CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Zelsuvmi**
Generic Name	**berdazimer**
Company	LNHC
Date of FDA Approval	01/05/2024
Indication	To treat molluscum contagiosum

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	NA	**NA**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	49.4%	445	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%	5.6%	47	Similar	**C**
Asian	5.9%	1.1%	8	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%	21.0%	195	Similar	**B**

References: Phase 3 trials NI-MC301, NI-MC302, NI-MC304 ;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2024/217424Orig1s000MultidisciplineR.pdf pg 80.
https://www.ncbi.nlm.nih.gov/books/NBK441898/;
https://www.wikidoc.org/index.php/Molluscum_contagiosum_epidemiology_and_demographics#:~:text=There%20is%20no%20racial%20predilection%20to%20molluscum%20contagiosum.

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Exblifep**
Generic Name	**cefepime, enmetazobactam**
Company	Allecra Therapeutics
Date of FDA Approval	02/22/2024
Indication	To treat **complicated urinary tract infections**

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%	38.6%	206	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%	284	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%	0.01%	1	Similar	**D**
Asian	5.9%	0.05%	4	Decreased	**C**

Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	18.5%	8.1%	40	Decreased	**C**

References: Phase 3 trial AT-301; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2024/216165Orig1s000IntegratedR.pdf pg28; https://www.ncbi.nlm.nih.gov/books/NBK436013/; https://doi.org/10.1016/j.ajic.2021.05.013; https://doi.org/10.1093/ofid/ofab591 https://doi.org/10.1093/ofid/ofz446; Incidence is higher in women <55yo and lower in women >65yo

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Clinical Trial Demographic Scorecard

Drug	
Tradename	**Letybo**
Generic Name	**letibotulinumtoxinA-wlbg**
Company	Hugel Inc
Date of FDA Approval	02/29/2024
Indication	To temporarily **improve the appearance of moderate-tosevere glabellar lines**

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%	12.0%	118	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%	91.3%	881	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%	6.8%	61	Decreased	**B**
Asian	5.9%	1.4%	13	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%	12.7%	124	Decreased	**B**

References: Phase 3 trials BLESS I,II,III;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2024/761225Orig1s000MultidisciplineR.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

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Clinical Trial Demographic Scorecard

Drug	
Tradename	**Tevimbra**
Generic Name	**tislelizumab-jsgr**
Company	BeiGene
Date of FDA Approval	03/13/2024
Indication	To treat **unresectable or metastatic esophageal squamous cell carcinoma (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%	37.9%	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%	15.6%	39	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%	0.4%	0	Increased	**F**
Asian	5.9%	79.7%	201	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%	0.8%	2	Decreased	**C**

References: Phase 3 trial RATIONALE-302, BGB-A317-302; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2024/761232Orig1s000MultidisciplineR.pdf pg 91; doi: 10.1155/2017/1204082; https://www.cancer.org/cancer/types/esophagus-cancer/about/key-statistics.html; DOI: 10.14309/ajg.0000000000002606

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Clinical Trial Demographic Scorecard

Drug	
Tradename	**Rezdiffra**
Generic Name	**resmetirom**
Company	Madrigal
Date of FDA Approval	03/14/2024
Indication	To treat **noncirrhotic nonalcoholic steatohepatitis with moderate to advanced liver scarring**

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%	25.7%	149	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%	56.0%	366	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%	2.1%	10	Decreased	**C**
Asian	5.9%	2.9%	17	Increased	**F**

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%	20.9%	140	Increased	**C**

References: Phase 3 trial MGL-3196-11; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2024/217785Orig1s000IntegratedR.pdf pg 53; https://doi.org/10.1210/jendso/bvac150.049; https://doi.org/10.1016/j.aohep.2022.100727; doi: 10.3390/nu14214556; doi: 10.1002/hep4.1981; https://liverfoundation.org/liver-diseases/fatty-liver-disease/nonalcoholic-steatohepatitis-nash/nash-causesrisk-factors/ Incidence in Females vs. Males varies by age >50

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Clinical Trial Demographic Scorecard

Drug	
Tradename	**Tryvio**
Generic Name	**aprocitentan**
Company	Idorsia Pharmaceuticals
Date of FDA Approval	03/19/2024
Indication	To treat **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%	44.0%	207	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%	40.5%	197	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%	11.2%	56	Increased	**C**
Asian	5.9%	5.2%	25	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%	10.0%	50	Similar	**C**

References: Phase 3 trial PRECISION;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2024/217686Orig1s000IntegratedR.pdf pg 32; NO PMR or PMC.
https://www.cdc.gov/bloodpressure/facts.htm#:~:text=Rates%20of%20High%20Blood%20Pressure%20Control%20Vary%20by%20Sex%20and%20Race&text=A%20greater%20percentage%20of%20men,pressure%20than%20women%20(44%25).&text=High%20blood%20pressure%20is%20more,or%20Hispanic%20adults%20(39%25);
https://www.cdc.gov/nchs/products/databriefs/db364.htm

