CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Leqembi**
Generic Name	**lecanemab-irmb**
Company	Eisai Inc. and Biogen
Date of FDA Approval	January 6, 2023
Indication	To treat **Alzheimer's disease**

OVERALL GRADE

C

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	16.5%	80.0%	476	Increased	**A**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	50.0%	272	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	13.4%	2.0%	15	Increased	**F**
Asian	5.9%	6.0%	36	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	18.5%	4.0%	26	Increased	**F**

References: Phase 3 trial NCT01767311 Study 201 (BAN2401-G000-201);
https://www.brightfocus.org/alzheimers/article/why-does-alzheimers-disease-affect-more-women-men;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/761269Orig1s000MedR.pdf pg 266;
doi:10.1001/jama.2022.3550

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Brenzavvy**
Generic Name	**bexagliflozin**
Company	TheracosBio, LLC
Date of FDA Approval	January 20, 2023
Indication	To improve glycemic control in adults with **type 2 diabetes mellitus** as an adjunct to diet and exercise

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	16.5%	43.6%	871	Increased	**A**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	38.5%	751	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	13.4%	5.7%	117	Increased	**D**
Asian	5.9%	15.9%	298	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	18.5%	16.7%	324	Increased	**B**

References: 6 Phase 3 trials C-419, C-423, C-448, C-450, C-476, C-480 ; doi: 10.2147/IJGM.S226010;
https://www.cdc.gov/diabetes/pdfs/library/diabetesreportcard2017
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/214373Orig1s000IntegratedR.pdf pg 39

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Orserdu**
Generic Name	**elacestrant**
Company	Stemline Therapeutics
Date of FDA Approval	January 27, 2023
Indication	To treat estrogen receptor-positive, human epidermal growth factor receptor 2-negative, ESR1-mutated, advanced or **metastatic breast cancer** with disease progression following at least one line of endocrine therapy

OVERALL GRADE

C

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	16.5%	55.0%	104	Increased	**B**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	98.5%	233	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	13.4%	2.7%	5	Similar	**D**
Asian	5.9%	7.0%	16	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	18.5%	7.7%	19	Decreased	**C**

References: Phase 3 trial EMERALD RAD1901-308 ; https://seer.cancer.gov/statfacts/html/breast.html; doi: 10.1200/JCO.22.00338; https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/breast-cancer-facts-and-figures/breast-cancer-facts-and-figures-2019-2020.pdf; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/217639Orig1s000MultidisciplineR.pdf pg. 128-129

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Jaypirca**
Generic Name	**pirtobrutinib**
Company	Eli Lilly
Date of FDA Approval	January 27, 2023
Indication	To treat **relapsed or refractory mantle cell lymphoma** in adults who have had at least two lines of systemic therapy, including a BTK inhibitor

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	16.5%	77.5%	93	Increased	**B**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	20.8%	25	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	13.4%	1.7%	2	Decreased	**C**
Asian	5.9%	14.2%	17	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	18.5%	2.5%	3	Decreased	**C**

References: Phase 3 trial LOXO-BTK-18001; DOI: 10.1186/1471-2407-14-764; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/216059Orig1s000MultidisciplineR.pdf pg 93

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Jesduvroq**
Generic Name	**daprodustat**
Company	GlaxoSmithKline
Date of FDA Approval	February 1, 2023
Indication	To treat **anemia caused by chronic kidney disease** for adults on dialysis for at least four months

OVERALL GRADE

A

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	16.5%	32%	>300	Increased	**A**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	43%	>300	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	13.4%	16%	228	Increased	**C**
Asian	5.9%	12%	176	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	18.5%	25%	>300	Increased	**A**

References: Phase 3 trial ASCEND-D; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/216951Orig1s000IntegratedR.pdf pg 173; https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216951s000lbl.pdf; https://www.niddk.nih.gov/health-information/health-statistics/kidney-disease; doi:10.1053/j.semvascsurg.2021.02.010

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Lamzede**
Generic Name	**velmanase alfa-tycv**
Company	CHIESI FARMACEUTICI SPA
Date of FDA Approval	February 16, 2023
Indication	To treat **non-central nervous system manifestations of alpha-mannosidosis**

OVERALL GRADE

D

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	16.5%	0.0%	0	Decreased	**NA**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	44%	6	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	13.4%	0.0%	0	Similar	**D**
Asian	5.9%	0.0%	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	18.5%	NR	NR	Similar	**D**

References: Phase 3 trial rhLAMAN-05 https://rarediseases.org/rare-diseases/alpha-mannosidosis/#affected
https://doi.org/10.1186/s13023-022-02422-6;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/761278Orig1s000IntegratedR.pdf pg28

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Clinical Trial Demographic Scorecard

Drug	
Tradename	**Filspari**
Generic Name	**Sparsentan**
Company	Travere
Date of FDA Approval	February 17, 2023
Indication	To reduce **proteinuria in adults with primary immunoglobulin A nephropathy** at risk of rapid disease progression (orphan)

OVERALL GRADE

C

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	16.5%	7.4%	<30	Decreased	**C**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	30.2%	30-299	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	13.4%	1.0%	<30	Similar	**D**
Asian	5.9%	28.5%	30-299	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	18.5%	8.2%	<30	Decreased	**D**

References: Phase 3 trial PROTECT ; PMID: 37227924 DOI: 10.34067/KID.0000000000000165; doi: 10.1016/j.ekir.2023.02.1086 PMCID: PMC10166729; PMID: 37180506; https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216403s000lbl.pdf;

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Clinical Trial Demographic Scorecard

Drug	
Tradename	**Skyclarys**
Generic Name	**omaveloxolone**
Company	Reata Pharms
Date of FDA Approval	February 28, 2023
Indication	To treat **Friedrich's ataxia**

