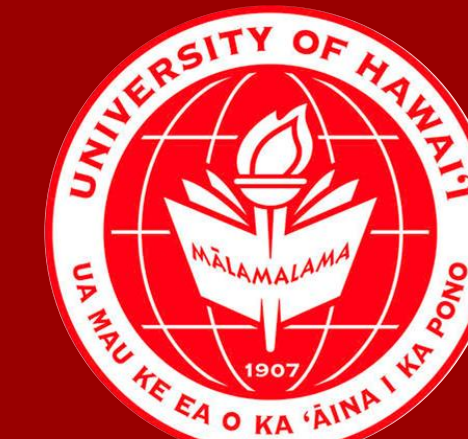




New Advances in US FDA Approved Oncology Drugs from 2015-2023

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BACKGROUND

Since 2015, the US Food and Drug Administration (FDA) has approved 416 new chemical entity and biologic drugs with the most approval category being oncology.

PURPOSE

The purpose of this study is to conduct a systematic review of the recently approved oncology drugs from 2015-2023, analyze recent trends in the cancer chemotherapy arena, and highlight the connections between foundational sciences and clinical applications.

METHODS

This data analysis was conducted using new drug approval online resources provided by the US FDA's Center for Drug Evaluation and Research (CDER). Drug information database Lexicomp and product prescribing information were also used in this study. Physicochemical properties such as molecular weight, hydrogen bond acceptor, hydrogen bond donor, LogP, and polar surface area were obtained from ChemSpider and Chemfinder database.

CONCLUSION

According to American Cancer Society, in 2023 there are estimated >1.9 million new cancer cases and approximately 610,000 cancer deaths in the United States. As such, there is an urgent and unmet clinical needs to develop new cancer therapies. In the last decade, significant medicine advances have been made with over 400 total new drug approvals from the US FDA. Among those, oncology has the most drug approvals with 108 new drugs, representing ~26% of total new drug approvals.