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Clinical Trial Demographic Scorecard

Drug	
Tradename	**Duvyzat**
Generic Name	**givinostat**
Company	ITALFARMACO SPA
Date of FDA Approval	03/21/2024
Indication	To treat **Duchenne muscular dystrophy in individuals aged 6 years and older (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	NA	**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	NA	**NA**

Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.4%	1.7%	3	Decreased	**C**
Asian	5.9%	3.4%	4	Unknown	**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%	6.7%	9	Increased	**F**

References: Phase 3 trial Study 48 ; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2024/217865Orig1s000IntegratedR.pdf pg 53; No PMR or PMC 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;

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Clinical Trial Demographic Scorecard

Drug	
Tradename	**Winrevair**
Generic Name	**sotatercept-csrk**
Company	MERCK SHARP DOHME
Date of FDA Approval	03/26/2024
Indication	To treat **pulmonary arterial hypertension (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%	17.0%	42	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%	81.1%	195	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%	2.6%	6	Similar	**D**
Asian	5.9%	1.6%	1	Similar	**D**

Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	18.5%	21.0%	49	Similar	**B**

References: Phase 2b/3 trials STELLAR (MK-7962-003) PULSAR (MK-7962-001); https://www.accessdata.fda.gov/drugsatfda_docs/nda/2024/761363Orig1s000IntegratedR.pdf pgs 35,46,47 ; No PMR or PMC; DOI: 10.1378/chest.09-1140; doi: 10.1177/2045893217732213; https://rarediseases.org/rare-diseases/pulmonary-arterialhypertension/#affected

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Clinical Trial Demographic Scorecard

Drug	
Tradename	**Vafseo**
Generic Name	**vadadustat**
Company	Akebia
Date of FDA Approval	03/27/2024
Indication	To treat **anemia due to chronic kidney disease**

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%	59.1%	1030	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%	55.7%	943	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%	16.8%	281	Increased	**C**
Asian	5.9%	5.8%	110	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%	32.4%	561	Increased	**A**

References: Phase 3 trials INNO2VATE-1 and INNO2VATE-2, AKB-6548-CI-0014 and AKB-6548-CI-0015; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2024/215192Orig1s000IntegratedR.pdf pg 70 ; NO PMR or PMC. https://www.niddk.nih.gov/health-information/health-statistics/kidney-disease; doi:10.1053/j.semvascsurg.2021.02.010

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Clinical Trial Demographic Scorecard

Drug	
Tradename	**Voydeya**
Generic Name	**danicopan**
Company	Alexion
Date of FDA Approval	03/29/2024
Indication	To treat **extravascular hemolysis with 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%	25.6%	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%	62.8%	34	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%	2.3%	2	Similar	**D**
Asian	5.9%	37.2%	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%	8.1%	6	Similar	**D**

References: Phase 3 trial ALXN2040-PNH-301
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2024/218037Orig1s000IntegratedR.pdf pg 39 ; No PMR or PMC;
https://rarediseases.org/rare-diseases/paroxysmal-nocturnal-hemoglobinuria/#affected;
https://www.ncbi.nlm.nih.gov/books/NBK562292/

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Clinical Trial Demographic Scorecard

Drug	
Tradename	**Zevtera**
Generic Name	**ceftobiprole medocaril sodium**
Company	BASILEA PHARM
Date of FDA Approval	4/3/2024
Indication	To treat **certain bloodstream infections, bacterial skin and associated tissue infections, and community-acquired bacterial pneumonia**

OVERALL GRADE

B

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	26.5%	210	Increased	**B**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	39.4%	333	Similar	**A**

Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	3.5%	29	Increased	**F**
Asian	6.3%	8.3%	69	Decreased	**A**

Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	23.7%	189	Similar	**B**

References: Pivotal trials BPR-CS-008, BPR-CS-009; No PMC or PMR; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2024/218275Orig1s000IntegratedR.pdf pgs 66,83,98; doi: 10.2105/AJPH.2009.181313; https://www.ncbi.nlm.nih.gov/books/NBK430749/; doi: 10.1007/s12325-020-01248-7; doi: 10.1186/1471-2334-13-252; doi: 10.1186/1471-2334-13-252; doi: 10.1164/rccm.200703-480OC

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Clinical Trial Demographic Scorecard

Drug	
Tradename	**Lumisight**
Generic Name	**pegulicianine**
Company	LUMICELL
Date of FDA Approval	4/17/2024
Indication	To use as an **optical imaging agent for the detection of cancerous tissue in breast cancer**

OVERALL GRADE

B

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	44%	348	Increased	**A**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	100%	744	Increased	**NA**

Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	8%	67	Similar	**C**
Asian	6.3%	6%	44	Decreased	**A**

Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	3%	21	Decreased	**C**

References: Pivotal trials CL007, CL0006;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2024/214511Orig1s000MultidisciplineR.pdf pgs 68,83,88;
No PMR or PMC; https://seer.cancer.gov/statfacts/html/breast.html; https://gis.cdc.gov/Cancer/USCS/#/Demographics/