OVERALL GRADE

C

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	16.5%	0.0%	0	Decreased	**NA**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	46.6%	31	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	13.4%	NR	NR	Decreased	**C**
Asian	5.9%	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	18.5%	4.9%	2	Decreased	**C**

References: Phase 3 trial MOXIe Study 408-C1402, Part 2; 97% White; 1 participant of "other race" treated with Skyclarys; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/216718Orig1s000MedR.pdf pg 49; https://www.wikidoc.org/index.php/Friedreich%27s_ataxia_epidemiology_and_demographics;

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Clinical Trial Demographic Scorecard

Drug	
Tradename	**Zavzpret**
Generic Name	**zavegepant**
Company	Pfizer
Date of FDA Approval	March 9, 2023
Indication	To treat **migraine**

OVERALL GRADE

A

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	16.5%	4.2%	79	Decreased	**B**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	84.3%	1,519	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	13.4%	14.9%	284	Similar	**B**
Asian	5.9%	3.3%	65	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	18.5%	19.1%	317	Similar	**A**

References: Phase 3 trials BHV3500-201, 301;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/216386Orig1s000MedR.pdf pg 33, 50-51,
https://www.webmd.com/migraines-headaches/migraine-epidemiology; doi:10.1001/jama.2021.21857;
https://doi.org/10.1111/head.12506

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Clinical Trial Demographic Scorecard

Drug	
Tradename	**Daybue**
Generic Name	**trofinetide**
Company	Acadia Pharmaceuticals
Date of FDA Approval	March 10 , 2023
Indication	To treat **Rett syndrome**

OVERALL GRADE

D

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	16.5%	NA	NA	Decreased	**NA**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	100%	151	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	13.4%	1.1%	2	Similar	**D**
Asian	5.9%	3.3%	7	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	18.5%	9.3%	15	Similar	**D**

References: Phase 2/3 trials ACP-2566-003, Neu-2566-RETT-002; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/217026Orig1s000MedR.pdf pg 55, 78-79; https://rarediseases.org/rare-diseases/rett-syndrome/#affected; https://www.ninds.nih.gov/health-information/disorders/rettsyndrome#:~:text=Who%20is%20more%20likely%20to,It%20affects%20girls%20almost%20exclusively. PMID: 8424025

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Zynyz**
Generic Name	**retifanlimab-dlwr**
Company	Incyte Corporation
Date of FDA Approval	March 22, 2023
Indication	To treat metastatic or recurrent locally advanced **Merkel cell carcinoma**

OVERALL GRADE

C

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	16.5%	78.5%	51	Increased	**B**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	35.4%	23	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	13.4%	0.0%	0	Decreased	**C**
Asian	5.9%	1.5%	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	18.5%	0.0%	0	Decreased	**C**

References: Phase 3 trial POD1UM-201;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/761334Orig1s000MultidisciplineR.pdf pg70;
https://www.cancer.org/cancer/merkel-cell-skin-cancer/about/key-statistics.html;
https://doi.org/10.1016/j.jaad.2017.10.028; doi:10.1001/jamadermatol.2023.0061

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Rezzayo**
Generic Name	**rezafungin**
Company	Melinta Therapeutics/ Cidara Theraps
Date of FDA Approval	March 22, 2023
Indication	To treat **candidemia and invasive candidiasis**

OVERALL GRADE

C

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	16.5%	40.6%	38	Increased	**B**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	36.9%	31	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	13.4%	4.8%	5	Increased	**F**
Asian	5.9%	28.9%	23	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	18.5%	11.7%	15	Similar	**D**

References: Phase 3 trial Study CD101.IV.3.05 (ReSTORE);
https://www.cdc.gov/fungal/diseases/candidiasis/invasive/statistics.html
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/217417Orig1s000IntegratedR.pdf pg 41, 83;
doi: 10.1371/journal.ppat.1011025;

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Joenja**
Generic Name	**leniolisib**
Company	PHARMING
Date of FDA Approval	March 24, 2023
Indication	To treat **activated phosphoinositide 3-kinase delta syndrome**

OVERALL GRADE

C

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	16.5%	NA	NA	Decreased	**NA**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	52.0%	10	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	13.4%	7.0%	1	Unknown	**D**
Asian	5.9%	7.0%	1	Unknown	**C**

Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	18.5%	3.0%	0	Unknown	**D**

References: Phase 3 trial 2201 Part 2;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/217759Orig1s000MultidisciplineR.pdf pg 111;
DOI: 10.1007/s12016-019-08738-9

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Qalsody**
Generic Name	**tofersen**
Company	Biogen
Date of FDA Approval	April 25, 2023
Indication	To treat **amyotrophic lateral sclerosis** in adults who have a SOD1 gene mutation

OVERALL GRADE

C

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	16.5%	13.0%	9	Increased	**D**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	42.6%	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	13.4%	0.9%	1	Decreased	**C**
Asian	5.9%	8.3%	5	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	18.5%	4.6%	4	Decreased	**C**

References: Phase 3 trial Study 233AS101 (Part C); ; DOI: 10.1007/s12016-019-08738-9; DOI: 10.1097/WCO.0000000000000730

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Elfabrio**
Generic Name	**Pegunigalsidase alfa-iwxj**
Company	Chiesi Farmaceutici
Date of FDA Approval	May 9, 2023
Indication	Treatment of **Fabry disease** in adults

OVERALL GRADE

C

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	16.5%	0.0%	0	Decreased	**C**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	40.0%	30	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	13.4%	6.0%	4	Similar	**D**
Asian	5.9%	2.0%	2	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	18.5%	5.0%	3	Similar	**D**

References: Phase 3 trial PB-102-F01/02 and PB-102-F-20 BALANCE;
https://www.ncbi.nlm.nih.gov/books/NBK435996/#article-21518.s4;
https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761161s000lbl.pdf;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/761161Orig1s000MultidisciplineR.pdf pg 30