DISCLOSURE & REFERENCES

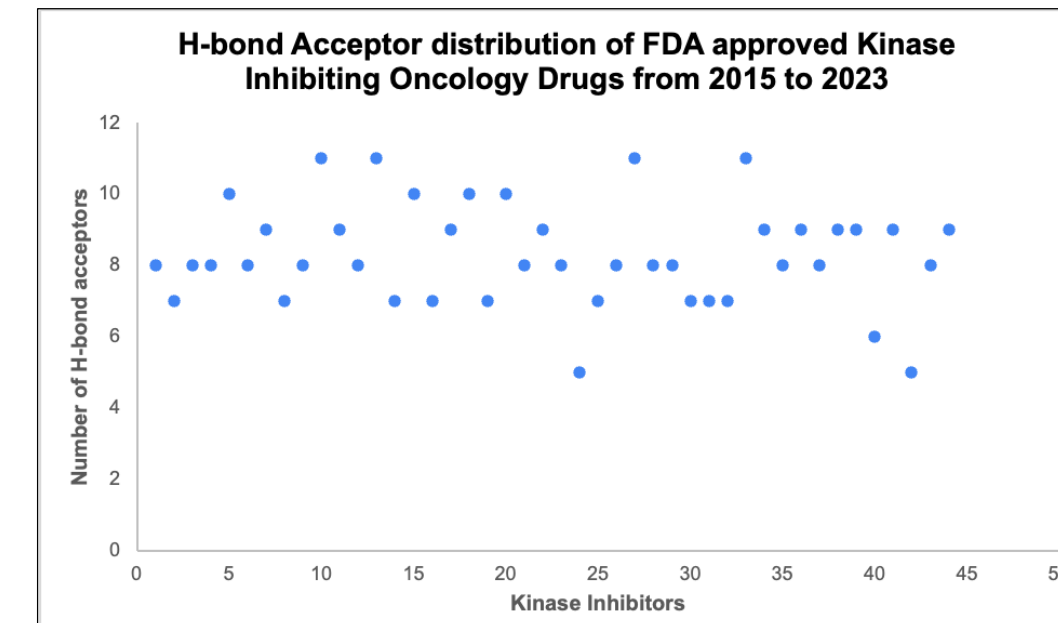
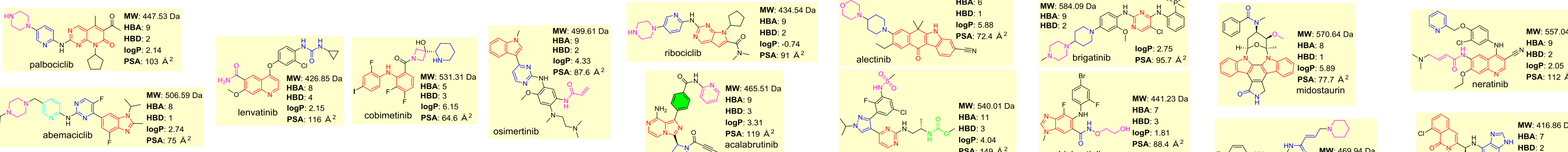
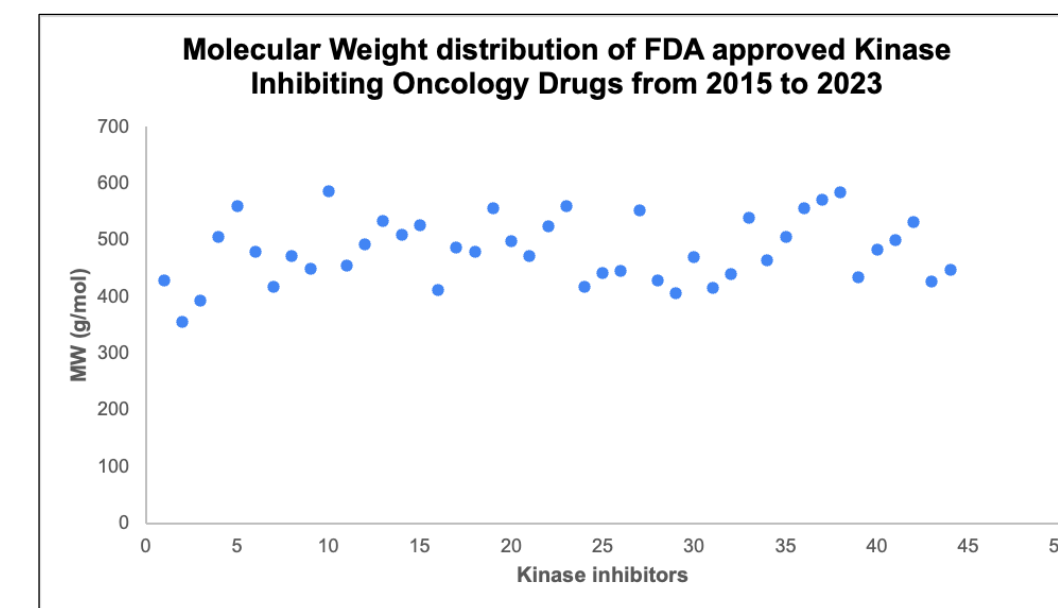
