CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Quviviq**
Generic Name	**daridorexant**
Company	Idorsia
Date of FDA Approval	January 7, 2022
Indication	Treatment of adult patients with **insomnia** characterized by difficulties with sleep onset and/or sleep maintenance

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%	39.0%	484	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%	69.0%	847	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%	8.0%	91	Increased	**D**
Asian	5.9%	2.0%	32	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%	10.0%	126	Similar	**C**

References: doi:10.3389/fpsyt.2020.577429; doi:10.5664/jcsm.7172; doi: 10.1016/j.socscimed.2016.02.012; doi:10.3390/brainsci9110306;
Three Phase 3 trials: ID-078A301 and ID078A302
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2022/214985Orig1s000IntegratedR.pdf {page 36)

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Cibinqo**
Generic Name	**abrocitinib**
Company	Pfizer
Date of FDA Approval	January 14, 2022
Indication	Treatment of adults with refractory, **moderate-to-severe atopic dermatitis** whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable

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%	5.5%	62	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%	46.9%	510	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%	5.4%	56	Increased	**D**
Asian	5.9%	11.7%	153	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	Similar	**D**

References: doi: 10.1111/exd.13514. PMID: 29457272. https://doi.org/10.1371/journal.pone.0258219
https://doi.org/10.1016/j.jaad.2019.06.498
Three Phase 3 trials: B7451012, B7451013 and B7451029
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2022/213871Orig1s000MultidisciplineR.pdf {page 89)

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Kimmtrak**
Generic Name	**TEBENTAFUSP-TEBN**
Company	Immunocore
Date of FDA Approval	January 25, 2022
Indication	Treatment of HLA-A*02:01-positive adult patients with unresectable or metastatic **uveal melanoma**

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%	49.5%	122	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%	49.7%	124	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%	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%	2.4%	3	Decreased	**C**

References: doi: 10.1016/S0161-6420(03)00078-2; doi: 10.1136/bjo.2008.150292; DOI: 10.1016/j.ophtha.2011.01.040; doi: 10.1038/eye.2015.51.
Phase 3 trial: IMCgp100-202
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2022/761228Orig1s000MultidisciplineR.pdf {page 99)

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Vabysmo**
Generic Name	**faricimab-svoa**
Company	Genentech
Date of FDA Approval	January 28, 2022
Indication	To treat **diabetic macular edema**

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%	42.9%	548	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%	39.7%	487	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%	6.6%	88	Increased	**D**
Asian	5.9%	9.8%	127	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%	NR	NR	Similar	**D**

References: Phase 3 trials: Yosemite, , ; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2022/215833Orig1s000MultidisciplineR.pdf (page 67, 77); doi: 10.1001/jamaophthalmol.2014.2854

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Vabysmo**
Generic Name	**faricimab-svoa**
Company	Genentech
Date of FDA Approval	January 28, 2022
Indication	To treat **Neovascular (Wet) Age-Indication 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%	59.3%	379	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%	59.7%	294	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%	2	Decreased	**C**
Asian	5.9%	9.5%	64	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	Similar	**D**

References: Phase 3 trials: GR40306 (TENAYA), GR40844 (LUCERNE);
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2022/215833Orig1s000MultidisciplineR.pdf (page 31, 39);
doi: 10.1186/s40662-016-0063-5;

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Enjaymo**
Generic Name	**sutimlimab-jome**
Company	Bioverativ USA, Sanofi
Date of FDA Approval	February 4, 2022
Indication	To decrease the need for red blood cell (RBC) transfusion due to hemolysis in adults with **cold agglutinin disease** (CAD)

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%	79.2%	19	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%	62.5%	15	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	13.4%	0.0%	0	Decreased	**C**
Asian	5.9%	12.5%	3	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	Decreased	**C**

References: https://doi.org/10.1182/blood.2020005674; https://doi.org/10.1182/blood-2013-02-474437; https://doi.org/10.1182/blood.V130.Suppl_1.928.928; Phase 3 trial: BIVV009-03 Part A (CARDINAL); https://www.accessdata.fda.gov/drugsatfda_docs/nda/2022/761164Orig1s000MedR.pdf {page 39)