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Veozah**
Generic Name	**fezolinetant**
Company	Astellas
Date of FDA Approval	May 12, 2023
Indication	To treat **moderate to severe hot flashes caused by menopause**

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	16.5%	46.7%	315	Similar	**A**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	100%	680	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	13.4%	17.0%	115	Increased	**C**
Asian	5.9%	1.0%	6	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	18.5%	23.8%	165	Decreased	**A**

References: Phase 3 trials 2693-CL-0301 and 2693-CL-0302; DOI: 10.1097/GME.0b013e3182952228; 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/diseasesconditions/menopause/symptoms-causes/syc-20353397 https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/216578Orig1s000MedR.pdf pg 97, 98, 129, 130

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Miebo**
Generic Name	**perfluorhexyloctane**
Company	BAUSCH AND LOMB INC
Date of FDA Approval	May 18, 2023
Indication	To treat **signs and symptoms of dry eye disease**

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	16.5%	39.2%	235	Increased	**B**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	75.7%	469	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	13.4%	12.4%	76	Increased	**C**
Asian	5.9%	10.3%	70	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	18.5%	18.2%	106	Increased	**C**

References: Phase 3 trials GOBI and MOJAVE NVU-003 and BL-904; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/216675Orig1s000MedR.pdf pg 23,24,28,29 doi:10.1001/jamaophthalmol.2022.4394; https://ophthalmologybreakingnews.com/the-role-of-ethnicity-in-dry-eye-disease; https://doi.org/10.1016/j.ajo.2017.06.033; doi: 10.1097/01.opx.0000156310.45736.fa. doi: 10.1016/j.ajo.2011.02.026

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Epkinly**
Generic Name	**EPCORITAMAB-BYSP**
Company	GENMAB US, INC.
Date of FDA Approval	May 19, 2023
Indication	To treat **relapsed or refractory diffuse large B-cell lymphoma (not otherwise specified) and high-grade B-cell lymphoma** after two or more lines of systemic therapy

OVERALL GRADE

C

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	16.5%	49.0%	77	Increased	**B**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	40.0%	63	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	13.4%	0.0%	0	Decreased	**C**
Asian	5.9%	19.0%	30	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	18.5%	0.0%	0	Increased	**F**

References: Phase 3 trial GCT3013-01; FDA review; Non-Hodgkin Lymphoma Recent Trends in SEER Age-Adjusted Incidence Rates, 2000-2020; *Incidence of extranodal non-Hodgkin lymphomas among whites, blacks, and Asians/Pacific Islanders in the United States: Anatomic site and histology differences.* (n.d.). Read by QxMD. Retrieved July 19, 2023, from https://read.qxmd.com/read/19853554/incidence-of-extranodal-non-hodgkin-lymphomas-among-whites-blacks-and-asians-pacific-islanders-in-the-united-states-anatomic-site-and-histology-differences; https://seer.cancer.gov/statfacts/html/dlbcl.html; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/761324Orig1s000MultidisciplineR.pdf pg 110

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Xacduro**
Generic Name	**sulbactam, durlobactam**
Company	Entasis Therapeutics Innoviva Specialty Therapeutics
Date of FDA Approval	May 23, 2023
Indication	To treat **hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia** caused by susceptible isolates of Acinetobacter baumannii-calcoaceticus complex

OVERALL GRADE

C

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	16.5%	52.2%	58	Increased	**B**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	25.9%	31	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	13.4%	0.5%	0	Similar	**D**
Asian	5.9%	39.5%	37	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	18.5%	12.2%	16	Similar	**D**

References: Phase 3 trial CS2514-2017-0004 Parts A and B; DOI: 10.1007/s12016-019-08738-9;
https://www.ajicjournal.org/article/S0196-6553(17)31056-8/pdf
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/216974Orig1s000IntegratedR.pdf pg. 55,56;
https://emedicine.medscape.com/article/234753-overview#a4

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Posluma**
Generic Name	**flotufolastat F 18**
Company	Blue Earth Diagnostics Ltd.
Date of FDA Approval	May 25, 2023
Indication	To **use with positron emission tomography imaging in certain patients with prostate 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	16.5%	62.0%	463	Increased	**A**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	NA	NA	Decreased	**NA**

Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.4%	12.2%	91	Increased	**C**
Asian	5.9%	<2.4%	<18	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	18.5%	4.7%	35	Decreased	**B**

References: Phase 3 trials BED-PSMA-301 LIGHTHOUSE and BED-PSMA-302 SPOTLIGHT; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/216023Orig1s000MultidisciplineR.pdf pg 101 ; https://www.cdc.gov/mmwr/volumes/69/wr/mm6941a1.htm; https://www.cancer.org/cancer/prostate-cancer/about/key-statistics.html#:~:text=Prostate%20cancer%20is%20more%20likely,at%20diagnosis%20is%20about%2066

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Paxlovid**
Generic Name	**nirmatrelvir, ritonavir**
Company	Pfizer
Date of FDA Approval	May 25, 2023
Indication	To treat **mild-to-moderate COVID-19 in adults at high risk for progression to severe COVID-19**

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	16.5%	9.3%	327	Increased	**C**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	51.7%	1,781	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	13.4%	9.0%	350	Increased	**C**
Asian	5.9%	8.2%	245	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	18.5%	55.4%	1,970	Increased	**A**

References: Phase 3 trials EPIC-HR, EPIC-SR, EPIC-PEP; https://www.accessdata.fda.gov/drugsatfda_docs/nda/20; https://covid.cdc.gov/covid-data-tracker/#nationwide-blood-donor-seroprevalence-2022 ; https://www.mayoclinic.org/diseases-conditions/coronavirus/expert-answers/coronavirus-infection-by-race/faq-20488802; https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html#:~:text=Older%20adults%20are%20at%20highest,people%20ages%2018%2D29%20years. doi: 10.3390/ijerph20020975; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/217188Orig1s000IntegratedR.pdf pg 35,36,50,57

