

Clinical Trial Demographic Scorecard

Drug	
Tradename	Nereus
Generic Name	tradipitant
Company	Vanda Pharma
Date of FDA Approval	December 30, 2025
Indication	To treat vomiting associated with motion



Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	13.2%	67	Decreased	A



Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	62.0%	287	Increased	C



Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	5.1%	24	Similar	D
Asian	6.3%	9.3%	40	Similar	A



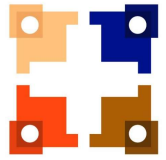
Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	12.0%	52	Similar	C

OVERALL GRADE

B

References: Phase 3 Pivotal trials 3401, 3404 https://www.accessdata.fda.gov/drugsatfda_docs/nda/2026/220152Orig1s000IntegratedR.pdf pgs 41-42; DOI:10.3233/VES-200702; DOI: 10.1016/s1550-8579(06)80211-1; PMID: 8216144; No PMR/PMC



Clinical Trial Demographic Scorecard

Drug	
Tradename	Yartemlea
Generic Name	narsoplimab-wuug
Company	OMEROS CORP
Date of FDA Approval	December 23, 2025
Indication	To treat hematopoietic stem cell transplant-associated thrombotic microangiopathy (orphan)



Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	8.4%	21	Similar	D



Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	42.6%	20	Increased	D



Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	4.3%	2	Similar	D
Asian	6.3%	14.9%	7	Similar	B



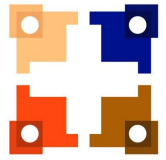
Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	4.3%	2	Similar	D

OVERALL GRADE

D

References: Phase 3 Pivotal trial TMA-001 and EAP;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2026/761152Orig1s000IntegratedR.pdf pg 29;
https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/761152Orig1s000lbl.pdf age>65yo ; DOI: 10.1186/s12882-025-04446-z; DOI: 10.1016/j.jtct.2022.01.009; No PMR/PMC



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Clinical Trial Demographic Scorecard

Drug	
Tradename	Myqorzo
Generic Name	aficamten
Company	Cytokinetics
Date of FDA Approval	December 19, 2025
Indication	To treat symptomatic obstructive hypertrophic cardiomyopathy (orphan)



Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	40.1%	57	Increased	B



Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	40.8%	56	Similar	B



Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	1.1%	3	Increased	F
Asian	6.3%	19.1%	29	Similar	B



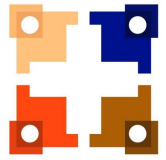
Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	3.2%	3	Decreased	C

OVERALL GRADE

C

References: Phase 3 Pivotal trial SEQUOIA-HCM (CY 6031);
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2026/219083Orig1s000IntegratedR.pdf pg 40; doi:
 10.1155/2018/3750879; <https://doi.org/10.1161/JAHA.119.014448>; PMID: 37232238; No PMR/PMC



Clinical Trial Demographic Scorecard

Drug	
Tradename	Exdensur
Generic Name	depemokimab-ulaa
Company	GLAXOSMITHKLINE LLC
Date of FDA Approval	December 16, 2025
Indication	To treat severe asthma characterized by an eosinophilic phenotype as an add-on maintenance therapy



Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	25.5%	133	Similar	A



Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	62.2%	304	Increased	B



Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	4.7%	22	Increased	F
Asian	6.3%	17.5%	90	Decreased	A



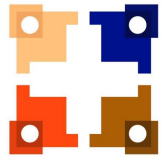
Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	11.5%	57	Similar	C

OVERALL GRADE

B

References: Phase 3 Pivotal trials SWIFT-1, SWIFT-2;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2026/761458Orig1s000MultidisciplineR.pdf pg 61;
<https://www.cdc.gov/asthma-data/about/most-recent-asthma-data.html>; <https://www.lung.org/research/trends-inlung-disease/asthma-trends-brief/current-demographics>; No PMR/PMC



Clinical Trial Demographic Scorecard

Drug	
Tradename	Cardamyst
Generic Name	etripamil
Company	Milestone Pharma
Date of FDA Approval	December 12, 2025
Indication	To convert acute symptomatic episodes of paroxysmal supraventricular tachycardia (PSVT) to sinus rhythm



Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	34.3%	28	Increased	C



Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	71.2%	69	Increased	B



Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	2.7%	3	Similar	D
Asian	6.3%	1.1%	0	Decreased	C



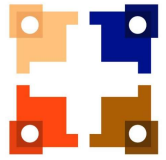
Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	6.5%	7	Similar	D

OVERALL GRADE



References: Phase 3 Pivotal trial RAPID (NODE-301) ; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2026/218571Orig1s000IntegratedR.pdf pg 32 ; <https://doi.org/10.1093/eurheartj/ehz745.0218>; doi: 10.1161/JAHA.118.008759; <https://doi.org/10.1111/jce.15109>; No PMR/PMC



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Clinical Trial Demographic Scorecard

Drug	
Tradename	Lerochol
Generic Name	lerodalcibep-liga
Company	LIB Therapeutics
Date of FDA Approval	December 12, 2025
Indication	To reduce low-density lipoprotein cholesterol in adults with hypercholesterolemia



Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	44.8%	680	Similar	A



Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	40.4%	629	Increased	B



Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	15.5%	235	Decreased	A
Asian	6.3%	3.9%	62	Increased	D



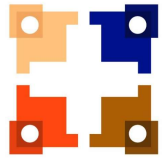
Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	5.9%	85	Similar	C