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Clinical Trial Demographic Scorecard

Drug	
Tradename	**Anktiva**
Generic Name	**nogapendekin alfa inbakicept-pmln**
Company	ALTOR BIOSCIENCE
Date of FDA Approval	4/22/2024
Indication	To treat **bladder 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	17.3%	80%	142	Increased	**B**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	20%	36	Decreased	**B**

Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	5%	9	Decreased	**C**
Asian	6.3%	2%	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	19.1%	3%	6	Decreased	**C**

References: Pivotal trial QUILT-3.032;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2024/761336Orig1s000MultidisciplineR.pdf pg 92;
No PMC or PMR; https://seer.cancer.gov/statfacts/html/urinb.html; DOI: 10.1038/s41598-018-29987-2

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Clinical Trial Demographic Scorecard

Drug	
Tradename	**Ojemda**
Generic Name	**tovorafenib**
Company	DAY ONE BIOPHARMS
Date of FDA Approval	4/23/2024
Indication	To treat **relapsed or refractory pediatric low-grade glioma (orphan)**

OVERALL GRADE

B

Age

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

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	46.7%	64	Similar	**B**

Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	2.2%	3	Decreased	**C**
Asian	6.3%	7.3%	10	Decreased	**B**

Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	2.9%	4	Decreased	**C**

References: Pivotal trial FIREFLY-1; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2024/217700Orig1s000,%20218033Orig1s000MultidisciplineR.pdf pg 131-132; No PMC or PMR; doi: 10.1093/noajnl/vdaa089; https://seer.cancer.gov/statfacts/html/childbrain.html

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Clinical Trial Demographic Scorecard

Drug	
Tradename	**XOLREMDI**
Generic Name	**mavorixafor**
Company	X4 PHARMS
Date of FDA Approval	4/26/2024
Indication	To treat **WHIM syndrome (warts, hypogammaglobulinemia, infections and myelokathexis) (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	17.3%	6.5%	0	Decreased	**C**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	58.1%	9	Similar	**C**

Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	0%	0	Decreased	**C**
Asian	6.3%	3.2%	0	Increased	**F**

Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	3.2%	1	Decreased	**C**

References: Pivotal trial X4P-001-103https://www.accessdata.fda.gov/drugsatfda_docs/nda/2024/218709Orig1s000IntegratedR.pdf pg 40; No PMC or PMR; doi: 10.1007/s10875-022-01312-7; https://rarediseases.org/rare-diseases/whim-syndrome/#affected

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Clinical Trial Demographic Scorecard

Drug	
Tradename	**Imdelltra**
Generic Name	**tarlatamab-dlle**
Company	Amgen
Date of FDA Approval	5/16/2024
Indication	To treat **extensive stage small cell lung cancer (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	17.3%	48.5%	48	Increased	**B**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	28.3%	28	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	13.6%	0%	0	Decreased	**C**
Asian	6.3%	41.4%	41	Decreased	**A**

Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	1.0%	1	Decreased	**C**

References: Pivotal trial 20200491 (DeLLphi-301); https://www.accessdata.fda.gov/drugsatfda_docs/nda/2024/761344Orig1s000MultidisciplineR.pdf PG 134 ; PMC for racial and ethnic minorities; https://www.ncbi.nlm.nih.gov/books/NBK482458/; https://ascopubs.org/doi/10.1200/JCO.2023.41.16_suppl.e20641; https://doi.org/10.1016/j.ejca.2023.112985

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Clinical Trial Demographic Scorecard

Drug	
Tradename	**Rytelo**
Generic Name	**imetelstat**
Company	Geron
Date of FDA Approval	6/6/2024
Indication	To treat **low- to intermediate-1 risk myelodysplastic syndromes (orphan)**

OVERALL GRADE

B

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	79.8%	91	Increased	**B**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	37.6%	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	13.6%	1.7%	1	Decreased	**C**
Asian	6.3%	5.6%	8	Decreased	**B**

Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	6.2%	6	Decreased	**C**

References: Phase 3 Pivotal trial MDS3001 IMerge;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2024/217779Orig1s000MultidisciplineR.pdf PG 123-124 ;
No PMC or PMR; https://acsjournals.onlinelibrary.wiley.com/doi/pdf/10.1002/cncr.22570;
https://doi.org/10.1182/blood-2008-01-134858; https://seer.cancer.gov

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Iqirvo**
Generic Name	**elafibranor**
Company	IPSEN BIOPHARM LTD
Date of FDA Approval	6/10/2024
Indication	To treat **primary biliary cholangitis in combination with ursodeoxycholic acid (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	17.3%	21.7%	25	Increased	**D**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	95.7%	102	Increased	**B**

Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	1.2%	2	Decreased	**C**
Asian	6.3%	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	19.1%	NR	NR	Decreased	**C**