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Inpefa**
Generic Name	**sotagliflozin**
Company	Lexicon Pharmaceuticals
Date of FDA Approval	May 26, 2023
Indication	To treat **heart failure**

OVERALL GRADE

C

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	16.5%	69.6%	5,502	Increased	**A**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	43.8%	2,545	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	13.4%	3.5%	201	Increased	**D**
Asian	5.9%	5.9%	325	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	18.5%	NR	NR	Increased	**F**

References: Phase 3 trials SOLOIST, SCORED; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/216203Orig1s000IntegratedR.pdf pg37-40 ; https://doi.org/10.1016/j.jacc.2021.06.058; DOI: 10.1161/CIR.0000000000000757 https://www.acc.org/latest-incardiology/articles/2020/10/01/11/39/latest-evidence-on-racial-inequities-and-biases-in-advanced-hf https://www.acc.org/latest-in-cardiology/articles/2019/05/07/12/42/cover-story-south-asians-and-cardiovascular-disease-the-hidden-threat#:~:text=People%20of%20South%20Asian%20descent,the%20fifth%20decade%20of%20life).

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Columvi**
Generic Name	**glofitamab-gxbm**
Company	Genentech
Date of FDA Approval	June 15, 2023
Indication	To treat **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

OVERALL GRADE

C

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	16.5%	56.0%	74	Increased	**B**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	36.0%	47	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	13.4%	0.8%	1	Decreased	**C**
Asian	5.9%	4.5%	6	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	18.5%	5.0%	7	Increased	**F**

References: Phase 3 trial NP30179;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/761309Orig1s000MultidisciplineR.pdf pg 123;
https://seer.cancer.gov/statfacts/html/dlbcl.html;

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Litfulo**
Generic Name	**ritlecitinib**
Company	Pfizer
Date of FDA Approval	June 23, 2023
Indication	To treat **severely patchy hair loss, alopecia areata**

OVERALL GRADE

C

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	16.5%	2.8%	15	Decreased	**C**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	62.1%	360	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	13.4%	3.8%	23	Increased	**F**
Asian	5.9%	25.9%	155	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	18.5%	12.1%	76	Increased	**D**

References: Phase 3 trial AA-I B7981015 ; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/215830Orig1s000MultidisciplineR.pdf pg94-95. doi: 10.1001/jamadermatol.2023.0002 ; DOI: 10.1016/j.jaad.2019.08.032; https://doi.org/10.1111/bjd.20628; DOI: https://doi.org/10.1016/j.jaad.2021.02.063; DOI:https://doi.org/10.1016/j.jaad.2019.06.1300; DOI:https://doi.org/10.1016/j.jisp.2017.10.007; https://www.healio.com/news/dermatology/20230308/asian-americans-experience-higher-rates-of-alopecia-areata

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Rystiggo**
Generic Name	**rozanolixizumab-noli**
Company	UCB Inc.
Date of FDA Approval	June 26, 2023
Indication	To treat **generalized myasthenia gravis in adults who are antiacetylcholine receptor- or antimuscle-specific tyrosine kinase antibody-positive** (orphan)

OVERALL GRADE

C

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	16.5%	24.5%	33	Increased	**B**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	60.5%	74	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	13.4%	2.5%	4	Increased	**F**
Asian	5.9%	10.5%	16	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	18.5%	6.5%	8	Unknown	**D**

References: Phase 3 trial MG0003;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/761286Orig1s000IntegratedR.pdf pg 51;
DOI: https://doi.org/10.1212/WNL.0000000000202945;
doi: 10.3390/jcm10112235; https://www.rarediseaseadvisor.com/disease-info-pages/myasthenia-gravis-epidemiology/

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Ngenla**
Generic Name	**somatrogon-ghla**
Company	Pfizer
Date of FDA Approval	June 27, 2023
Indication	To treat **growth failure due to inadequate secretion of endogenous growth hormone** (orphan)

OVERALL GRADE

C

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	16.5%	NA	NA	Decreased	**NA**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	28.1%	27	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	13.4%	0.9%	0	Similar	**D**
Asian	5.9%	20.1%	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	18.5%	10.7%	NR (<30)	Similar	**D**

References: Phase 3 trial CP-4-006; https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761184Orig1s000Corrected_lbl.pdf; doi: 10.1210/clinem/dgac220; PMCID: PMC9202717';PMID: 3540501 ; https://emedicine.medscape.com/article/923688-overview#a6; https://rarediseases.org/rare-diseases/growth-hormone-deficiency/#affected;

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Beyfortus**
Generic Name	**nirsevimab-alip**
Company	AstraZeneca
Date of FDA Approval	July 17, 2023
Indication	To **prevent respiratory syncytial virus (RSV) lower respiratory tract disease** in neonates, infants and children up to 24 months of age

OVERALL GRADE

A

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	16.5%	NA	NA	Decreased	**NA**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	47.2%	1,798	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	13.4%	14.0%	558	Similar	**A**
Asian	5.9%	4.2%	163	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	18.5%	26.4%	1,023	Similar	**A**

References: Phase 3 trials D5290C00003, D5290C00004, D5290C00005;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/761328Orig1s000IntegratedR.pdf pgs 47,59, 71,76;
https://www.marchofdimes.org/peristats/data?reg=99&top=2&stop=10&lev=1&slev=1&obj=3 ;
https://en.wikipedia.org/wiki/Demographics_of_the_United_States#:~:text=As%20of%202022%2C%20births%20to,%25%20and%206%25%2C%20respectively.