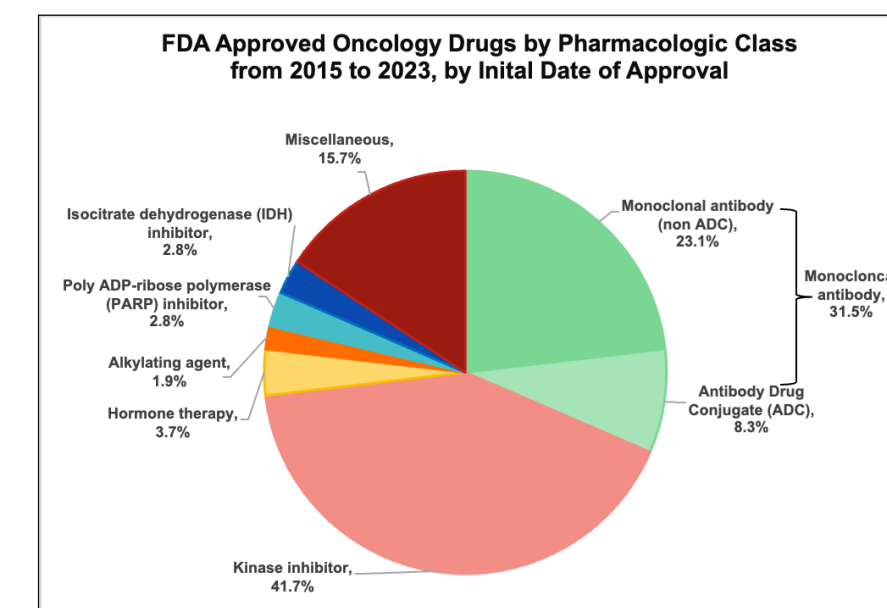
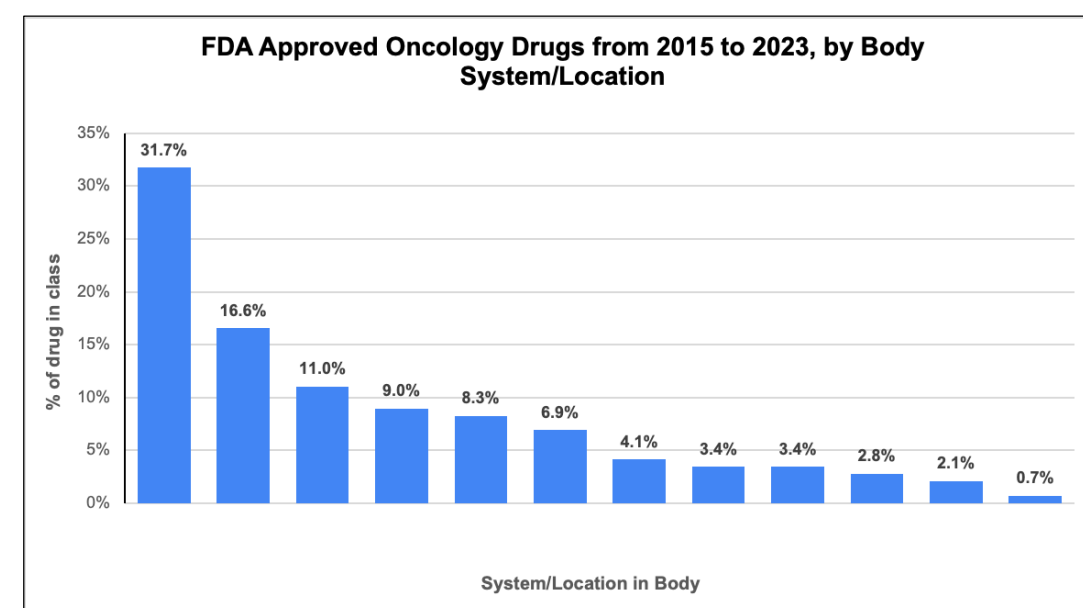
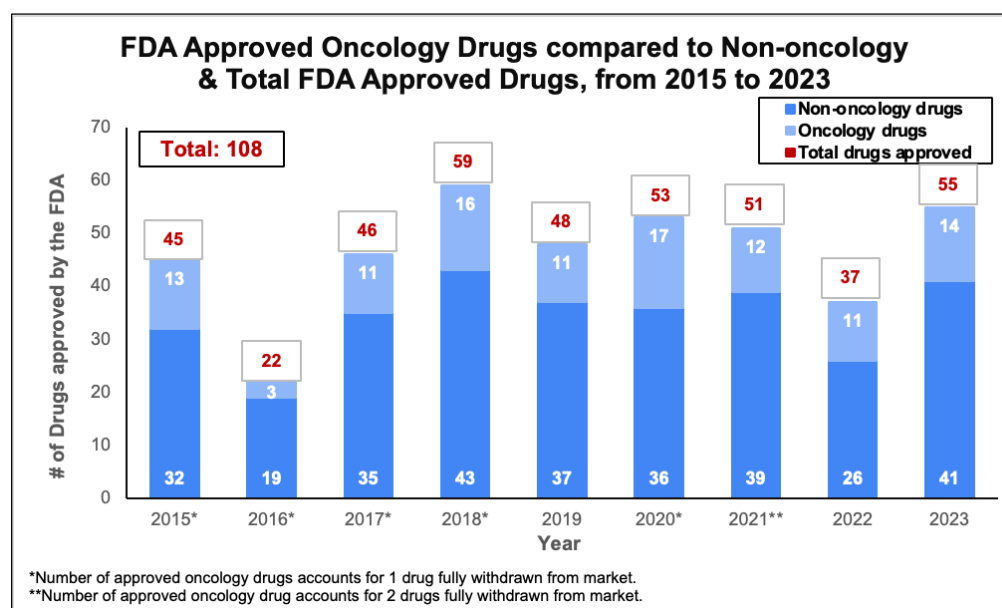
The authors of this presentation have nothing to disclose.