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Pyrukynd**
Generic Name	**mitapivat**
Company	Agios Pharmaceuticals
Date of FDA Approval	February 17, 2022
Indication	Treatment of **hemolytic anemia in adults with pyruvate kinase (PK) deficiency**

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%	4.7%	3	Decreased	**C**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	63.6%	44	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%	0.0%	0	Similar	**D**
Asian	5.9%	10.3%	8	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%	NR	NR	Decreased	**C**

References: https://doi.org/10.1182/blood.V95.11.3585’ n Study AG-348-C-006 (Study 006) Study AG-348-C-007 (Study 007); https://www.accessdata.fda.gov/drugsatfda_docs/nda/2022/216196Orig1s000IntegratedR.pdf {page 35, 51)

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Vonjo**
Generic Name	**pacritinib**
Company	CTI Biopharma
Date of FDA Approval	February 28, 2022
Indication	Treatment of adults with intermediate or high-risk primary or secondary (postpolycythemia vera or post-essential thrombocythemia) **myelofibrosis** with a platelet count below 50,000. This indication is approved under accelerated approval based on spleen volume reduction

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%	99	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%	43.0%	63	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%	0.5%	1	Similar	**D**
Asian	5.9%	2.0%	3	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%	3.0%	3	Decreased	**C**

References: doi:10.3324/haematol.2016.149559. PMC 5210236; https://doi.org/10.1007/s00277-020-04055-w; https://doi.org/10.1016/j.hemonc.2021.01.005; doi: 10.1111/bjh.14061
Phase 3 trial: PERSIST-2
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2022/208712Orig1s000IntegratedR.pdf {page 38)

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Ztalmy**
Generic Name	**ganaxolone**
Company	Marinus
Date of FDA Approval	March 18, 2022
Indication	Treat **seizures in cyclin-dependent kinase-like 5 deficiency disorder in patients 2 years of age and older**

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%	79.2%	39	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%	NR	NR	Decreased	**C**
Asian	5.9%	5.0%	2	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%	9.9%	4	Similar	**D**

References: Phase 3 trial: 1042-CDD-3001;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2022/215904Orig1s000MedR.pdf(page 42-43);
https://rarediseases.org/rare-diseases/cdkl5/; https://doi.org/10.1186/s11689-021-09384-z;

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Opdualag**
Generic Name	**nivolumab and relatlimab-rmbw**
Company	Bristol Myers Squibb
Date of FDA Approval	March 18, 2022
Indication	To treat **unresectable or metastatic melanoma**

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%	46.4%	168	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%	41.7%	145	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%	0.7%	0	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%	6.6%	27	Decreased	**C**

References: https://www.cancer.org/cancer/melanoma-skin-cancer/about/key-statistics.html
DOI:https://doi.org/10.1016/j.jaad.2020.08.086; Phase 3 Trial: CA224047 (RELATIVITY -047);
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2022/761234Orig1s000MultidisciplineR.pdf (page 132)

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Pluvitco**
Generic Name	**lutetium (177Lu) vipivotide tetraxetan**
Company	Advanced Accelerator Applications USA, Inc.
Date of FDA Approval	March 23, 2022
Indication	To treat **prostate-specific membrane antigen-positive metastatic castration-resistant prostate cancer** following other therapies

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%	75.3%	406	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%	6.6%	34	Increased	**D**
Asian	5.9%	2.4%	9	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%	1.7%	11	Decreased	**C**

References: Phase 3 trials: PSMA-617-01;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2022/215833Orig1s000MultidisciplineR.pdf (page 98);
https://www.cancer.org/cancer/prostate-cancer/about/keystatistics.
html#:~:text=Prostate%20cancer%20is%20more%20likely,at%20diagnosis%20is%20about%2066.;
https://stacks.cdc.gov/view/cdc/94593