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Vanflyta**
Generic Name	**quizartinib**
Company	Daiichi Sankyo
Date of FDA Approval	July 20, 2023
Indication	To use as part of a treatment regimen for **newly diagnosed acute myeloid leukemia that meets certain criteria** (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	16.5%	25.0%	70	Increased	**B**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	54.5%	144	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	13.4%	1.3%	2	Similar	**D**
Asian	5.9%	29.3%	80	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	18.5%	4.1%	7	Similar	**D**

References: Phase 3 trial AC220-A-U302 QuANTUM-First ; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/216993Orig1s000MultidisciplineR.pdf pg 151; https://seer.cancer.gov/statfacts/html/amyl.html ; https://www.leukaemia.org.au/blood-cancer/leukaemia/acute-myeloid-leukaemia

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Xdemvy**
Generic Name	**lotilaner**
Company	Tarsus
Date of FDA Approval	July 25, 2023
Indication	To treat **Demodex blepharitis**

OVERALL GRADE

C

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	16.5%	62.2%	245	Increased	**B**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	52.8%	220	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	13.4%	7.4%	31	Similar	**C**
Asian	5.9%	1.3%	6	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	18.5%	7.1%	31	Similar	**C**

References: Phase 3 trials Saturn-1 TRS-009, Saturn-2 TRS-010 ; doi: 10.1097/ICL.0000000000001003
PMCID: PMC10351901 PMID: 37272680
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/217603Orig1s000MedR.pdf pgs 24, 33;
doi: 10.2147/OPTH.S354692;

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Zurzuvae**
Generic Name	**zuranolone**
Company	Sage Therapeutics
Date of FDA Approval	August 4, 2023
Indication	To treat **post-partum depression**

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	16.5%	NA	NA	Decreased	**NA**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	NA	NA	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	13.4%	30.6%	56	Increased	**B**
Asian	5.9%	1.2%	2	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	18.5%	31.4%	51	Increased	**B**

References: Phase 3 trials PPD-301, PPD-201B ; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/217369Orig2s000IntegratedR.pdf pgs 67,151; https://doi.org/10.1016/j.ajog.2022.11.248; doi: 10.1111/j.1552-6909.2012.01352.x; DOI: 10.1097/01.AOG.0000164050.34126.37; https://ifdhe.aha.org/news/news/2022-07-19-supporting-black-womens-maternal-mental-health-journey; DOI: 10.1007/s10995-008-0379-4

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Izervay**
Generic Name	**avacincaptad pegol**
Company	IVERIC BIO
Date of FDA Approval	August 4, 2023
Indication	To treat **geographic atrophy secondary to age-related macular degeneration**

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	16.5%	91.2%	263	Increased	**B**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	69.6%	199	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	13.4%	0.3%	0	Decreased	**C**
Asian	5.9%	0.3%	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	18.5%	NR	NR	Decreased	**C**

References: Phase 3 trials GATHER1, GATHER2 (OPH2003 and ISEE2008)
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/217225Orig1s000MedR.pdf pgs 26, 40
https://www.cdc.gov/visionhealth/vehss/estimates/amd-prevalence.html; DOI: 10.1016/j.ophtha.2005.12.013; DOI: 10.1016/j.ophtha.2015.12.026 DOI: 10.1016/j.ophtha.2009.10.007 DOI: 10.1016/j.ophtha.2020.04.019; https://doi.org/10.1016/j.ophtha.2020.04.019

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Talvey**
Generic Name	**talquetamab-tgvs**
Company	JANSSEN BIOTECH
Date of FDA Approval	August 9, 2023
Indication	To treat adults with **relapsed or refractory multiple myeloma who have received at least four prior therapies** (orphan)

OVERALL GRADE

C

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	16.5%	51.8%	255	Increased	**B**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	42.7%	210	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	13.4%	8.7%	43	Increased	**D**
Asian	5.9%	2.2%	11	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	18.5%	12.2%	60	Similar	**C**

References: Pivotal trial MMY1001 (MonumenTAL-1);
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/761342Orig1s000MultidisciplineR.pdf pg 249;
https://www.cancer.org/cancer/types/multiple-myeloma/causes-risks-prevention/risk-factors.html;
https://seer.cancer.gov/statfacts/html/mulmy.html

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Elrexfio**
Generic Name	**elranatamab-bcmm**
Company	Pfizer
Date of FDA Approval	August 14, 2023
Indication	To treat adults with **relapsed or refractory multiple myeloma who have received at least four prior therapies** (orphan)

OVERALL GRADE

C

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	16.5%	62.0%	116	Increased	**B**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	47.6%	89	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	13.4%	5.9%	11	Increased	**F**
Asian	5.9%	9.1%	17	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	18.5%	9.6%	18	Similar	**D**

References: Pivotal trial C1071003 MagnetisMM-3;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/761345Orig1s000MultidisciplineR.pdf pg 115-116;
https://www.cancer.org/cancer/types/multiple-myeloma/causes-risks-prevention/risk-factors.html;
https://seer.cancer.gov/statfacts/html/mulmy.html

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Sohonos**
Generic Name	**palovarotene**
Company	IPSEN INC
Date of FDA Approval	August 16, 2023
Indication	To reduce **the volume of new heterotopic ossification** in adults and pediatric patients (aged 8 years and older for females and 10 years and older for males) **with fibrodysplasia ossificans progressiva** (orphan)

OVERALL GRADE

C

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	16.5%	NA	NA	Decreased	**NA**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	50.0%	69	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	13.4%	1.0%	2	Similar	**D**
Asian	5.9%	5.0%	7	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	18.5%	16.0%	22	Similar	**C**

References: Pivotal trial PVO-1A-301,Study 301, PVO-1A-201 and PVO-1A202A/B/C Studies 201/202 ; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/215559Orig1s000IntegratedR.pdf pg 55-56; https://rarediseases.org/rare-diseases/fibrodysplasia-ossificans-progressiva/#affected; DOI: 10.1266/ggs.87.213