OVERALL GRADE

B

References: Phase 3 Pivotal trials 004, 005, 006;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2026/761427Orig1s000IntegratedR.pdf pgs 51, 52, 60, 69;
<https://www.cdc.gov/cholesterol/data-research/facts-stats/index.html>; PMID: 40282972; No PMR/PMC



Clinical Trial Demographic Scorecard

Drug	
Tradename	Nuzolvence
Generic Name	zoliflodacin
Company	ENTASIS Therapeutics
Date of FDA Approval	December 12, 2025
Indication	To treat uncomplicated urogenital gonorrhea due to Neisseria gonorrhoeae



Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	0.4%	3	Decreased	C



Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	12.4%	77	Decreased	B



Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	55.3%	349	Increased	A
Asian	6.3%	30.6%	193	Decreased	A



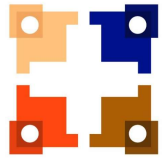
Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	3.3%	18	Increased	F

OVERALL GRADE

B

References: Phase 3 Pivotal trial STI_Zoli001;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2026/219491Orig1s000IntegratedR.pdf pg 34-35;
<https://www.kff.org/other-health/state-indicator/gonorrhea-cases-by-sex/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D>;
https://www.cdc.gov/sti-statistics/media/pdfs/2025/09/2023_STI_Surveillance_Report_FINAL_508.pdf;
 PMID: 36598837; No PMR/PMC



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Clinical Trial Demographic Scorecard

Drug	
Tradename	Voyxact
Generic Name	sibeprenlimab-szsi
Company	OTSUKA PHARM CO LTD
Date of FDA Approval	November 25, 2025
Indication	To reduce proteinuria in primary immunoglobulin A nephropathy in adults at risk for disease progression



Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	3.1%	9	Decreased	C



Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	41.2%	103	Decreased	A



Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	0.8%	1	Decreased	C
Asian	6.3%	59.0%	159	Increased	B



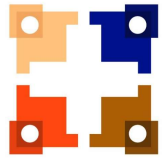
Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	10.7%	26	Similar	D

OVERALL GRADE

C

References: Pivotal trial VISIONARY 417-201-00007 ;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/761434Orig1s000IntegratedR.pdf pg 76; PMID: 37227924
 DOI: 10.34067/KID.0000000000000165; doi: 10.1016/j.ekir.2023.02.1086 PMID: PMC10166729; PMID: 37180506;
 DOI: 10.1159/000541869; No PMR/PMC



Clinical Trial Demographic Scorecard

Drug	
Tradename	Hyrnuo
Generic Name	sevabertinib
Company	Bayer Healthcare
Date of FDA Approval	November 19, 2025
Indication	To treat non-squamous non-small cell lung cancer with tumors that have activating HER2 tyrosine kinase domain activating mutations (orphan)



Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	39.3%	48	Increased	B



Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	67.2%	82	Increased	B



Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	3.3%	4	Similar	D
Asian	6.3%	66.4%	81	Increased	B



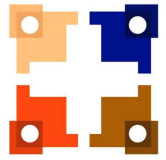
Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	2.5%	3	Similar	D

OVERALL GRADE



References: Pivotal trial SOHO-01 ;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/219972Orig1s000MultidisciplineR.pdf pg 130; DOI: 10.4143/crt.2022.359; DOI: 10.1016/j.annonc.2024.08.1355; No PMR/PMC



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Clinical Trial Demographic Scorecard

Drug	
Tradename	Redemplo
Generic Name	plozasiran
Company	Arrowhead
Date of FDA Approval	November 18, 2025
Indication	To reduce triglycerides in adults with familial chylomicronemia syndrome (orphan)



Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	12.0%	6	Decreased	C



Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	50.7%	27	Similar	C



Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	0%	0	Similar	D
Asian	6.3%	23.1%	12	Similar	B



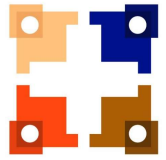
Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	2.7%	1	Similar	D

OVERALL GRADE

C

References: Pivotal Phase 3 trial AROAPOC3-3001;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/219947Orig1s000IntegratedR.pdf pgs 55-56
<https://rarediseases.org/rare-diseases/familial-chylomicronemia-syndrome/#affected>; No PMR/PMC



Clinical Trial Demographic Scorecard

Drug	
Tradename	Komzifti
Generic Name	ziftomenib
Company	Kura
Date of FDA Approval	November 13, 2025
Indication	To treat adults with relapsed or refractory acute myeloid leukemia with a susceptible nucleophosmin 1 mutation (orphan)



Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	62.5%	70	Increased	B



Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	56.3%	63	Increased	C



Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	1.8%	2	Decreased	C
Asian	6.3%	3.6%	4	Decreased	C



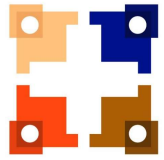
Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	2.7%	3	Decreased	C

OVERALL GRADE

C

References: Pivotal trials KO-MEN-001, KOMET-001;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/220305Orig1s000MultidisciplineR.pdf pg 172; doi: 10.1158/2159-8290.CD-20-1579; <https://doi.org/10.3390/cancers17132095>; <https://doi.org/10.1182/blood-2022-165285>; <https://doi.org/10.1002/ajh.25018>; No PMR/PMC



Clinical Trial Demographic Scorecard

Drug	
Tradename	Kygevvi
Generic Name	doxycitine and doxribtimine
Company	UCB Inc.
Date of FDA Approval	November 3, 2025
Indication	To treat thymidine kinase 2 deficiency in patients who start to show symptoms when they are 12 years old or younger (orphan)



Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	NR	NR	Decreased	C



Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	49.5%	46	Similar	B



Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	2.6%	5	Similar	D
Asian	6.3%	3.2%	4	Similar	D