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Vivjoa**
Generic Name	**oteseconazole**
Company	Mycovia
Date of FDA Approval	April 26, 2022
Indication	To reduce the incidence of **recurrent vulvovaginal candidiasis** (RVVC) in females with a history of RVVC who are NOT of reproductive potential

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%	0.6%	3	Decreased	**C**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	NA	580	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%	17.1%	96	Similar	**B**
Asian	5.9%	5.9%	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%	14.8%	86	Similar	

References: Phase 3 trials: -CL-011, CL-012, CL-017; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2022/215888Orig1s000IntegratedR.pdf (page 255); doi: 10.1186/s12905-019-0748-8; https://bmcwomenshealth.biomedcentral.com/articles/10.1186/s12905-022-01741-x/tables/4

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Camzyos**
Generic Name	**mavacamten**
Company	Bristol Myers Squibb
Date of FDA Approval	April 28, 2022
Indication	To treat certain classes of **obstructive hypertrophic cardiomyopathy**

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%	33.9%	45	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%	40.6%	57	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%	2.4%	1	Increased	**F**
Asian	5.9%	2.4%	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	18.5%	4.8%	8	Similar	**D**

References: doi: 10.1155/2018/3750879; https://doi.org/10.1161/JAHA.119.014448; Phase 3 Study EXPLORER-HCM (NCT-03470545);
hhttps://www.accessdata.fda.gov/drugsatfda_docs/nda/2022/214998Orig1s000Med_StatR.pdf (page 39)

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Voquezna**
Generic Name	**vonoprazan, amoxicillin, and clarithromycin**
Company	Phathom Pharmaceuticals
Date of FDA Approval	May 3, 2022
Indication	To treat **Helicobacter pylori infection**

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%	19.9%	153	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%	62.3%	262	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%	52	Increased	**D**
Asian	5.9%	1.5% (100%)*	10 (329)*	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%	27.1%	194	Increased	**B**

References: Phase 3 trial: HP-301;*CCT-401 (Japan; all Asian); doi: 10.1086/315384 DOI: 10.1111/hel.12199;
https://wwwnc.cdc.gov/eid/article/10/6/03-0744_article
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2022/215152Orig1s000,215153Orig1s000IntegratedR.pdf (page 25)

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Mounjaro**
Generic Name	**tirzepatide**
Company	Eli Lilly
Date of FDA Approval	May 13, 2022
Indication	To improve blood sugar control in **diabetes**, in addition 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%	31.8%	1,466	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%	43.3%	2,166	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%	3.6%	186	Increased	**D**
Asian	5.9%	14.8%	792	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%	42.3%	2,041	Increased	**A**

References: Seven Phase 3 trial: (AS2); doi: 10.2147/IJGM.S226010; https://www.cdc.gov/diabetes/pdfs/library/diabetesreportcard2017-508.pdf https://www.accessdata.fda.gov/drugsatfda_docs/nda/2022/215866Orig1s000StatR.pdf(page 22)

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Vtama**
Generic Name	**tapinarof**
Company	Dermavant
Date of FDA Approval	May 23, 2022
Indication	To treat **plaque psoriasis**

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%	13.6%	99	Similar	**B**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	42.5%	282	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%	4.6%	30	Decreased	**B**
Asian	5.9%	6.9%	46	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%	14.9%	96	Decreased	**A**

References: Phase 3 trials: 3001, 3002; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2022/215272Orig1s000MultidisciplineR.pdf(page 88-89); https://doi.org/10.1038/JID.2015.378; 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	**Amvuttra**
Generic Name	**vutrisiran**
Company	Alnylam
Date of FDA Approval	June 13, 2022
Indication	Treatment of the **polyneuropathy of hereditary transthyretin-mediated** amyloidosis 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%	34.8%	46	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%	35.4%	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%	4.9%	4	Similar	**D**
Asian	5.9%	17.7%	21	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%	9.8%	12	Decreased	**C**

References: Phase 3 trials: HELIOS-A (ALN-TTRSC02-002);
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2022/215515Orig1s000MedR.pdf (page 54-55);
https://doi.org/10.1038/JID.2015.378;
DOI: 10.1590/0004-282X-ANP-2020-0590; DOI https://doi.org/10.2147/TCRM.S219979