References: Pivotal Phase 3 trial GFT505B-319-1; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2024/218860Orig1s000IntegratedR.pdf pg 45; doi: 10.1097/HC9.0000000000000179; https://www.rarediseaseadvisor.com/disease-info-pages/primary-biliary-cholangitis-epidemiology/; No PMR or PMC

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Sofdra**
Generic Name	**sofpironium**
Company	BOTANIX SB
Date of FDA Approval	6/18/2024
Indication	To treat **primary axillary hyperhidrosis**

OVERALL GRADE

B

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	1.3%	4	Decreased	**C**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	55.9%	190	Similar	**B**

Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	20.0%	63	Similar	**A**
Asian	6.3%	1.3%	5	Increased	**F**

Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	30.5%	109	Similar	**A**

References: Pivotal trialsBBI-4000-CL-301 Cardigan I, BBI-4000-CL-302 Cardigan II; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2024/217347Orig1s000MultidisciplineR.pdf pg 91; No PMR or PMC; https://sweathelp.org/pdf/Strutton_2004.pdf; https://emedicine.medscape.com/article/1073359-overview ; doi: 10.1007/s00403-016-1697-9

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Piasky**
Generic Name	**crovalimab-akkz**
Company	Genentech
Date of FDA Approval	6/20/2024
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	17.3%	10.8%	13	Decreased	**C**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	45.1%	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	13.6%	2.0%	3	Similar	**D**
Asian	6.3%	67.2%	86	Increased	**B**

Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	11.8%	18	Similar	**D**

References: Pivotal Phase 3 trial COMMODORE 2, BO42162;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2024/761388Orig1s000IntegratedR.pdf pg 47; No PMR or PMC;
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	**Ohtuvayre**
Generic Name	**ensifentrine**
Company	VERONA PHARMA
Date of FDA Approval	6/26/2024
Indication	To treat **chronic obstructive pulmonary 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	17.3%	54.9%	534	Increased	**A**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	46.9%	548	Increased	**B**

Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	3.9%	40	Decreased	**B**
Asian	6.3%	1.7%	14	Decreased	**C**

Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	3.9%	41	Decreased	**B**

References: Pivotal Phase 3 trials RPL554-CO-301 (Trial 301) ENHANCE-1, RPL554-CO-302 (Trial 302) ENHANCE-2; ; No PMR or PMC; doi: 10.2147/COPD.S96391; https://healthequitytracker.org/exploredata?mls=1.copd-3.00&demo=sex; https://www.lung.org/research/trends-in-lung-disease/copd-trends-brief/data-tables/trends-copd-race-ethnicity-sex-age;

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Kisunla**
Generic Name	**donanemab-azbt**
Company	Eli Lilly
Date of FDA Approval	7/2/2024
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	17.3%	89.9%	772	Increased	**A**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	57.4%	493	Increased	**B**

Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	2.3%	19	Increased	**F**
Asian	6.3%	6.0%	57	Similar	**B**

Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	4.1%	35	Increased	**D**

References: Pivotal Phase 3 trial AACI (I5T-MC-AACI);
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2024/761248Orig1s000MedR.pdf pg 42;
https://www.brightfocus.org/alzheimers/article/why-does-alzheimers-disease-affect-more-women-men;
doi:10.1001/jama.2022.3550 ; No PMR or PMC

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Leqselvi**
Generic Name	**deuruxolitinib**
Company	SUN PHARM
Date of FDA Approval	7/25/2024
Indication	To treat **severe 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	17.3%	0.3%	6	Decreased	**C**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	64.3%	556	Increased	**B**

Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	9.6%	91	Increased	**C**
Asian	6.3%	5.6%	51	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	19.1%	7.9%	75	Increased	**D**

References: Pivotal Phase 3 trials CP543.3001/3002;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2024/217900Orig1s000MultidisciplineR.pdf pg 105, 128;
https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/217900Orig1s000correctedlbl.pdf;
doi:10.1001/jamadermatol.2023.0016; doi: 10.1159/000510880 ; No PMR or PMC

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**VORANIGO**
Generic Name	**vorasidenib**
Company	SERVIER
Date of FDA Approval	8/6/2024
Indication	To treat **Grade 2 astrocytoma or oligodendroglioma (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	17.3%	0.9%	2	Similar	**D**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	43.5%	67	Decreased	**A**

Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	0.9%	2	Decreased	**C**
Asian	6.3%	3.9%	5	Decreased	**C**

Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	5.4%	9	Decreased	**C**

References: Pivotal Phase 3 trial AG881-C-004 (INDIGO; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2024/218784Orig1s000MultidisciplineR.pdf pg 152; doi:10.1001/jamaoncol.2018.1789; No PMR or PMC

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Yorvipath**
Generic Name	**palopegteriparatide**
Company	ASCENDIS PHARMA BONE
Date of FDA Approval	8/9/2024
Indication	To treat **hypoparathyroidism (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	17.3%	12.2%	8	Increased	**D**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	78.0%	46	Increased	**B**

Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	0%	0	Unknown	**D**
Asian	6.3%	6.1%	3	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	19.1%	0%	0	Unknown	**D**

References: Pivotal Phase 3 trial TCP-304 ;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2024/216490Orig1s000MultidisciplineR.pdf pg 39;
doi: 10.3389/fendo.2016.00172;
https://doi.org/10.1002/jbmr.2004; No PMR or PMC

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Nemluvio**
Generic Name	**nemolizumab-ilto**
Company	GALDERMA
Date of FDA Approval	8/12/2024
Indication	To treat **prurigo nodularis**

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	17.3%	25.3%	100	Increased	**B**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	59.5%	223	Increased	**C**

Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	7.1%	23	Increased	**F**
Asian	6.3%	8.7%	33	Decreased	**A**

Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	3.7%	9	Decreased	**C**

References: Pivotal Phase 3 trials (OLYMPIA 1 [RD.06.SPR.202685] and OLYMPIA 2 [RD.06.SPR.203065]); https://emedicine.medscape.com/article/1088032-overview#a6 ; https://doi.org/10.1016/j.jaad.2020.04.183; https://doi.org/10.1111/bjd.21843; doi: 10.1016/j.jaad.2018.04.047; https://www.jaad.org/article/S0190-9622(23)01265-3/pdf; No PMR or PMC

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Livdelzi**
Generic Name	**seladelpar**
Company	Gilead Sciences
Date of FDA Approval	8/14/2024
Indication	To treat **primary biliary cholangitis (orphan)**

OVERALL GRADE

B

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	21.2%	29	Increased	**D**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	94.8%	123	Increased	**B**

Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	2.1%	2	Decreased	**C**
Asian	6.3%	5.7%	7	Decreased	**B**

Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	29.0%	29	Decreased	**A**

References: Pivotal Phase 3 trial CB8025-32048 (RESPONSE) https://www.accessdata.fda.gov/drugsatfda_docs/nda/2024/217899Orig1s000IntegratedR.pdf pg 36-37; https://doi.org/10.1016/j.jhepr.2024.101132; DOI: 10.1016/j.cgh.2017.12.033; DOI: 10.1097/HC9.0000000000000179; No PMR or PMC

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Niktimvo**
Generic Name	**axatilimab-csfr**
Company	Incyte
Date of FDA Approval	8/14/2024
Indication	To treat **chronic graft-versus-host 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	17.3%	23.2%	56	Similar	**A**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	37.3%	90	Decreased	**A**

Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	2.1%	5	Similar	**D**
Asian	6.3%	6.6%	16	Similar	**C**

Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	7.9%	19	Similar	**D**

References: Pivotal trial AGAVE-201, SNDX-6352-0504; No PMR or PMC
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2024/761411Orig1s000MultidisciplineR.pdf pg 77-78.
https://bethematchclinical.org/medical-education-and-research/browse-research/socioeconomic-status-but-not-race-and-ethnicity-is-likely-associated-with-chronic-gvhd-outcomes-after-allogeneic-hct/;
doi: 10.1371/journal.pone.0282753; doi: 10.1016/j.jtct.2021.10.002; https://doi.org/10.3389/fonc.2022.801879

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Lazcluze**
Generic Name	**lazertinib**
Company	Janssen
Date of FDA Approval	8/19/2024
Indication	To treat **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	17.3%	45.0%	291	Increased	**B**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	61.6%	411	Increased	**B**

Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	1.0%	8	Decreased	**C**
Asian	6.3%	58.6%	378	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	19.1%	11.6%	80	Similar	**C**

References: Pivotal Phase 3 trial MARIPOSA; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2024/219008Orig1s000MultidisciplineR.pdf pg 147-148; DOI: 10.1200/OP.20.00961; https://doi.org/10.1200/JCO.2005.08.043; https://seer.cancer.gov/statfacts/html/lungb.html; https://doi.org/10.1097/JTO.0b013e3181f38816; DOI: 10.1016/j.jtho.2021.01.751; doi:10.1001/jamaoncol.2016.6108; PMC for Black representation

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Ebglyss**
Generic Name	**lebrikizumab-lbkz**
Company	ELI LILLY
Date of FDA Approval	9/13/2024
Indication	To treat **moderate-to-severe atopic dermatitis**

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	17.3%	7.9%	59	Increased	**D**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	49.7%	347	Similar	**A**

Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	10.5%	77	Increased	**C**
Asian	6.3%	21.0%	135	Increased	**B**

Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	12.8%	88	Similar	**C**

References: Pivotal Phase 3 trials ADvocate 1 (KGAB), ADvocate 2 (KGAC) and Adhere (KGAD); https://www.accessdata.fda.gov/drugsatfda_docs/nda/2024/761306Orig1s000MultidisciplineR.pdf pgs 105-107,118-120; 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; No PMR or PMC