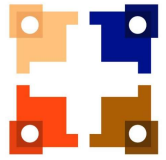
Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	21.6%	28	Similar	C

OVERALL GRADE



References: Pivotal trials MT-1621-101, TK0102, MT-1621-107, EAP; TK0114 ;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/219792Orig1s000IntegratedR.pdf pg 35-37;
<https://rarediseases.org/rare-diseases/thymidine-kinase-2-deficiency/#affected>;
<https://www.rarediseaseadvisor.com/disease-info-pages/thymidine-kinase-2-deficiency-epidemiology/>
 No PMR/PMC



Clinical Trial Demographic Scorecard

Drug	
Tradename	Lynkuet
Generic Name	elinzanetant
Company	Bayer Healthcare
Date of FDA Approval	October 24, 2025
Indication	To treat moderate-to-severe vasomotor symptoms due to menopause



Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	N/A	N/A	N/A	N/A



Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	100%	712	N/A	N/A



Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	16.2%	123	Increased	C
Asian	6.3%	0.6%	4	Decreased	C



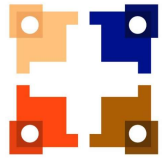
Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	9.6%	65	Decreased	B

OVERALL GRADE



References: Pivotal trials OASIS 1, OASIS 2, OASIS 3;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/219469Orig1s000IntegratedR.pdf pgs 40, 41, 74;
<https://doi.org/10.1016/j.maturitas.2013.03.003>; DOI:<https://doi.org/10.1016/j.maturitas.2009.06.002>;
<https://www.mayoclinic.org/diseases-conditions/menopause/symptoms-causes/syc-20353397>
 No PMR/PMC



Clinical Trial Demographic Scorecard

Drug	
Tradename	Rhapsido
Generic Name	remibrutinib
Company	Novartis
Date of FDA Approval	September 30, 2025
Indication	To treat chronic spontaneous urticaria in adults who remain symptomatic despite H1 antihistamine treatment



Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	8.4%	53	Decreased	B



Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	66.6%	403	Increased	A



Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	2.7%	19	Increased	F
Asian	6.3%	37.3%	223	Similar	A



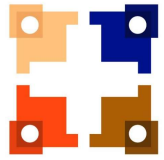
Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	15.0%	90	Decreased	A

OVERALL GRADE

B

References: Pivotal trials A2301 and A2302 ;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/218436Orig1s000IntegratedR.pdf pg 39 DOI:
 10.1016/j.jaad.2019.02.064; DOI: 10.4236/aid.2025.152019 ;
 No PMR/PMC



Clinical Trial Demographic Scorecard

Drug	
Tradename	Inluriyo
Generic Name	imlunestrant
Company	ELI LILLY AND CO
Date of FDA Approval	September 25, 2025
Indication	To treat estrogen receptor-positive, human epidermal growth factor receptor 2-negative, estrogen receptor-1-mutated advanced or metastatic breast cancer



Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	38.3%	120	Increased	B



Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	99.2%	327	N/A	N/A



Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	2.7%	11	Decreased	C
Asian	6.3%	28.4%	92	Decreased	A



Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	24.1%	79	Decreased	A

OVERALL GRADE

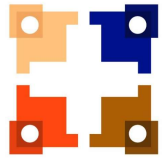
A

References: Pivotal trial EMBER-3;

https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/218881Orig1s000MultidisciplineR.pdf pg 133-134;

https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/breast-cancer-facts-and-figures/2024/breast-cancer-facts-and-figures-2024.pdf?utm_source=chatgpt.com;

https://seer.cancer.gov/statfacts/html/breast-subtypes.html?utm_source=chatgpt.com; No PMR/PMC



CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	Jascayd
Generic Name	nerandomilast
Company	BOEHRINGER INGELHEIM
Date of FDA Approval	September 25, 2025
Indication	To treat idiopathic pulmonary fibrosis (orphan)



Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	79.0%	701	Increased	A



Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	34.2%	163	Decreased	B



Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	0.5%	4	Decreased	C
Asian	6.3%	30.6%	279	Decreased	A



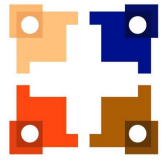
Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	8.2%	75	Decreased	B

OVERALL GRADE

B

References: Pivotal trials FIBRONEER-IPF (study 14), Study 13 ;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/218764Orig1s000IntegratedR.pdf pg 36, 52;
<https://rarediseases.org/rare-diseases/idiopathic-pulmonary-fibrosis/#affected>; <https://doi.org/10.1186/s12890-023-02565-7>; No PMR/PMC



Clinical Trial Demographic Scorecard

Drug	
Tradename	Palsonify
Generic Name	paltusotine
Company	CRINETICS
Date of FDA Approval	September 25, 2025
Indication	To treat acromegaly in adults who had an inadequate response to surgery and/or for whom surgery is not an option (orphan)



Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	15.4%	17	Decreased	B



Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	53.8%	41	Similar	B



Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	3.6%	4	Similar	D
Asian	6.3%	21.3%	15	Similar	B



Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	32.5%	29	Similar	B

OVERALL GRADE

B

References: Pivotal trials 08, 09;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/219070Orig1s000IntegratedR.pdf pgs 36,50,51
<https://rarediseases.org/rare-diseases/acromegaly/#affected> ; No PMR/PMC

Clinical Trial Demographic Scorecard

Drug	
Tradename	Keytruda Qlex
Generic Name	pembrolizumab and berahyaluronidase alfapmph
Company	MERCK SHARP DOHME
Date of FDA Approval	September 19, 2025
Indication	To treat adult and pediatric (12 years and older) solid tumor indications