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Xenpozyme**
Generic Name	**Olipudase alfa**
Company	Genzyme
Date of FDA Approval	August 31, 2022
Indication	To treat **Acid Sphingomyelinase Deficiency**

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%	1.8%	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%	57.1%	19	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%	7.1%	3	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%	21.4%	6	Increased	**C**

References: Phase 3 trials: DFI12712 (ASCEND) DFI13803 (ASCEND-Peds);
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2022/761261Orig1s000IntegratedR.pdf pg 38-39, 61-62, 92
https://doi.org/10.1016/j.jpeds.2006.06.034; https://rarediseases.org/rare-diseases/acid-sphingomyelinase-deficiency/;
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6122055/pdf/978-3-662-58081-3_Chapter_120.pdf;

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Spevigo**
Generic Name	**Spesolimab-sbzo**
Company	Boehringer Ingelheim Pharmaceuticals
Date of FDA Approval	September 1, 2022
Indication	To treat **generalized pustular psoriasis flares**

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%	4.0%	2	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%	68.0%	21	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%	0.0%	0	Decreased	**C**
Asian	5.9%	55.0%	16	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%	0.0%	0	Decreased	**C**

References: Phase 3 trial: Effisayil-1; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2022/761244Orig1s000MultidisciplineR.pdf pg 72; https://doi.org/10.1080/1744666X.2019.1708193; 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	**Daxxify**
Generic Name	**daxibotulinumtoixnA-lanm**
Company	Revance Therapeutics
Date of FDA Approval	September 7, 2022
Indication	To treat **moderate-to-severe glabellar lines** associated with corrugator and/or procerus muscle activity

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%	30.4%	105	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%	87.4%	354	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%	4.9%	19	Decreased	**C**
Asian	5.9%	2.6%	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%	16.6%	66	Decreased	**A**

References: Phase 3 trials: 301. 302 (GL1, GL2)
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2022/761127Orig1s000MultidisciplineR.pdf pg 49
https://doi.org/10.1111/jocd.12806; https://jddonline.com/articles/ethnicity-and-aging-skin-S1545961617S0077X/; DOI: 10.1097/DSS.0000000000002237; DOI: 10.1111/dsu.12377

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Rolvedon**
Generic Name	**eflapegrastim**
Company	Spectrum Pharmaceuticals
Date of FDA Approval	September 9, 2022
Indication	To **decrease the incidence of infection** in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with clinically significant incidence of febrile neutropenia

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%	37.8%	122	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%	99.7%	313	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%	11.8%	37	Similar	**B**
Asian	5.9%	8.4%	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%	16.6%	52	Decreased	**A**

References: Phase 3 trials: SPI-GCF-301 and SPI-GCF-302 ;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2022/761148Orig1s000MedR.pdf pp 44 ;
https://seer.cancer.gov/statfacts/html/disparities.html

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Sotyktu**
Generic Name	**deucravacitinib**
Company	Bristol Myers Squibb
Date of FDA Approval	September 9, 2022
Indication	To treat moderate-to-severe **plaque psoriasis**

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%	10.0%	80	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%	33.0%	277	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%	2.0%	10	Decreased	**C**
Asian	5.9%	10.0%	83	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: IM011046/47 (PSO-1, PSO-2); https://www.accessdata.fda.gov/drugsatfda_docs/nda/2022/214958Orig1s000MultidisciplineR.pdfhttps://doi.org/10.1038/JID.2015.378 (pg 121) ; 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	**Terlivaz**
Generic Name	**terlipressin**
Company	Mallinckrodt
Date of FDA Approval	September 14, 2022
Indication	To improve kidney function in adults with **hepatorenal syndrome** with rapid reduction in kidney function

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%	17.7%	35	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%	40.3%	79	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%	5.7%	12	Similar	**D**
Asian	5.9%	2.0%	5	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%	15.0%	32	Similar	**B**