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Veopoz**
Generic Name	**pozelimab-bbfg**
Company	Regeneron Pharmaceuticals
Date of FDA Approval	August 18, 2023
Indication	To treat patients 1 year old and older with **CD55-deficient protein-losing enteropathy (PLE), also known as CHAPLE disease** (orphan)

OVERALL GRADE

C

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	16.5%	NA	NA	Decreased	**NA**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	60.0%	6	Unknown	**C**

Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.4%	0.0%	0	Unknown	**D**
Asian	5.9%	20.0%	2	Unknown	**B**

Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	18.5%	10.0%	1	Unknown	**D**

References: Pivotal trial Study 1878;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/761339Orig1s000MultidisciplineR.pdf pg 92;

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Aphexda**
Generic Name	**motixafortide**
Company	BIOLINERX, LTD
Date of FDA Approval	September 8, 2023
Indication	To use with filgrastim (G-CSF) to **mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with multiple myeloma** (orphan)

OVERALL GRADE

C

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	16.5%	44.0%	42	Increased	**B**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	35.8%	30	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	13.4%	9.0%	10	Increased	**F**
Asian	5.9%	1.5%	2	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	18.5%	9.7%	10	Similar	**D**

References: Phase 3 GENESIS BL-8040.SCM.301 Parts 1 and 2
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/217159Orig1s000IntegratedR.pdf pg 79
https://www.cancer.org/cancer/types/multiple-myeloma/causes-risks-prevention/risk-factors.html;
https://seer.cancer.gov/statfacts/html/mulmy.html

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Ojjaara**
Generic Name	**momelotinib**
Company	GLAXOSMITHKLINE
Date of FDA Approval	September 15, 2023
Indication	To treat **intermediate or high-risk myelofibrosis in adults with anemia** (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	16.5%	64.1%	226	Increased	**B**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	41.5%	142	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	13.4%	1.3%	4	Decreased	**C**
Asian	5.9%	8.8%	29	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	18.5%	3.3%	11	Unknown	**D**

References: Phase 3 trials SIMPLIFY-1, MOMENTUM; https://doi.org/10.1080/10428194.2021.1992756
https://www.wikidoc.org/index.php/Myelofibrosis_epidemiology_and_demographics
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/216873Orig1s000IntegratedR.pdf pgs 38,55,56

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Exxua**
Generic Name	**gepirone**
Company	Fabre-Kramer Pharmaceuticals
Date of FDA Approval	September 22 , 2023
Indication	To treat **major depressive disorder**

OVERALL GRADE

C

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	16.5%	0.7%	12	Decreased	**C**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	65.0%	>30 <300	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	13.4%	16.0%	>30 <300	Decreased	**A**
Asian	5.9%	1.5%	<30	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	18.5%	11.0%	<30	Decreased	**C**

References: Phase 3 trials 134001, FK-GBE-007; https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/021164s000lbl.pdf (data based on label and averages of 2 Phase 3 pivotal trials) ; https://www.nimh.nih.gov/health/statistics/major-depression; https://www.cdc.gov/mmwr/volumes/72/wr/mm7224a1.htm#:~:text=The%20age%2Dstandardized%20prevalence%20of%20depression%20was%20higher%20among%20women,(14.6%25)%2C%20and%20non%2D ;

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Pombiliti**
Generic Name	**cipaglucosidase alfa-atga**
Company	AMICUS THERAP US
Date of FDA Approval	September 28, 2023
Indication	To treat **late-onset Pompe disease** (orphan)

OVERALL GRADE

D

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	16.5%	11.4%	11	Decreased	**C**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	54.5%	49	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	13.4%	0.8%	0	Increased	**F**
Asian	5.9%	8.1%	5	Increased	**C**

Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	18.5%	NR	NR	Unknown	**D**

References: Phase 3 ATB200-03
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/761204Orig1s000IntegratedR.pdf pg 41
https://www.med.umich.edu/1libr/Pediatrics/Genetics/PompeDiseaseBooklet.pdf
https://www.ncbi.nlm.nih.gov/books/NBK1261/table/gsd2.T.incidence_of_pompe_disease_in_dif/
https://doi.org/10.1016/j.ymgmr.2021.100734

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Rivfloza**
Generic Name	**nedosiran**
Company	Novo Nordisk
Date of FDA Approval	September 29, 2023
Indication	To **lower urinary oxalate levels** in patients 9 years and older with primary hyperoxaluria type 1 and relatively preserved kidney function (orphan)

OVERALL GRADE

C

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	16.5%	NA	NA	Decreased	**NA**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	51.4%	12	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	13.4%	0.0%	0	Decreased	**C**
Asian	5.9%	17.1%	6	Unknown	**B**

Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	18.5%	5.7%	2	Unknown	**D**

References: Pivotal trial DCR-PHXC-201 (PHYOX2);
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/215842Orig1s000IntegratedR.pdf pg 38;
https://rarediseases.org/rare-diseases/primary-hyperoxaluria/#affected

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Velsipity**
Generic Name	**etrasimod**
Company	Pfizer
Date of FDA Approval	October 12, 2023
Indication	To treat **moderately to severely active ulcerative colitis** in adults

OVERALL GRADE

C

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	16.5%	5.9%	28	Similar	**D**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	43.6%	226	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	13.4%	1.8%	8	Decreased	**C**
Asian	5.9%	12.3%	60	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	18.5%	5.0%	21	Decreased	**C**

References: Phase 3 trials APD334-301, APD334-302;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/216956Orig1s000TOC.cfm pgs 102, 121;
https://inflammatoryboweldisease.net/types-of-ibd/ulcerative-colitis/ulcerative-colitis-statistics;
https://www.cdc.gov/mmwr/volumes/65/wr/mm6542a3.htm#T1_down;
DOI: 10.1053/j.gastro.2023.07.003; DOI: 10.1093/ibd/izab219