OVERALL GRADE

B



Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	53.3%	132	Increased	B



Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	28.9%	69	Decreased	B



Race

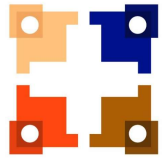
Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	2.7%	5	Increased	F
Asian	6.3%	29.2%	74	Decreased	A



Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	30.5%	74	Decreased	A

References: Pivotal trial MK-3475A-D77 ;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/761467Orig1,Orig2s000MultidisciplineR.pdf pg 96-97;
<https://pmc.ncbi.nlm.nih.gov/articles/PMC9309496/>; No PMR/PMC



CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	Forzinity
Generic Name	Elamipretide
Company	STEALTH BIOTHERAPS
Date of FDA Approval	September 19, 2025
Indication	To improve muscle strength in patients with Barth syndrome (orphan)



Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	N/A	N/A	N/A	N/A



Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	0%	0	Decreased	C



Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	0%	0	Similar	D
Asian	6.3%	0%	0	Similar	D



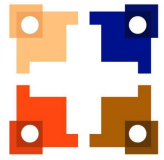
Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	0%	0	Similar	D

OVERALL GRADE

D

References: Pivotal trial SPIBA-201 TAZPOWER ; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/215244Orig1s000IntegratedR.pdf pgs 36-37; <https://www.barthsyndrome.org/barthsyndrome/>; <https://rarediseases.org/rare-diseases/barth-syndrome/>; No PMR/PMC



Clinical Trial Demographic Scorecard

Drug	
Tradename	Wayrilz
Generic Name	rilzabrutinib
Company	Genzyme
Date of FDA Approval	August 29, 2025
Indication	To treat persistent or chronic immune thrombocytopenia (orphan)



Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	17.8%	21	Increased	D



Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	62.9%	78	Increased	C



Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	0.5%	1	Similar	D
Asian	6.3%	31.7%	40	Similar	A



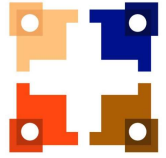
Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	20.3%	28	Similar	C

OVERALL GRADE



References: Pivotal trial LUNA-3;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/219685Orig1s000IntegratedR.pdf pg 57;
<https://doi.org/10.1182/blood-2014-05-578336>; DOI: 10.1111/j.1365-2141.2009.07615.x;
<https://doi.org/10.1182/blood-2006-03-010405>; <https://doi-org.proxy.cc.uic.edu/10.1182/blood-2022-170342>; No PMR/PMC



Clinical Trial Demographic Scorecard

Drug	
Tradename	Dawnzera
Generic Name	donidalorsen
Company	IONIS PHARMS INC
Date of FDA Approval	August 21, 2025
Indication	To prevent attacks of hereditary angioedema (orphan)



Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	2.2%	2	Decreased	C



Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	53.3%	48	Similar	B



Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	2.2%	1	Similar	D
Asian	6.3%	1.1%	1	Similar	D



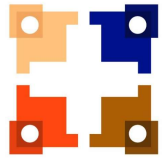
Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	6.7%	5	Similar	D

OVERALL GRADE

D

References: Pivotal trial OASIS-HAE CS5 ; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/219407Orig1s000IntegratedR.pdf pg 42; <https://rarediseases.org/rare-diseases/hereditary-angioedema/#affected>; <https://rarediseases.org/rarediseases/hereditary-angioedema/#affected>; No PMR/PMC



Clinical Trial Demographic Scorecard

Drug	
Tradename	Brinsupri
Generic Name	brensocatib
Company	INSMED INC
Date of FDA Approval	August 12, 2025
Indication	To treat non-cystic fibrosis bronchiectasis



Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	50.0%	676	Increased	A



Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	64.8%	864	Increased	B



Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	0.7%	9	Decreased	C
Asian	6.3%	10.8%	137	Decreased	A



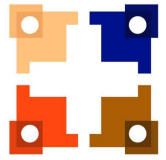
Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	26.2%	347	Decreased	A

OVERALL GRADE

A

References: Pivotal trials ASPEN 301, WILLOW 201;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/217673Orig1s000IntegratedR.pdf pgs 31,43,231; doi: 10.1177/1479972317709649; DOI: 10.1016/j.rmed.2023.107167; No PMR/PMC



Clinical Trial Demographic Scorecard

Drug	
Tradename	Hernexeos
Generic Name	zongertinib
Company	BOEHRINGER INGELHEIM
Date of FDA Approval	August 8, 2025
Indication	To treat unresectable or metastatic non-squamous non-small cell lung cancer whose tumors have HER2 tyrosine kinase domain activating mutations



Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	40.0%	42	Increased	B



Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	68.6%	72	Increased	B



Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	0%	0	Similar	D
Asian	6.3%	48.6%	51	Increased	B



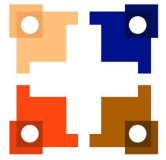
Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	1.9%	2	Similar	D

OVERALL GRADE



References: Pivotal trial 1479-0001 (Beamion LUNG-1) ; DOI: 10.1016/j.annonc.2024.08.1355; doi: 10.3978/j.issn.2218-6751.2013.02.02; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/219042Orig1s000MultidisciplineR.pdf pg 146, 177 ; No PMR/PMC



Clinical Trial Demographic Scorecard

Drug	
Tradename	Modeyso
Generic Name	dordaviprone
Company	CHIMERIX
Date of FDA Approval	August 6, 2025
Indication	To treat diffuse midline glioma harboring an H3 K27M mutation (orphan)



Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	2.0%	1	Decreased	C



Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	46.0%	23	Decreased	B



Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	6.0%	3	Decreased	C
Asian	6.3%	2.0%	1	Decreased	C



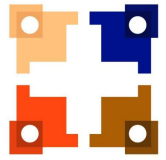
Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	8.0%	4	Decreased	C

OVERALL GRADE



References: Pivotal trials ONC006,013,014,016,018;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/219876Orig1s000MultidisciplineR.pdf pg 114; DOI:
 10.1001/jamaoncol.2018.1789; No PMR/PMC



Clinical Trial Demographic Scorecard

Drug	
Tradename	Sepience
Generic Name	sepiapterin
Company	PTC THERAP
Date of FDA Approval	July 28, 2025
Indication	To treat hyperphenylalaninemia in patients with sepiapterinresponsive phenylketonuria (orphan)

OVERALL GRADE

B



Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	N/A	N/A	N/A	N/A



Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	47.9%	129	Similar	B



Race

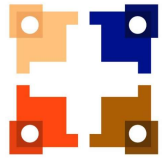
Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	0%	0	Decreased	C
Asian	6.3%	4.6%	15	Decreased	B



Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	17.5%	45	Decreased	A

References: Pivotal trials PKU-003, PKU-004;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/219666Orig1s000IntegratedR.pdf pgs 38,39,63;
<https://rarediseases.org/rare-diseases/phenylketonuria/#affected>;
<https://www.ncbi.nlm.nih.gov/books/NBK535378/#:~:text=The%20overall%20incidence%20of%20PKU,with%201/4000%20live%20births;No%20PMR/PMC>



Clinical Trial Demographic Scorecard

Drug	
Tradename	Vizz
Generic Name	aceclidine
Company	LENZ THERAP
Date of FDA Approval	July 31, 2025
Indication	To treat presbyopia



Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	7.0%	32	Increased	D



Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	65.3%	311	Increased	B



Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	4.6%	21	Increased	F
Asian	6.3%	4.9%	22	Similar	C



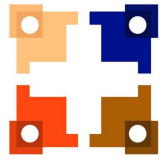
Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	24.6%	111	Increased	C

OVERALL GRADE

D

References: Pivotal trials Clarity 1, Clarity 2;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/218585Orig1s000IntegratedR.pdf pgs 16-17 ;
 doi: 10.1016/j.ajo.2016.11.004; No PMR/PMC



Clinical Trial Demographic Scorecard

Drug	
Tradename	Anzupgo
Generic Name	delgocitinib
Company	Leo Pharma
Date of FDA Approval	July 23, 2025
Indication	To treat moderate-to-severe chronic hand eczema when topical corticosteroids are not advisable or produce an inadequate response



Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	7.6%	56	Decreased	B



Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	64.3%	405	Increased	B



Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	0.7%	5	Similar	D
Asian	6.3%	3.5%	22	Similar	D



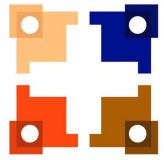
Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	2.6%	16	Decreased	C

OVERALL GRADE



References: Pivotal trials DELTA 1, DELTA 2;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/219155Orig1s000IntegratedR.pdf pgs 47, 150;
 doi: 10.1111/cod.13804; doi: 10.1093/bjd/ljaf020; <https://www.webmd.com/skin-problems-and-treatments/eczema/eczema-epidemiology?page=1>; No PMR/PMC



CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	Ekterly
Generic Name	sebetralstat
Company	KALVISTA
Date of FDA Approval	July 3, 2025
Indication	To treat acute attacks of hereditary angioedema (orphan)



Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	3.6%	3	Decreased	C



Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	60.0%	66	Similar	B



Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	0.9%	1	Similar	D
Asian	6.3%	9.1%	10	Similar	B



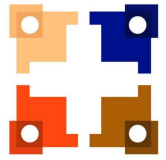
Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	6.4%	7	Similar	D

OVERALL GRADE

C

References: Phase 3 pivotal trial KONFIDENT (301);
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/219301Orig1s000IntegratedR.pdf pgs 34-35;
<https://rarediseases.org/rare-diseases/hereditary-angioedema/#affected>;
 No PMR/PMC



Clinical Trial Demographic Scorecard

Drug	
Tradename	Zegfrovy
Generic Name	sunvozertinib
Company	DIZAL JIANGSU
Date of FDA Approval	July 2, 2025
Indication	To treat locally advanced or metastatic non-small cell lung cancer with epidermal growth factor receptor exon 20 insertion mutations



Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	46.9%	90	Increased	B



Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	60.9%	117	Increased	C



Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	1.0%	2	Decreased	C
Asian	6.3%	60.9%	117	Increased	B



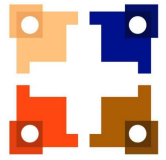
Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	6.3%	12	Similar	D

OVERALL GRADE

C

References: Pivotal trial n WU-KONG1B/DZ2019E001;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/219839Orig1s000MultidisciplineR.pdf pgs 128-129;
<https://doi.org/10.1038/s41598-021-98275-3>; <https://doi.org/10.1016/j.clcc.2019.07.003>; PMID: 28717712;
<https://doi.org/10.1200/OP.20.009>; No PMR/PMC



Clinical Trial Demographic Scorecard

Drug	
Tradename	Lynozytic
Generic Name	linvoseltamab-gcpt
Company	REGENERON PHARMACEUTICALS, INC.
Date of FDA Approval	July 2, 2025
Indication	To treat relapsed or refractory multiple myeloma (orphan)



Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	66.3%	53	Increased	B



Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	36.3%	29	Decreased	B



Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	13.8%	11	Increased	D
Asian	6.3%	12.5%	10	Decreased	A



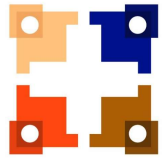
Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	2.5%	2	Similar	D

OVERALL GRADE



References: Pivotal trial LINKER-MM1 (R5458-ONC-1826); https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/761400Orig1s000MultidisciplineR.pdf pg 107; <https://seer.cancer.gov/statfacts/html/mulmy.html>; No PMR/PMC



Clinical Trial Demographic Scorecard

Drug	
Tradename	Andembry
Generic Name	garadacimab-gxii
Company	CSL BEHRING LLC
Date of FDA Approval	June 16, 2025
Indication	To prevent attacks of hereditary angioedema (orphan)



Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	9.4%	6	Decreased	C



Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	59.4%	24	Similar	C



Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	1.6%	0	Similar	D
Asian	6.3%	9.4%	4	Similar	B



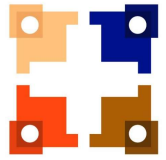
Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	4.7%	1	Similar	D

OVERALL GRADE

C

References: Pivotal Phase 3 trial VANGUARD 3001;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/761367Orig1s000IntegratedR.pdf pg 28, 260;
<https://rarediseases.org/rare-diseases/hereditary-angioedema/#affected>; No PMR/PMC



CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	Enflonsia
Generic Name	Clesrovimab-cfor
Company	MERCK SHARP DOHME
Date of FDA Approval	June 9, 2025
Indication	To prevent respiratory syncytial virus (RSV) lower respiratory tract disease in neonates and infants



Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	N/A	N/A	N/A	N/A



Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	49.2%	1,404	Similar	A



Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	14.1%	393	Similar	A
Asian	6.3%	24.9%	723	Similar	A



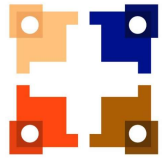
Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	28.8%	820	Similar	A

OVERALL GRADE

A

Ref: Pivotal Studies: MK-1654-004 (Phase 2b/3 Trial) + MK-1654-007 (Phase 3 trial)
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/761432Orig1s000IntegratedR.pdf Pages. 45, 215,223
<https://www.cdc.gov/acip/downloads/slides-2025-04-15-16/02-moulia-maternal-peds-rsv-508.pdf>; No PMR/PMC



CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	Ibtrozi
Generic Name	taletrectinib
Company	NUVATION
Date of FDA Approval	June 11, 2025
Indication	To treat locally advanced or metastatic ROS1-positive non-small cell lung cancer (orphan)



Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	22.9%	62	Decreased	A



Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	57.0%	154	Increased	C



Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	0.7%	2	Decreased	C
Asian	6.3%	83.7%	226	Increased	B



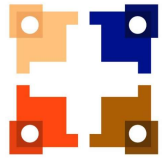
Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	1.1%	3	Decreased	C

OVERALL GRADE

B

References: Pivotal Phase 3 trials TRUST-I, TRUST-II (G208, C203); https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/219713Orig1s000MultidisciplineR.pdf pg 138, 175; <https://doi.org/10.1200/OP.20.00961>; <https://doi.org/10.1016/j.lungcan.2023.107378>; <https://lcfamerica.org/about-lung-cancer/diagnosis/biomarkers/ros1/#:~:text=A%20ROS1%2Dpositive%20lung%20cancer,Dr> ; No PMR/PMC



Clinical Trial Demographic Scorecard

Drug	
Tradename	Tryptyr
Generic Name	acoltremon
Company	Alcon Labs
Date of FDA Approval	May 28, 2025
Indication	To treat the signs and symptoms of dry eye disease



Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥75 years old*	17.3%	11.2%	50	Increased	B



Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	74.8%	350	Increased	A



Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	13.9%	70	Similar	B
Asian	6.3%	8.5%	40	Increased	B



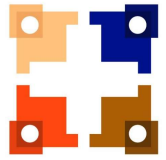
Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	11.8%	47	Increased	D

OVERALL GRADE

B

References: Phase 3 pivotal trials: COMET-2 [NCT-05285644] and COMET-3 [NCT-05360966]; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/217370Orig1s000IntegratedR.pdf pgs 21,22, 32; doi:10.1001/jamaophthalmol.2022.4394; doi: 10.1016/j.ajo.2011.02.026; <https://www.ajo.com/action/showPdf?pii=S0002-9394%2817%2930290-8>; DOI: 10.1016/s0002-9394(03)00218-6; No PMR/PMC



Clinical Trial Demographic Scorecard

Drug	
Tradename	Emrelis
Generic Name	telisotuzumab vedotin-tllv
Company	Abbvie
Date of FDA Approval	May 14, 2025
Indication	To treat locally advanced or metastatic, non-squamous non-small cell lung cancer (NSCLC) with high c-Met protein overexpression after prior systemic therapy



Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	50.0%	84	Increased	B



Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	30.4%	51	Similar	C



Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	1.8%	3	Similar	D
Asian	6.3%	32.7%	55	Decreased	A



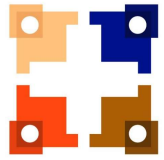
Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	0.6%	1	Decreased	C

