



Accelerated Cancer Drugs

Currently, 24 oncology-related drugs have received accelerated approval from the FDA. Although only a handful of these drugs have gone on to receive full approval, the FDA says drug companies must be allowed time to do phase III trials, which can take three years on average.

DRUG>	ACCELERATED APPROVAL INDICATION>	YEAR OF ACCELERATED APPROVAL/FULL APPROVAL>	ADDITIONAL INDICATION>
Clolar (clofarabine)	Pediatric relapsed or refractory acute lymphoblastic leukemia	2004	No additional indication to date
Femara (letrozole)	Adjuvant treatment of early breast cancer in postmenopausal women	2004	Approved in 1997 for treatment of advanced breast cancer in women whose cancer had not responded to anti-estrogen drugs; approved in 2001 for newly diagnosed postmenopausal women with hormone receptor-positive/unknown locally advanced or metastatic breast cancer
Erbix (cetuximab)	Metastatic colorectal cancer	2004	No additional indication to date
Alimta (pemetrexed)	Locally advanced or metastatic non-small-cell lung cancer	2004	Approved in early 2004 for use in combination with cisplatin for malignant pleural mesothelioma
Iressa (gefitinib)	Third-line non-small-cell lung cancer [new labeling in June 2005 limits Iressa use to clinical trial subjects or those benefiting from the drug]	2003	No additional indication to date
Bexxar (tositumomab)	Relapsed or refractory non-Hodgkin's lymphoma	2003	No additional indication to date
Gleevec (imatinib)	Pediatric chronic myelogenous leukemia	2003	No additional indication to date
	Newly diagnosed CML	2002	
	Metastatic or unresectable gastrointestinal stromal tumors	2002	
	CML after interferon therapy	2001/2003	
Velcade (bortezomib)	Multiple myeloma	2003/2005	No additional indication to date
Arimidex (anastrozole)	Adjuvant treatment for hormone receptor-positive early breast cancer in postmenopausal women	2002/2005	Initially approved in 1996 for metastatic breast cancer refractory to tamoxifen and later in 2000 for first-line treatment of postmenopausal women with hormone receptor-positive/unknown locally advanced or metastatic breast cancer
Eloxatin (oxaliplatin)	Second-line colorectal cancer	2002/2004	Approved in early 2004 for first-line therapy for metastatic colorectal cancer; approved in late 2004 for adjuvant stage III colon cancer treatment
Zevalin (ibrutinomab)	Relapsed or refractory follicular non-Hodgkin's lymphoma	2002	No additional indication to date
Campath (alemtuzumab)	Third-line B-cell chronic lymphocytic leukemia	2001	No additional indication to date
Mylotarg (gemtuzumab)	Second-line acute myelogenous leukemia for patients 60 or older	2000	No additional indication to date
Celebrex (celecoxib)	Reduction of polyps in patients with familial adenomatous polyposis, a genetic disorder that puts a person at high risk for colorectal cancer	1999	Approved in 2005 for relief of signs and symptoms associated with ankylosing spondylitis; approved in 2001 for acute pain in adults and treatment of primary dysmenorrhea (painful menstrual cramps); approved in 1998 for signs and symptoms of rheumatoid arthritis and osteoarthritis
Temodar (temozolomide)	Refractory anaplastic astrocytoma	1999/2005	Approved in 2005 for glioblastoma multiforme
Doxil (doxorubicin)	Refractory ovarian cancer	1999/2005	No additional indication to date
	Second-line Kaposi's sarcoma	1995	
DepoCyt (cytarabine)	Lymphomatous meningitis	1999	No additional indication to date
Ontak (denileukin diftitox)	Relapsed or refractory cutaneous T-cell lymphoma	1999	No additional indication to date
Xeloda (capecitabine)	Refractory breast cancer	1998/2001	Approved in 2005 for advanced colon cancer
Camptosar (irinotecan)	Second-line colon cancer	1996/1998	Approved in 2000 for newly diagnosed metastatic colon cancer
Taxotere (docetaxel)	Second-line breast cancer	1996/1998	Approved in 1999 for cisplatin-refractory non-small-cell lung cancer; approved in 2002 for unresectable locally advanced and metastatic non-small-cell lung cancer; approved in 2004 for metastatic prostate cancer
Ethylol (amifostine)	Reduction of cisplatin toxicity in non-small-cell lung cancer	1996	Approved in 1995 for cisplatin toxicity in advanced ovarian cancer; approved in 1999 for radiation-induced xerostomia
Zinecard (dexrazoxane)	Prevention of heart disease associated with doxorubicin	1995/2002	No additional indication to date

SOURCE: FDA