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Miplyffa**
Generic Name	**arimoclomol**
Company	ZEVRA DENMARK
Date of FDA Approval	9/20/2024
Indication	To treat **Niemann-Pick disease type C (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	17.3%	NA	NA	NA	**NA**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	52.0%	26	Similar	**C**

Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	0%	0	Similar	**D**
Asian	6.3%	4.0%	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	19.1%	4.0%	2	Increased	**F**

References: Pivotal trials NPC-002; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2024/214927Orig1s000IntegratedR.pdf pg 43; https://rarediseases.org/rare-diseases/niemann-pick-disease-type-c/#affected; https://myriad.com/womens-health/diseases/niemannpick-disease-type-c1/; No PMR or PMC

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Aqneursa**
Generic Name	**levacetylleucine**
Company	INTRABIO
Date of FDA Approval	9/24/2024
Indication	To treat **Niemann-Pick disease type C (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	17.3%	NA	NA	NA	**NA**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	39.8%	37	Similar	**B**

Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	0%	0	Similar	**D**
Asian	6.3%	4.3%	4	Similar	**D**

Ethnicity

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

References: Pivotal trials IB1001-301 and l IB1001-201; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2024/219132Orig1s000IntegratedR.pdf pgs 33, 46-47; https://rarediseases.org/rare-diseases/niemann-pick-disease-type-c/#affected; https://myriad.com/womens-health/diseases/niemannpick-disease-type-c1/; No PMR or PMC

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Cobenfy**
Generic Name	**xanomeline and trospium chloride**
Company	BRISTOL-MYERS
Date of FDA Approval	9/26/2024
Indication	To treat **schizophrenia**

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	17.3%	0.4%	1	Decreased	**C**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	25.1%	65	Decreased	**B**

Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	67.9%	163	Increased	**B**
Asian	6.3%	0.6%	3	Increased	**F**

Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	10.9%	29	Increased	**F**

References: Pivotal trials KAR-007 and KAR-009; PMID: 36617355; DOI: 10.1016/j.psychres.2018.05.043; doi: 10.1016/j.biopsych.2005.04.034; PMID: 36846217; doi:10.1001/archpsyc.60.6.565; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2024/216158Orig1s000IntegratedR.pdf pg 27; No PMR or PMC

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Flyrcado**
Generic Name	**flurpiridaz F 18**
Company	GE Healthcare
Date of FDA Approval	9/27/2024
Indication	A **radioactive diagnostic drug to evaluate for myocardial ischemia and infarction**

OVERALL GRADE

B

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	45.0%	629	Increased	**A**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	31.8%	455	Decreased	**A**

Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	10.6%	148	Increased	**C**
Asian	6.3%	1.1%	16	Decreased	**C**

Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	9.4%	131	Decreased	**B**

References: Pivotal trials BMS747158-301, GE-265-303 ; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2024/215168Orig1s000MultidisciplineR.pdfm pgs 116-117, 135; PMID: 34769805 ; https://doi.org/10.1016/j.atherosclerosis.2022.03.003 ; No PMR or PMC

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Itovebi**
Generic Name	**inavolisib**
Company	GENENTECH
Date of FDA Approval	10/10/2024
Indication	To treat **locally advanced or metastatic breast 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	17.3%	14.5%	19	Increased	**D**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	98.2%	156	Increased	**NA**

Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	0.6%	1	Decreased	**C**
Asian	6.3%	38.2%	61	Decreased	**A**

Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	6.2%	10	Decreased	**C**

References: Phase 3 Pivotal trial WO41554 (INAVO120); https://seer.cancer.gov/statfacts/html/breast-subtypes.html; PMID: 36895447;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2024/219249Orig1s000MultidisciplineR.pdf pg 104 ;
PMC for race, ethnicity and >65yo

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Hympavzi**
Generic Name	**marstacimab-hncq**
Company	Pfizer
Date of FDA Approval	10/11/2024
Indication	To prevent or reduce bleeding episodes related to **hemophilia A or B (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	17.3%	0.9%	1	Decreased	**C**

Sex

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

Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	0.9%	1	Decreased	**C**
Asian	6.3%	50.0%	58	Decreased	**A**

Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	10.3%	12	Similar	**D**

References: Phase 3 Pivotal trial BASIS study B7841005; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2024/761369Orig1s000IntegratedR.pdf pg 198; DOI: 10.1111/hae.13998 ; DOI: 10.1182/asheducation-2010.1.191; No PMR or PMC

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Vyloy**
Generic Name	**zolbetuximab-clzb**
Company	Astellas
Date of FDA Approval	10/18/2024
Indication	To treat **gastric or gastroesophageal junction adenocarcinoma (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	17.3%	32.9%	179	Increased	**B**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	37.8%	199	Decreased	**A**

Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	0.6%	5	Increased	**F**
Asian	6.3%	47.5%	253	Increased	**B**

Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	8.4%	46	Increased	**D**

References: Phase 3 Pivotal trials SPOTLIGHT, GLOW; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2024/761365Orig1s000MultidisciplineR.pdf pg ag 186; https://www.cancer.org/cancer/types/stomach-cancer/about/key-statistics.html; PMID: 35785449; https://seer.cancer.gov/statfacts/html/stomach.html; PMC for underrepresented racial and ethnic minority populations

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Orlynvah**
Generic Name	**sulopenem etzadroxil, probenecid**
Company	ITERUM THERAPEUTICS
Date of FDA Approval	10/25/2024
Indication	To treat **uncomplicated urinary tract infections (uUTI)**

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	17.3%	23.0%	442	Increased	**A**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	100%	1,932	Increased	**A**

Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	14.3%	268	Similar	**B**
Asian	6.3%	1.3%	30	Similar	**C**

Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	53.0%	1,032	Similar	**A**

References: Phase 3 Pivotal trials 301 and 310; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2024/213972Orig1s000IntegratedR.pdf pg 55, doi: 10.1177/1756287219832172; https://www.ncbi.nlm.nih.gov/books/NBK470195/; No PMC or PMR

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Revuforj**
Generic Name	**revumenib**
Company	Syndax
Date of FDA Approval	11/15/2024
Indication	To treat **relapsed or refractory acute leukemia (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	17.3%	13.5%	14	Similar	**C**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	64.4%	67	Similar	**B**

Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	7.7%	8	Similar	**D**
Asian	6.3%	9.6%	10	Similar	**B**

Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	22.1%	23	Similar	**C**

References: Phase 3 Pivotal trial AUGMENT-101 (SNDX-5613-0700); https://www.accessdata.fda.gov/drugsatfda_docs/nda/2024/218944Orig1s000MultidisciplineR.pdf pg 23, 145; https://seer.cancer.gov/statfacts/html/alyl.html; https://seer.cancer.gov/statfacts/html/amyl.html; No PMC or PMR

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Ziihera**
Generic Name	**ZANIDATAMAB-HRII**
Company	Jazz Pharmaceuticals
Date of FDA Approval	11/20/2024
Indication	To treat **unresectable or metastatic HER2-positive (IHC 3+) biliary tract cancer (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	17.3%	48.8%	39	Increased	**B**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	56.3%	45	Similar	**B**

Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	0%	0	Similar	**D**
Asian	6.3%	65.0%	53	Increased	**B**

Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	6.3%	5	Increased	**F**

References: Phase 3 Pivotal trial ZWI-ZW25-203; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2024/761416Orig1s000MultidisciplineR.pdf pg 73; PMID: 23504585; https://seer.cancer.gov/statfacts/html/livibd.html; PMC for underrepresented racial and ethnic minority populations

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Attruby**
Generic Name	**acoramidis**
Company	BRIDGEBIO PHARMA
Date of FDA Approval	11/22/2024
Indication	To treat **cardiomyopathy of wild-type or variant 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	17.3%	96.7%	409	Increased	**A**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	9.2%	35	Decreased	**B**

Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	4.8%	19	Increased	**F**
Asian	6.3%	2.1%	10	Similar	**D**

Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	1.8%	7	Similar	**D**

References: Phase 3 trial AG10-301 ATTR-CM; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2024/216540Orig1s000IntegratedR.pdf pgs ,38,91, https://doi.org/10.1016/j.jaccao.2024.05.001; https://doi.org/10.1007/s12170-021-00670-y; doi: 10.1161/CIRCHEARTFAILURE.115.002558; doi: 10.1002/ejhf.2646; https://www.rarediseaseadvisor.com/disease-infopages/hereditary-transthyretin-amyloidosis-epidemiology/; No PMC or PMR

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Iomervu**
Generic Name	**iomeprol**
Company	BRACCO
Date of FDA Approval	11/27/2024
Indication	For use as a **radiographic contrast agent**

OVERALL GRADE

B

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	41.1%	1,976	Increased	**A**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	34.1%	1,636	Decreased	**A**

Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	1.1%	54	Similar	**C**
Asian	6.3%	9.2%	442	Decreased	**A**

Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	0.5%	26	Similar	**D**

References: Phase 3 trials IOM-104 A, C,D,E and publications;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2024/216016Orig1s000,216017Orig1s000MultidisciplineR.pdf pg 131; PMID:https://doi.org/10.1016/j.cpcardiol.2024.102645; doi:10.1001/jamacardio.2021.5613; No PMC or PMR

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Bizengri**
Generic Name	**zenocutuzumab-zbco**
Company	Merus N.V.
Date of FDA Approval	12/04/2024
Indication	To treat **non-small cell lung cancer and pancreatic adenocarcinoma (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	17.3%	36.4%	47	Increased	**B**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	59.7%	77	Similar	**B**

Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	1.6%	2	Similar	**D**
Asian	6.3%	36.4%	47	Increased	**B**

Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	2.3%	3	Decreased	**C**

References: Pivotal trial eNRGy study MCLA-128-CL01 ; No PMC or PMR https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/761352Orig1s000MultidisciplineR.pdf pg. 139; doi: 10.4143/crt.2023.682; https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/cancer-facts-andfigures-for-african-americans/cancer-facts-and-figures-for-african-americans-2019-2021.pdf; https://seer.cancer.gov/statfacts/html/pancreas.html; https://seer.cancer.gov/statfacts/html/lungb.html

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Crenessity**
Generic Name	**crinecerfont**
Company	NEUROCRINE
Date of FDA Approval	12/13/2024
Indication	To treat **classic congenital adrenal hyperplasia (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	17.3%	NA	NA	NA	**NA**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	49.1%	95	Increased	**C**

Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	1.8%	5	Decreased	**C**
Asian	6.3%	4.9%	12	Increased	**D**

Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	8.8%	14	Similar	**D**

References: Phase 3 Pivotal trials NBI-74788-CAH3003, NBI-74788-CAH2006 ; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/218808Orig1s000,%20218820Orig1s000IntegratedR.pdf pgs 44, 60-61 ; https://doi.org/10.1159/000526401; PMID: 36891552; No PMC or PMR

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Unloxcyt**
Generic Name	**cosibelimab-ipdl**
Company	CHECKPOINT THERAPEUTICS
Date of FDA Approval	12/13/2024
Indication	To treat **cutaneous squamous cell carcinoma**

OVERALL GRADE

B

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	79.4%	112	Increased	**B**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	25.5%	36	Decreased	**B**

Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	0.7%	1	Decreased	**C**
Asian	6.3%	4.3%	6	Decreased	**B**

Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	5.7%	8	Decreased	**C**

References: Phase 3 Pivotal trial CK-301-101 ; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/761297Orig1s000MultidisciplineR.pdf pgs 101-102; DOI: 10.1001/jamaoto.2021.0760; DOI: 10.1016/j.jaad.2013.11.038; No PMC or PMR

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Ensacove**
Generic Name	**ensartinib**
Company	Xcovery
Date of FDA Approval	12/18/2024
Indication	To treat **non-small cell lung 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	17.3%	16.2%	24	Similar	**C**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	48.6%	71	Similar	**B**

Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	1.4%	1	Decreased	**C**
Asian	6.3%	55.5%	77	Increased	**B**

Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	7.6%	15	Increased	**F**

References: Phase 3 Pivotal trial 301 eXALT3 ;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/218171Orig1s000IntegratedR.pdf pg 34 ;
doi: 10.21037/tlcr-22-631;
doi: 10.1200/OP.20.00961. PMID: 19667264; ; PMC for Age, Race and Ethnicity

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Tryngolza**
Generic Name	**olezarsen**
Company	IONIS PHARMS INC
Date of FDA Approval	12/19/2024
Indication	To treat **familial chylomicronemia syndrome (orphan)**

OVERALL GRADE

B

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	31.8%	51	Decreased	**A**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	46.8%	67	Decreased	**A**

Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	5.9%	8	Similar	**D**
Asian	6.3%	1.8%	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	19.1%	29.1%	48	Similar	**A**

References: Pivotal trials ISIS 678354-CS3, ISIS-678354-CS8 ; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/218614Orig1s000IntegratedR.pdf pgs 42-43,67-68 . https://rarediseases.org/rare-diseases/familial-chylomicronemia-syndrome/#affected; https://www.ahajournals.org/doi/10.1161/circ.140.suppl_1.14986; https://doi.org/10.1016/j.jacl.2018.04.009; No PMR/PMC.

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Alyftrek**
Generic Name	**vanzacaftor, tezacaftor, and deutivacaftor**
Company	Vertex
Date of FDA Approval	12/20/2024
Indication	To treat **cystic fibrosis (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	17.3%	0.4%	2	Decreased	**C**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	45.6%	215	Similar	**B**

Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	0.5%	4	Decreased	**C**
Asian	6.3%	0.3%	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	19.1%	3.4%	17	Decreased	**C**

References: Pivotal trials VX20-121-102, VX20-121-103 ; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/218730Orig1s000IntegratedR.pdf pgs 43, 50, 51, label for >65yo; https://rarediseases.org/rare-diseases/cystic-fibrosis/#affectedhttps://www.healthline.com/health/cystic-fibrosis-facts#prevalence; doi: 10.1016/j.pcl.2016.04.001 ; No PMR/PMC.

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Alhemo**
Generic Name	**concizumab-mtci**
Company	Novo Nordisk
Date of FDA Approval	12/20/2024
Indication	For routine **prophylaxis to prevent bleeding episodes in hemophilia A and B (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	17.3%	1.5%	1	Decreased	**C**

Sex

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

Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	6.8%	9	Decreased	**C**
Asian	6.3%	27.8%	34	Decreased	**A**

Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	4.5%	6	Similar	**D**

References: Pivotal trial explorer7, Study 4311 ; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/761315Orig1s000IntegratedR.pdf pg 43; DOI: 10.1111/hae.13998 ; DOI: 10.1182/asheducation-2010.1.191; No PMR/PMC.