Scan for references:



RESULTS

From 2015-2023, the US FDA has approved 416 new chemical entity and therapeutic biologic drugs with a total of 108 new oncology drug approvals, representing ~26% of all new drugs approved in the last nine years. Among these new oncology drugs, ~63% are small molecules and ~32% were biologic monoclonal antibodies. In addition, ~41% (44) belong to kinase inhibitors; detailed drug characteristics including molecular weight, hydrogen bond acceptors and donors, polar surface areas (PSA), and logP will be analyzed and presented. Furthermore, the top 3 approved cancer categories are hematologic/blood cancer (32%), respiratory/lung cancer (16%), and gastrointestinal related cancer (11%).



Drug Name	Approval Date	Active Ingredient	FDA approved Indication	Progression	Route of admin.	MW (g/mol)	HBA	HBD	logP	ROS violations	PSA	Vd (L)
Truqap	11/16/23	Capivasertib	HR+, HER2- breast cancer	Locally advanced or metastatic	tablets - ORAL	428.92	8	5	1.04	0	120	1847
Augtyro	11/15/23	repotrectinib	Non-small cell lung cancer (NSCLC)	Locally advanced or metastatic	capsules - ORAL	355.37	7	2	1.71	0	81	432
Fruzaqla	11/8/23	fruquintinib	Colorectal cancer	Metastatic	capsules - ORAL	393.39	8	1	3.08	0	96	46
Ojjaara	9/15/23	momelotinib	Myelofibrosis (MF)	Intermediate or high risk	tablets - ORAL	414.47	8	2	1.22	0	103	984
Vanlyta	7/20/23	quizartinib	Acute myeloid leukemia (AML)	Newly diagnosed	tablets - ORAL	560.67	10	2	4.03	2	134	275
Jaypirca	1/27/23	piribrotinib	(1) Mantle cell lymphoma (MCL) (2) Chronic lymphocytic lymphoma/Small lymphocytic lymphoma (CLL/SLL)	Relapsed or refractory	tablets - ORAL	479.44	8	5	3.39	0	125	32.8
Lytgobi	9/30/22	futibatinib	Intrahepatic cholangiocarcinoma	Locally advanced or metastatic	Tablets - ORAL	418.45	9	2	3.47	0	108	66
Vonjo	2/28/22	pacritinib	MF	Intermediate/High risk	Capsules - ORAL	472.58	7	1	4.23	0	68	229
Scemblix	10/29/21	asciminib	Philadelphia chromosome-positive chronic myeloid leukemia	N/A	Tablets - ORAL	449.84	8	3	2.1	0	103	151
Exkivity	9/15/21	mobocertinib	NSCLC	Locally advanced or metastatic	Capsules - ORAL	585.70	11	2	3.86	2	114	3509
Fotivda	3/10/21	tivozanib	Renal cell carcinoma (RCC)	Relapsed or refractory advanced	capsules - ORAL	454.86	9	2	4.31	0	108	123
Tepmetko	2/3/21	tepotinib	NSCLC	Metastatic	tablets - ORAL	492.57	8	0	2.72	0	95	1038
Gavreto	9/4/20	pralsetinib	(1) NSCLC (2) Thyroid cancer (ages 12+)	(2) Advanced or metastatic	capsules - ORAL	533.60	11	3	3.57	2	136	228
Qinlock	5/15/20	ripretinib	Gastrointestinal stromal tumor (GIST)	Advanced	tablets - ORAL	510.36	7	3	5.1	2	86	307
Retevmo	5/8/20	selipercatinib	(1) NSCLC (2) Thyroid cancer (ages 12+)	(1) Locally advanced or metastatic (2) Advanced or metastatic	capsules - ORAL	525.60	10	1	1.66	2	112	191
Tabrecta	5/6/20	capmatinib	NSCLC	Metastatic	tablets - ORAL	412.42	7	1	-0.12	0	85	164
Pemazyre	4/17/20	pemigatinib	Cholangiocarcinoma	Locally advanced or metastatic	tablets - ORAL	487.50	9	1	0.66	0	83	235
Tukysa	4/17/20	tucatinib	(1) Breast cancer (2) Urothelial cancer	(1) Locally advanced or metastatic (2) Locally advanced or metastatic	tablets - ORAL	480.52	10	2	3.62	1	111	1670
Koselugo	4/10/20	selumetinib	Neurofibromatosis type 1 (NF1) (ages 2+)	N/A	capsules - ORAL	555.76	7	3	5.55	1	88	78 - 171
