with metastatic or recurrent locally advanced MCC who have not received prior systemic therapies for metastatic or recurrent locally advanced MCC. The trial will enroll at least 100 patients to be followed for a minimum of 12 months to establish the ORR and characterize the DOR. Include an analysis of OS, when 70% of patients have died, or all patients have been followed for at least three years.	3/31/2025

Drug Name	Accelerated Approval (AA) Indication	AA Date	Original Projected Completion	AA Post-Marketing Requirement 1
Jaypirca (pirtobrutinib)	Adult patients with relapsed or refractory mantle cel lymphoma (MCL) after at least two lines of systemic therapy, including a BTK inhibitor. (/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-pirtobrutinib-relapsed-or-refractory-mantle-cell-lymphoma)	1/27/2023	4389-1: Complete a randomized clinical trial to obtain data on the clinical efficacy and safety of pirtobrutinib in patients with MCL. The trial should compare pirtobrutinib monotherapy to an investigator's choice of approved BTK inhibitors in patients with MCL. The primary endpoint should be PFS as assessed by an independent review committee, with secondary endpoints that include OS and objective response rate. The trial should enroll a sufficiently representative study population to reflect the racial and ethnic diversity of the U.S. patient population with MCL and allow for interpretation of the results in these patient populations.	12/31/2026

Drug Name	Accelerated Approval (AA) Indication	AA Date	Original Projected Completion	AA Post-Marketing Requirement 1
Tukysa (tucatinib)	In combination with trastuzumab for the treatment of adult patients with RAS wild-type, HER2-positive, unresectable or metastatic colorectal cancer that has progressed following treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy (/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-tucatinib-trastuzumab-colorectal-cancer)	1/19/2023	4388-1: Conduct a randomized clinical trial to obtain data on the clinical efficacy of tucatinib for patients with RAS wild type, HER2-positive, unresectable or metastatic colorectal carcinoma. The trial should compare tucatinib in combination with trastuzumab with the standard of care in patients with RAS wild type, HER2-positive, unresectable or metastatic colorectal carcinoma. The primary endpoint should be PFS per blinded assessment or OS. The trial should enroll a sufficiently representative study population to reflect the racial and ethnic diversity of the U.S. patient population with RAS wild type, HER2-positive, unresectable or metastatic colorectal carcinoma and allow for interpretation of the results across this representative study population.	04/30/2026

Drug Name	Accelerated Approval (AA) Indication	AA Date	Original Projected Completion	AA Post-Marketing Requirement 1
Lunsumio (mosunetuzumab-axgb)	Adult patients with relapsed or refractory follicular lymphoma after two or more lines of systemic therapy. (/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-mosunetuzumab-axgb-relapsed-or-refractory-follicular-lymphoma)	12/22/2022	4375-1: Conduct a randomized clinical trial in patients with relapsed or refractory follicular lymphoma (FL), with patients randomized to receive mosunetuzumab in combination with lenalidomide or rituximab in combination with lenalidomide. The primary endpoint should be PFS, with secondary endpoints that include RR and OS. The trial should enroll a sufficiently representative study population to reflect the racial and ethnic diversity of the U.S. patient population with FL and allow for interpretation of the results in these patient populations.	12/31/2025

Showing 11 to 20 of 64 entries

Previous 1 2 3 4 5 6 7 Next

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