References: Phase 3 trial:
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2022/022231Orig1s000IntegratedR.pdf pg 26, 33;
https://rarediseases.org/rarediseases/hepatorenalsyndrome/#:~:text=The%20exact%20incidence%20of%20hepatorenal,abdomen%20(ascites)%20and%20cirrhosis.10.1001/jamadermatol.2021.2007;
https://www.wikidoc.org/index.php/Hepatorenal_syndrome_epidemiology_and_demographics

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Elucirem**
Generic Name	**gadopiclenol**
Company	Guerbet
Date of FDA Approval	September 21 2022
Indication	To detect and visualize **lesions with abnormal vascularity**, together with MRI, in the central nervous system and the body

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%	34.3%	189	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%	56.8%	313	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%	2.0%	11	Similar	**D**
Asian	5.9%	11.8%	65	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%	12.5%	69	Similar	**C**

References: Phase 3 trials: GDX-44-010 GDX-44-011
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2022/216986Orig1s000MultidisciplineR.pdf pg 117. 131

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Omlonti**
Generic Name	**oomidenepag isopropyl ophthalmic solution**
Company	Santen
Date of FDA Approval	September 22, 2022
Indication	To reduce elevated intraocular pressure in patients with **open-angle glaucoma or ocular hypertension**

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%	46.6%	285	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%	55.1%	322	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%	18.8%	120	Increased	**B**
Asian	5.9%	32.2%	192	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%	NR	NR	Increased	**F**

References: Phase 3 trials: 01171505, 011710IN, and 011709IN;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2022/215092Orig1s000MedR.pdf pg 48;
DOI: 10.1001/archopht.122.4.532 ;
https://www.brightfocus.org/glaucoma/article/how-glaucoma-affects-different-ethnicgroups#:~:text=The%20prevalence%20of%20open%2Dangle,not%20know%20they%20had%20glaucoma.

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Relyvrio**
Generic Name	**sodium phenylbutyrate/taurursodiol**
Company	Amylyx Pharmaceuticals
Date of FDA Approval	September 29, 2022
Indication	To treat **amyotrophic lateral sclerosis (ALS)**

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%	23.4%	25	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%	32.1%	28	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%	2.2%	2	Decreased	**C**
Asian	5.9%	2.2%	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%	5.1%	6	Decreased	**C**

References: Phase 3 trial: NCT03127514; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2022/216660Orig1s000Med_StatR.pdf p47; https://www.als.org/understanding-als/whogetsals#:~:text=Most%20people%20who%20develop%20ALS,common%20in%20men%20than%20women. doi: 10.3109/21678421.2014.971813.; https://www.cdc.gov/mmwr/volumes/67/wr/mm6707a3.htm

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Lytgobi**
Generic Name	**futibatinib**
Company	Taiho Oncology
Date of FDA Approval	September 30, 2022
Indication	To treat intrahepatic **cholangiocarcinoma** harboring fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements

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%	22.3%	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%	56.3%	58	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%	7.8%	8	Decreased	**C**
Asian	5.9%	29.1%	30	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%	1.9%	2	Increased	**F**

References: Phase 3 trial: TAS-120-101; ;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2022/214801Orig1s000MultidisciplineR.pdf pp 99
https://www.cancer.org/cancer/bile-duct-cancer/about/key-statistics.html; DOI:10.5604/01.3001.0010.8663;
https://doi.org/10.1016/j.gastha.2021.12.003

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Imjudo**
Generic Name	**tremelimumab**
Company	AstraZeneca
Date of FDA Approval	October 21, 2022
Indication	To treat unresectable **hepatocellular 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%	50.6%	277	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%	16.3%	98	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%	1.7%	11	Increased	**F**
Asian	5.9%	50.7%	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	18.5%	5.0%	32	Increased	**D**

References: Phase 3 trial: HIMALAYA;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2022/761289Orig1s000MultidisciplineR.pdf pg 91
https://seer.cancer.gov/statfacts/html/livibd.html; https://doi.org/10.1002/hep4.1575