Ayvakit	1/9/20	avapritinib	(1) GIST (2) Mastocytosis	(1) Unresectable or advanced (2) Advanced	tablets - ORAL	498.56	10	2	1.28	1	106	1200
Brukinsa	11/14/19	zanubrutinib	(1) MCL (2) Marginal zone lymphoma (MZL) (3) CLL/SLL	(1) N/A (2) Relapsed or refractory (3) N/A	capsules - ORAL	471.55	8	3	3.64	0	102	537
Inrebic	8/16/19	fedratinib	(4) Follicular lymphoma (FL) Myelofibrosis	(4) Relapsed or refractory Intermediate/High risk	capsules - ORAL	524.68	9	3	3.27	1	117	1770
Rozlytrek	8/15/19	entrectinib	(1) NSCLC (2) Solid tumors with NTRK gene fusion (ages 1 month and older)	N/A	capsules - ORAL	560.64	8	3	5.66	2	86	551
Turalio	8/2/19	peixidartinib	Tenosynovial giant cell tumor (TGCT)	Severe, no improvement with surgery	capsules - ORAL	417.82	5	2	4.77	0	66	187
Pigra	5/24/19	alpelisib	HR+, HER2- breast cancer	Advanced or metastatic	tablets - ORAL	441.47	7	3	-0.02	0	129	114
Balversa	4/12/19	erdafitinib	Urothelial carcinoma	Locally advanced or metastatic	tablets - ORAL	446.55	8	1	3.6	0	77	29
Xospata	11/28/18	gilteritinib	AML	Relapsed or refractory	tablets - ORAL	552.71	11	4	4.35	2	121	1092
Vitrakvi	11/26/18	larotrectinib	Solid tumors that have NTRK gene fusion	Metastatic	capsules - ORAL	428.44	8	2	1.48	0	86	48
Lorbrena	11/2/18	lorlatinib	NSCLC	Metastatic	tablets - ORAL	406.41	8	2	1.24	0	110	305
Vizimpro	9/27/18	dacomitinib	NSCLC (first-line)	Metastatic	tablets - ORAL	469.94	7	2	2.84	1	79.4	1889
Copiktra	9/24/18	duvelisib	CLL/SLL	Relapsed or refractory	capsules - ORAL	416.86	7	2	4.6	0	87	28.5
Mektovi	6/27/18	binimetinib	(1) Melanoma (2) NSCLC	(1) Unresectable or metastatic (2) Metastatic	tablets - ORAL	441.23	7	3	5.42	1	88	92
Bratovi	6/27/18	encorafenib	(1) Melanoma (2) Colorectal cancer (3) NSCLC	(1) Unresectable or metastatic (2) Metastatic (3) Metastatic	capsules - ORAL	540.01	11	3	2.56	2	149	164
Calquence	10/31/17	acalabrutinib	MCL	N/A	capsules - ORAL	465.51	9	3	0.77	0	119	34
Verzenio	9/28/17	abemaciclib	HR+, HER2- breast cancer	Advanced & metastatic; High- risk of recurrence	tablets - ORAL	506.59	8	1	2.74	1	75	690.3
Nerlynx	7/17/17	neratinib maleate	HER2+ breast cancer	Early-stage and Advanced	tablets - ORAL	557.04	9	2	5.46	2	112	6433
Rydapt	4/28/17	midostaurin	(1) AML (2) Mastocytosis or Mast cell leukemia	(1) Newly diagnosed (2) N/A	capsules - ORAL	570.64	8	1	5.27	2	78	95.2
Alunbrig	4/28/17	brigatinib	NSCLC	Metastatic	tablets - ORAL	584.09	9	2	0.43	1	96	307
Kisqali	3/13/17	ribociclib	HR+, HER2- breast cancer	Advanced or metastatic	tablets - ORAL	434.54	9	2	-0.74	0	91	1090
Alecensa	12/11/15	alectinib	NSCLC	Metastatic	capsules - ORAL	482.62	6	1	5.48	1	72	4016
Tagrisso	11/13/15	osimertinib	NSCLC	Metastatic (first-line)	tablets - ORAL	499.61	9	2	3.3	0	88	986
Cotellic	11/10/15	cobimetinib	(1) Melanoma (2) Histocytic neoplasm	(1) Unresectable or metastatic (2) N/A	tablets - ORAL	531.31	5	3	5.96	2	65	806
Lenvima	2/13/15	lenvatinib	(1) Differentiate thyroid cancer (2) RCC (3) Hepatocellular carcinoma (4) Endometrial cancer	(1) Locally recurrent or metastatic (2) Unresectable (3) Unresectable (4) Advanced	capsules - ORAL	426.85	8	4	3.39	0	116	97
Ibrance	2/3/15	palbociclib	HR+, HER2- breast cancer	Advanced or metastatic	capsules - ORAL	447.53	9	2	2.14	0	103	2583