OVERALL GRADE

C

References: Phase 3 pivotal trial Luminosity M14-239 ; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/761384Orig1s000MultidisciplineR.pdf pgs 96-97; doi: 10.1177/17588359241279715; <https://doi.org/10.1186/s12885-024-12126-8>; [https://www.ncbi.nlm.nih.gov/books/NBK519578/#:~:text=Lung%20adenocarcinoma%20is%20the%20most,p atients%20affected%20by%20lung%20adenocarcinoma.](https://www.ncbi.nlm.nih.gov/books/NBK519578/#:~:text=Lung%20adenocarcinoma%20is%20the%20most,p atients%20affected%20by%20lung%20adenocarcinoma.;); No PMR/PMC



CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	Avmapki Fakzynja Co-Pack
Generic Name	avutometinib and defactinib
Company	VERASTEM INC
Date of FDA Approval	May 8, 2025
Indication	To treat KRAS-mutated recurrent low-grade serous ovarian cancer (LGSOC) after prior systemic therapy (orphan)



Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	28.7%	33	Increased	B



Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	100%	115	Increased	NA



Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	4.3%	5	Decreased	C
Asian	6.3%	3.5%	4	Decreased	C



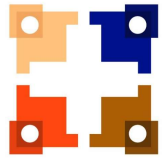
Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	2.2%	3	Similar	D

OVERALL GRADE



References: Phase 3 pivotal trial RAMP-201; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/219616Orig1s000MultidisciplineR.pdf pgs 173,175; <https://seer.cancer.gov/statfacts/html/ovary.html>; <https://gis.cdc.gov/Cancer/USCS/#/explore/incidence>; No PMR/PMC



CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	Imaavy
Generic Name	nipocalimab-aahu
Company	JANSSEN BIOTECH
Date of FDA Approval	April 29, 2025
Indication	To treat generalized myasthenia gravis (orphan)



Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	24.2%	18	Increased	C



Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	60.1%	50	Increased	C



Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	1.3%	1	Increased	F
Asian	6.3%	32.0%	24	Similar	B



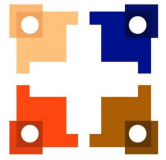
Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	7.8%	8	Decreased	C

OVERALL GRADE

C

References: Phase 3 pivotal trial 011;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/761430Orig1s000IntegratedR.pdf pgs 47-48;
<https://doi.org/10.1212/WNL.0000000000202945>; doi: 10.3389/fneur.2024.1339167;
doi: 10.3390/jcm10112235; <https://www.rarediseaseadvisor.com/disease-info-pages/myasthenia-gravis/epidemiology/>;
<https://rarediseases.org/rare-diseases/myasthenia-gravis/#affected>; No PMR/PMC



Clinical Trial Demographic Scorecard

Drug	
Tradename	penpulimab-kcqx
Generic Name	penpulimab-kcqx
Company	AKESO BIOPHARMA
Date of FDA Approval	April 23, 2025
Indication	To treat adults with non-keratinizing nasopharyngeal carcinoma (orphan)



Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	5.0%	16	Similar	D



Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	20.4%	56	Decreased	B



Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	0.2%	0	Similar	D
Asian	6.3%	98.3%	270	Increased	B



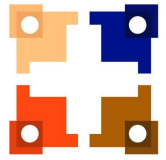
Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	1.0%	2	Decreased	C

OVERALL GRADE

C

References: Phase 3 pivotal trials AK105-304, AK105-202; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/761258Orig1s000MultidisciplineR.pdf pgs 95,99,131, 220; PMID: 37227924 DOI: 10.34067/KID.000000000000165; doi: 10.1016/j.ekir.2023.02.1086 PMID: PMC10166729; PMID: 37180506; DOI: 10.1159/000541869; PMID: 35757475; doi:10.1001/archotol.132.10.1035 PMC for demographic subgroups that are reflective of the U.S. patient population



Clinical Trial Demographic Scorecard

Drug	
Tradename	Vanrafia
Generic Name	atrasentan
Company	Novartis
Date of FDA Approval	April 2, 2025
Indication	To reduce proteinuria in adults with primary IgA nephropathy at risk of rapid disease progression



Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	6.3%	11	Decreased	C



Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	41.1%	54	Decreased	A



Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	1.9%	4	Decreased	C
Asian	6.3%	57.0%	75	Increased	B



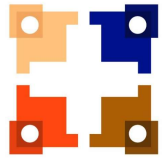
Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	20.7%	32	Similar	B

OVERALL GRADE

B

References: Phase 3 pivotal trial ALIGN;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/219208Orig1s000IntegratedR.pdf pgs 36-37;
 PMID: 37227924 DOI: 10.34067/KID.000000000000165; doi: 10.1016/j.ekir.2023.02.1086 PMCID:
 PMC10166729; PMID: 37180506; DOI: 10.1159/000541869; No PMR/PMC



Clinical Trial Demographic Scorecard

Drug	
Tradename	Qfitlia
Generic Name	fitusiran
Company	Genzyme
Date of FDA Approval	March 28, 2025
Indication	To prevent or reduce the frequency of bleeding episodes in hemophilia A or B (orphan)



Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	1.0%	3	Decreased	C



Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	NA	NA	NA	NA



Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	1.1%	3	Decreased	C
Asian	6.3%	62.1%	169	Decreased	A



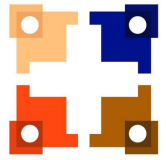
Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	4.0%	5	Similar	D

OVERALL GRADE

C

References: Phase 3 pivotal trials ATLAS-INH (EFC14768), ATLAS-A/B (EFC14769); DOI: 10.1111/hae.13998 ; DOI: 10.1182/asheducation-2010.1.191; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/219019Orig1s000IntegratedR.pdf pgs. 49, 53, 62, 100, 252 ; No PMR/PMC



CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	Blujepa
Generic Name	gepotidacin
Company	GSK
Date of FDA Approval	March 25, 2025
Indication	To treat uncomplicated urinary tract infections



Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	23.3%	353	Increased	A



Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	100%	1,572	Increased	A



Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	6.9%	114	Similar	C
Asian	6.3%	5.1%	74	Similar	B



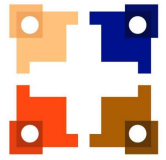
Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	32.7%	524	Similar	A

OVERALL GRADE

A

References: Phase 3 pivotal trials EAGLE-2, EAGLE-3;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/218230Orig1s000IntegratedR.pdf pg 23, 50;
 doi: 10.1177/1756287219832172; <https://www.ncbi.nlm.nih.gov/books/NBK470195/>; No PMR/PMC



Clinical Trial Demographic Scorecard

Drug	
Tradename	Romvimza
Generic Name	vimseltinib
Company	DECIPHERA PHARMS
Date of FDA Approval	February 14, 2025
Indication	To treat symptomatic tenosynovial giant cell tumor



Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	9.8%	5	Decreased	C



Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	59.3%	46	Increased	C



Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	3.3%	4	Unknown	D
Asian	6.3%	4.1%	1	Increased	D



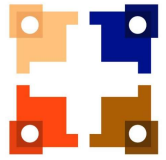
Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	3.3%	3	Unknown	D

OVERALL GRADE

D

References: Pivotal Phase 3 trial DCC-3014-03-001 MOTION; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/219304Orig1s000MultidisciplineR.pdf pg 132; <https://rarediseases.org/rare-diseases/tenosynovial-giant-cell-tumor/#affected>; DOI: 10.1016/j.ctrv.2022.102491; DOI: 10.1038/srep36332; No PMR/PMC



Clinical Trial Demographic Scorecard

Drug	
Tradename	Gomekli
Generic Name	mirdametinib
Company	SPRINGWORKS
Date of FDA Approval	February 11, 2025
Indication	To treat neurofibromatosis type 1 (orphan)



Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	1.8%	2	Decreased	C



Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	58.8%	67	Similar	B



Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	14.0%	16	Similar	C
Asian	6.3%	3.5%	4	Similar	D



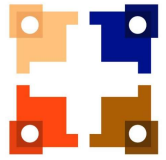
Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	7.9%	9	Similar	D

OVERALL GRADE



References: Pivotal Phase 3 trial MEK-NF-201 ReNeu ; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/219379Orig1s000,219389Orig1s000MultidisciplineR.pdf pg 150; <https://rarediseases.org/rare-diseases/neurofibromatosis-type-1-nf1/#affected>; DOI: 10.3928/01913913-20190321-02; <https://nfpittsburgh.org/whatisnf/facts-statistics/>; No PMR/PMC



Clinical Trial Demographic Scorecard

Drug	
Tradename	Journavx
Generic Name	suzetrigine
Company	Vertex
Date of FDA Approval	January 30, 2025
Indication	To treat moderate to severe acute pain



Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	4.8%	47	Increased	D



Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	91.7%	803	Increased	A



Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	25.5%	239	Increased	B
Asian	6.3%	1.8%	16	Decreased	C



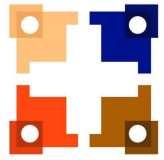
Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	34.0%	281	Increased	B

OVERALL GRADE

B

References: Pivotal Phase 3 trials VX22-548-104, VX22-548-105 ; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/219209Orig1s000IntegratedR.pdf pgs 26,27,33; doi: 10.7861/clinmed.22.4.ac-p; PMID: 26526704; <https://doi.org/10.1111/pme.12528>; PMID: 35260338; PMID: 25422152; No PMR/PMC



Clinical Trial Demographic Scorecard

Drug	
Tradename	Grafapex
Generic Name	treosulfan
Company	MEDEXUS
Date of FDA Approval	January 21, 2025
Indication	For use in allogeneic hematopoietic stem cell transplantation for AML and MDS (orphan)



Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	26.0%	76	Increased	B



Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	39.1%	109	Decreased	A



Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	NR	NR	Decreased	C
Asian	6.3%	NR	NR	Decreased	C



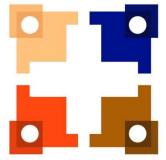
Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	NR	NR	Decreased	C

OVERALL GRADE



References: Pivotal Phase 3 trial MC-FludT.14/L Trial II; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/214759Orig1s000MultidisciplineR.pdf pg 37; <https://seer.cancer.gov/statfacts/html/amyl.html>; https://seer.cancer.gov/statistics-network/explorer/application.html?site=409&data_type=1&graph_type=10&compareBy=sex&chk_sex_3=3&chk_sex_2=2&series=9&race=8&age_range=1&hdn_stage=101&advopt_precision=1&advopt_show_ci=on&hdn_view=0; PMC for race and ethnicity



CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	Datroway
Generic Name	datopotamab deruxtecan-dlnk
Company	DAIICHI SANKYO INC
Date of FDA Approval	January 17, 2025
Indication	To treat unresectable or metastatic, HR-positive, HER2-negative breast cancer

OVERALL GRADE

B



Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	22.3%	91	Increased	B



Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	98.8%	360	Increased	NA



Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	1.5%	4	Decreased	C
Asian	6.3%	40.7%	146	Decreased	A



Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	11.3%	40	Decreased	B

References: Pivotal Phase 3 trial TROPION-Breast01;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/761394Orig1s000MultidisciplineR.pdf pgs 135-6;
<https://seer.cancer.gov/statfacts/html/breast-subtypes.html>; PMID: 36895447; PMC for race and ethnicity