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Tecvayli**
Generic Name	**teclistamab-cqyv**
Company	Janssen
Date of FDA Approval	October 25, 2022
Indication	To treat **relapsed or refractory multiple myeloma** among adults who have received at least four specific lines of 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%	48.8%	78	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%	40.6%	65	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%	10.0%	16	Increased	**D**
Asian	5.9%	1.9%	3	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%	9.4%	15	Similar	**D**

References: Phase 3 trial: -MajesTEC-1, NCT03145181 [Phase 1] and NCT04557098 [Phase 2]; (Study 64007957MMY1001; Pivotal RP2D); https://www.accessdata.fda.gov/drugsatfda_docs/nda/2022/761291Orig1s000MultidisciplineR.pdf pg 184 , RP2D SC (Part 1/2+Part 3A) (n=160) https://www.cancer.org/cancer/multiple-myeloma/causes-risks-prevention/risk-factors.html; https://seer.cancer.gov/statfacts/html/mulmy.html

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Elahere**
Generic Name	**minretumomab soravtansine-gynx**
Company	ImmunoGen
Date of FDA Approval	November 14, 2022
Indication	To treat patients with **recurrent ovarian cancer** that is resistant to platinum 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%	43.0%	45	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%	100.0%	104	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%	0.0%	0	Decreased	**C**
Asian	5.9%	2.0%	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%	2.0%	2	Similar	**D**

References: Phase 3 trial: Study 0417;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2022/761310Orig1s000MultidisciplineR.pdf pg 109
https://seer.cancer.gov/statfacts/html/ovary.html; https://doi.org/10.1002/cncr.11349;
https://gis.cdc.gov/Cancer/USCS/#/Demographics/

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Tzield**
Generic Name	**teplizumab-mzwv**
Company	Provention Bio
Date of FDA Approval	November 18, 2022
Indication	To delay the onset of stage 3 **type 1 diabetes**

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%	44.7%	19	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	Decreased	**C**
Asian	5.9%	1.3%	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%	2.6%	2	Decreased	**C**

References: Phase 3 trial: Study TN-10l; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/761183Orig1s000MedR.pdf pg 69; https://doi.org/10.1136/bmj.k1497; https://doi.org/10.1186/s12916-017-0958-6; doi:10.1056/NEJMoa1610187; doi: 10.1007/s001250051573; (non-Hispanic)

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Rezlidhia**
Generic Name	**olutasidenib**
Company	Rigel Pharmaceuticals
Date of FDA Approval	December 1, 2022
Indication	To treat adults with **relapsed or refractory acute myeloid leukemia** with a susceptible isocitrate dehydrogenase-1 (IDH1) 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%	75.0%	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%	48.0%	74	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%	3.0%	5	Similar	**D**
Asian	5.9%	3.0%	5	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%	8	Similar	**D**

References: Phase 3 trial: 2102-HEM-101; https://www.leukaemia.org.au/blood-cancer/leukaemia/acute-myeloid-leukaemia/;
https://seer.cancer.gov/statfacts/html/amyl.html
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2022/215814Orig1s000MultidisciplineR.pdf pg 111;

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Krazati**
Generic Name	**adagrasib**
Company	Mirati Therapeutics
Date of FDA Approval	December 12, 2022
Indication	To treat KRAS G12C-mutated locally advanced or metastatic **non-small cell lung cancer** in adults who have received at least one prior 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%	47.0%	53	Increased	**B**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	55.0%	62	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%	8.0%	9	Similar	**D**
Asian	5.9%	4.5%	5	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%	2.7%	3	Decreased	**C**

References: Phase 3 trial: KRYSTAL-1 ; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/216340Orig1s000MultidisciplineR.pdf pg120; DOI: 10.1056/NEJMc2030638 ; Cancer Control. 2016 October ; 23(4): 338–346; although females have lower incidence of NSLC, they have increased KRAS mutations in Whites=overall similar

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Lunsumio**
Generic Name	**mosunetuzumab-axgb**
Company	Genentech
Date of FDA Approval	December 22, 2022
Indication	To treat adults with **relapsed or refractory follicular lymphoma**, a type of non-Hodgkin lymphoma