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Zilbrysq**
Generic Name	**zilucoplan**
Company	UCB
Date of FDA Approval	October 17, 2023
Indication	To treat **generalized myasthenia gravis in adults who are antiacetylcholine receptor (AChR) antibody positive** (orphan)

OVERALL GRADE

C

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	16.5%	27.6%	23	Increased	**C**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	56.9%	52	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	13.4%	7.5%	6	Increased	**F**
Asian	5.9%	12.1%	7	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	18.5%	6.9%	7	Unknown	**D**

References: Pivotal trial MG0010;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/216834Orig1s000TOC.cfm pg28, 40 ;
https://doi.org/10.1212/WNL.0000000000202945; doi: 10.3390/jcm10112235;
https://www.rarediseaseadvisor.com/disease-info-pages/myasthenia-gravis-epidemiology/;
https://rarediseases.org/rare-diseases/myasthenia-gravis/#affected;

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Bimzelx**
Generic Name	**bimekizumab**
Company	UCB
Date of FDA Approval	October 17, 2023
Indication	To treat **moderate to severe plaque psoriasis** in adults who are candidates for systemic therapy or phototherapy

OVERALL GRADE

C

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	16.5%	8.9%	79	Similar	**C**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	29.3%	291	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	13.4%	1.6%	19	Decreased	**C**
Asian	5.9%	12.1%	107	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	18.5%	NR	NR	Decreased	**C**

References: Phase 3 trials PS0008, PS0009 and PS0013; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/761151Orig1s000MultidisciplineR.pdf pgs 98-99; doi: 10.1001/jamadermatol.2021.2007; Alexis AF, Blackcloud P. Psoriasis in skin of color: epidemiology, genetics, clinical presentation, and treatment nuances. J Clin Aesthet Dermatol. 2014 Nov;7(11):16-24. PMID: 25489378; PMCID: PMC4255694.

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Agamree**
Generic Name	**vamorolone**
Company	SANTHERA PHARMA
Date of FDA Approval	October 26, 2023
Indication	To treat **Duchenne muscular dystrophy** (orphan)

OVERALL GRADE

D

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	16.5%	NA	NA	Decreased	**NA**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	NA	NA	Decreased	**NA**

Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.4%	1.7%	2	Decreased	**C**
Asian	5.9%	10.2%	7	Unknown	**B**

Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	18.5%	4.2%	3	Increased	**F**

References: Phase 3 trial VBP15-004;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/215239Orig1s000IntegratedR.pdf pg 29;
https://www.cdc.gov/ncbddd/musculardystrophy/data.html#:~:text=The%20estimated%20prevalence%20of%20Duchenne,males%20aged%205%2D9%20years.&text=The%20prevalence%20of%20DBMD%20among,Hispanics%20than%20Non%2DHispanic%20whites. doi: 10.1542/peds.2014-2044;

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Omvoh**
Generic Name	**mirikizumab-mrkz**
Company	ELI LILLY AND CO
Date of FDA Approval	October 26, 2023
Indication	To treat moderately to severely **active ulcerative colitis** in adults (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	16.5%	7.6%	77	Similar	**C**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	39.6%	367	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	13.4%	0.9%	10	Decreased	**C**
Asian	5.9%	22.8%	223	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	18.5%	3.4%	32	Decreased	**B**

References: Phase 3 trial AMAN ;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/761279Orig1s000MultidisciplineR.pdf pg 115
https://inflammatoryboweldisease.net/types-of-ibd/ulcerative-colitis/ulcerative-colitis-statistics;
https://www.cdc.gov/mmwr/volumes/65/wr/mm6542a3.htm#T1_down; DOI: 10.1053/j.gastro.2023.07.003; DOI: 10.1093/ibd/izab219

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Loqtorzi**
Generic Name	**toripalimab-tpzi**
Company	Coherus Biosciences Inc
Date of FDA Approval	October 27, 2023
Indication	To treat **recurrent or metastatic nasopharyngeal carcinoma** when used together with or following other therapies (orphan)

OVERALL GRADE

C

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	16.5%	5.0%	17	Increased	**F**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	16.9%	54	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	13.4%	0.0%	0	Similar	**D**
Asian	5.9%	100%	336	Increased	**A**

Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	18.5%	0.0%	0	Decreased	**C**

References: Phase 3 trials JUPITER-02, Cohort3/POLARIS-02;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/761240Orig1s000MultidisciplineR.pdf pg 108;
https://doi.org/10.1093/aje/kwk008; DOI: 10.1016/j.oraloncology.2017.08.006;
https://www.cancer.org/cancer/types/nasopharyngeal-cancer/causes-risks-prevention/risk-factors.html ;
doi: 10.1016/j.canep.2013.08.008

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Fruzaqla**
Generic Name	**FRUQUINTINIB**
Company	Takeda
Date of FDA Approval	November 8, 2023
Indication	To treat **refractory, metastatic colorectal cancer**

OVERALL GRADE

C

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	16.5%	36.4%	264	Increased	**B**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	42.3%	336	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	13.4%	1.8%	13	Increased	**F**
Asian	5.9%	43.1%	321	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	18.5%	3.1%	20	Similar	**D**

References: Phase 3 trials FRESCO, FRESCO-2;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/217564Orig1s000MultidisciplineR.pdf pgs 79-80, 94-94
https://seer.cancer.gov/statfacts/html/colorect.html

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Augtyro**
Generic Name	**repotrectinib**
Company	Bristol Myers Squibb
Date of FDA Approval	November 15, 2023
Indication	To treat ROS1-positive **non-small cell lung 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	16.5%	26.8%	34	Increased	**B**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	63.8%	81	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	13.4%	1.6%	2	Similar	**D**
Asian	5.9%	59.1%	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	18.5%	3.1%	4	Decreased	**C**

References: Phase 3 trial TPX-0005-01 TRIDENT-1;
TPX-0005-01https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/218213Orig1s000TOC.cfm pg 113,114
doi: 10.1016/j.jtocrr.2022.100374 ; doi: 10.2147/LCTT.S244366; DOI: 10.1200/OP.20.00961