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%	33.0%	30	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%	39.0%	35	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%	4.0%	4	Decreased	**C**
Asian	5.9%	9.0%	8	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%	8.0%	7	Similar	**D**

References: Phase 3 trial: GO29781; https://seer.cancer.gov/statfacts/html/follicular.html; doi:10.1016/j.hoc.2020.02.001

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Sunlenca**
Generic Name	**lenacapavir**
Company	Gilead
Date of FDA Approval	December 22, 2022
Indication	To treat adults with **HIV** whose HIV infections cannot be successfully treated with other available treatments due to resistance, intolerance, or safety considerations

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%	75.0%	16	Decreased	**A**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	25.0%	15	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%	37.5%	21	Increased	**C**
Asian	5.9%	20.8%	14	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%	21.5%	NR	Increased	**D**

References: Phase 3 trial: CAPELLA 4625 ; https://www.gileadhiv.com/landscape/state-of-epidemic/?gclid=CjwKCAiAzKqdBhAnEiwAePEjkn-NINPZDHcdpXKfkXq9yiN1R8-XbjlFnUMnLXcLE-rY_WO966cnchoCC6EQAvD_BwE&gclsrc=aw.ds ; https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/215973s000lbl.pdf; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/215973,215974Orig1s000IntegratedR.pdf pg 29 https://www.jchs.harvard.edu/sites/default/files/jchs-housing_americas_older_adults_2014-ch2_0.pdf

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Xenoview**
Generic Name	**hyperpolarized Xe-129**
Company	Polarean
Date of FDA Approval	December 23, 2022
Indication	To evaluate **pulmonary function and imaging**

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%	44.4%	36	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%	30.9%	25	Similar	**D**

Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.4%	11.1%	9	Decreased	**B**
Asian	5.9%	1.2%	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%	1.2%	1	Decreased	**C**

References: Phase 3 trials: POL-Xe-001; POL-Xe-002;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/214375Orig1s000MultidisciplineR.pdf pg 50,58 ;
Xenoview USPI for age >65yo; DOI: 10.1183/23120541.00630-2021 ; doi:10.1016/j.rmed.2012.01.002.
https://www.lung.org/research/trends-in-lung-disease/copd-trendsbrief/copd-prevalence;
DOI: https://doi.org/10.2147/COPD.S96391

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**NexoBrid**
Generic Name	**anacaulase-bcdb**
Company	MediWound
Date of FDA Approval	December 28, 2022
Indication	To **remove eschar** in adults with deep partial thickness or full thickness **thermal burns**

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%	4.8%	6	Decreased	**C**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	25.1%	47	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%	10.0%	12	Increased	**D**
Asian	5.9%	3.0%	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%	9.1%	14	Similar	**D**

References: Phase 3 trials: 2010, 2004; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/761192Orig1s000MultidisciplineR.pdf pgs 83, 112; https://ameriburn.org/who-we-are/media/burn-incidence-fact-sheet/ ; https://www.researchgate.net/figure/Age-distribution-of-burnedpatients_fig1_269185690

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Briumvi**
Generic Name	**ublituximab-xiiy**
Company	TG Therapeutics
Date of FDA Approval	December 28, 2022
Indication	To treat relapsing forms of **multiple sclerosis**

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%	35.0%	172	Decreased	**A**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	64.1%	345	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%	1.6%	8	Increased	**F**
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%	1.7%	13	Decreased	**C**

References: Phase 3 trials: TG1101-RMS301 and TG1101-RMS302;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/761238Orig1s000MedR.pdf pg 105;
https://www.nationalmssociety.org/What-is-MS/Who-GetsMS#:~:text=Research%20has%20demonstrated%20that%20MS,people%20of%20northern%20European%20descent;
https://mymsaa.org/ms-information/overview/who-gets-ms/; 10.1212/WNL.0b013e3182918cc2;
https://learningenglish.voanews.com/a/studymajority-of-us-population-now-under-age-40-/5532061.html