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Defencath**
Generic Name	**taurolidine, heparin**
Company	CORMEDIX
Date of FDA Approval	November 15, 2023
Indication	To reduce the incidence of **catheter-related bloodstream infections**

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	16.5%	41.1%	164	Increased	**B**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	41.9%	184	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	13.4%	29.5%	126	Increased	**B**
Asian	5.9%	4.1%	15	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	18.5%	45.4%	177	Increased	**B**

References: Phase 3 trial LOCK-IT-10; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/214520Orig1s000MultidisciplineR.pdf pg 46; https://www.niddk.nih.gov/health-information/health-statistics/kidney-disease; DOI: https://doi.org/10.1016/j.ekir.2021.11.018; https://usrds-adr.niddk.nih.gov/2023/end-stage-renal-disease/1-incidence-prevalence-patient-characteristics-and-treatment-modalities

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Ryzneuta**
Generic Name	**efbemalenograstim alfa-vuxw**
Company	EVIVE BIOTECHNOLOGY
Date of FDA Approval	November 16, 2023
Indication	To treat **neutropenia**

OVERALL GRADE

C

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	16.5%	13.8%	33	Increased	**C**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	100%	280	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	13.4%	0.2%	1	Similar	**D**
Asian	5.9%	0.0%	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	18.5%	0.6%	1	Decreased	**C**

References: Phase 3 trials GC627-04, GC-627-05; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/761134Orig1s000IntegratedR.pdf pg 58; DOI: 10.2147/CEOR.S168298; https://seer.cancer.gov/statfacts/html/disparities.html

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Truqap**
Generic Name	**capivasertib**
Company	AstraZeneca
Date of FDA Approval	November 16, 2023
Indication	To treat **breast cancer** that meets certain disease criteria

OVERALL GRADE

C

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	16.5%	30.7%	115	Increased	**B**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	99.0%	352	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	13.4%	1.1%	4	Increased	**F**
Asian	5.9%	26.7%	95	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	18.5%	8.8%	31	Similar	**C**

References: Phase 3 trial CAPItello-291;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/218197Orig1s000MultidisciplineR.pdf pg 100;
https://doi.org/10.1158/1055-9965.EPI-15-0293;

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Ogsiveo**
Generic Name	**nirogacestat**
Company	SPRINGWORKS
Date of FDA Approval	November 27, 2023
Indication	To treat adults with **progressing desmoid tumors** who require systemic treatment (orphan)

OVERALL GRADE

C

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	16.5%	4.4%	4	Decreased	**C**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	66.3%	59	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	13.4%	6.9%	6	Decreased	**C**
Asian	5.9%	2.5%	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	18.5%	6.3%	1	Similar	**D**

References: Pivotal efficacy studies (150 mg) DeFi NIR-DT-301, 14-C-0007, A8641014; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/217677Orig1s000MultidisciplineR.pdf pg 208 DT pool ; https://www.cancer.net/cancer-types/desmoid-tumor/risk-factors; https://rarediseases.org/rare-diseases/desmoid-tumor/#affected; https://rarediseases.org/wp-content/uploads/2019/06/Power-of-Patients-5-Desmoid-Tumor-chapter.pdf; https://www.uptodate.com/contents/desmoid-tumors-epidemiology-molecular-pathogenesis-clinical-presentation-diagnosis-and-local-therapy

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Fabhalta**
Generic Name	**iptacopan**
Company	Novartis
Date of FDA Approval	December 5, 2023
Indication	To treat **paroxysmal nocturnal hemoglobinuria** (orphan)

OVERALL GRADE

C

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	16.5%	21.2%	21	Decreased	**B**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	61.3%	60	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	13.4%	3.6%	3	Similar	**D**
Asian	5.9%	33.6%	39	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	18.5%	8.8%	10	Similar	**D**

References: Phase 3 trials APPOINT-PNH, APPLY-PNH ;
https://rarediseases.org/rare-diseases/paroxysmal-nocturnal-hemoglobinuria/#affected;
https://www.ncbi.nlm.nih.gov/books/NBK562292/;

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Filsuvez**
Generic Name	**birch triterpenes**
Company	Amryt
Date of FDA Approval	December 18, 2023
Indication	To **treat wounds associated with dystrophic and junctional epidermolysis bullosa** (orphan)

OVERALL GRADE

C

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	16.5%	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	50.8%	40.0%	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	13.4%	1.0%	1	Similar	**D**
Asian	5.9%	5.0%	4	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	18.5%	35.0%	38	Similar	**A**

References: Phase 3 trial EASE BEB-13;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2024/215064Orig1s000MultidisciplineR.pdf pg 71;
https://rarediseases.org/rare-diseases/epidermolysis-bullosa/#affected

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Wainua**
Generic Name	**eplontersen**
Company	IONIS PHARMA INC
Date of FDA Approval	December 21 , 2023
Indication	To treat **polyneuropathy of hereditary transthyretin-mediated amyloidosis** (orphan)

OVERALL GRADE

C

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	16.5%	34.2%	43	Increased	**B**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	30.7%	43	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	13.4%	3.0%	5	Increased	**F**
Asian	5.9%	12.6%	22	Increased	**C**

Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	18.5%	14.2%	22	Similar	**C**

References: Phase 3 trial ION-682884-CS3; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2024/217388Orig1s000IntegratedR.pdf pg41s ,99; https://rarediseases.org/rare-diseases/amyloidosis/#affected; doi: 10.1038/s41408-020-00385-0; doi: 10.1161/CIRCHEARTFAILURE.115.002558; doi: 10.1002/ejhf.2646; https://www.rarediseaseadvisor.com/disease-info-pages/hereditary-transthyretin-amyloidosis-epidemiology/