CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Awiqli**
Generic Name	insulin icodec-abae
Company	NOVO NORDISK INC
Date of FDA Approval	3/26/2026
Indication	**To improve glycemic control in adults with type 2 diabetes mellitus (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%	34.6%	646	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%	42.9%	777	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%	3.7%	67	Increased	**D**
Asian	6.3%	23.2%	418	Similar	**A**

Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	13.4%	247	Increased	**C**

References: Phase 3 trials ONWARDS 1-5 ;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2026/761326Orig2s000MedR.pdf pg 47;
https://usdss.cdc.gov/diabetes/report.html; No PMR/PMC

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Decnupaz**
Generic Name	pivekimab sunirine-pvzy
Company	Abbvie
Date of FDA Approval	5/27/2026
Indication	**To treat adults with blastic plasmacytoid (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%	71.4%	60	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%	17.9%	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	13.6%	3.6%	3	Similar	**D**
Asian	6.3%	1.2%	1	Similar	**D**

Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	14.3%	12	Similar	**C**

References: Pivotal Trial CADENZA;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2026/761460Orig1s000MultidisciplineR.pdf pgs 118-119;
https://doi.org/10.1182/hem.V22.5.202551; https://doi.org/10.3389/fonc.2023.1178147; No PMR/PMC

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Baxfendy**
Generic Name	baxdrostat
Company	AstraZeneca
Date of FDA Approval	5/15/2026
Indication	**To treat hypertension in combination with other antihypertensive drugs**

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%	43.1%	217	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%	198	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%	7.4%	44	Increased	**D**
Asian	6.3%	26.3%	137	Similar	**A**

Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	13.1%	66	Similar	**C**

References: Phase 3 Pivotal Trial BaxHTN;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2026/219878Orig1s000MedR.pdf pg 40-41;
https://www.cdc.gov/high-blood-pressure/data-research/facts-stats/index.html;
https://theworlddata.com/hypertension-statistics-in-us/; No PMR/PMC

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Clinical Trial Demographic Scorecard

Drug	
Tradename	**Beqalzi**
Generic Name	sonrotoclax
Company	BEONE MEDICINES USA
Date of FDA Approval	5/13/2026
Indication	**To treat adults with relapsed or refractory mantle cell lymphoma (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%	63.1%	65	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%	26.2%	27	Decreased	**C**

Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	2.9%	3	Decreased	**C**
Asian	6.3%	33.0%	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%	24.3%	25	Decreased	**B**

References: Pivotal Trial BGB-11417-201;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2026/220711Orig1s000MultidisciplineR.pdf pg 89;
https://link.springer.com/article/10.1186/1471-2407-14-764; PMR for racial and ethnic representation

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Veppanu**
Generic Name	vepdegestrant
Company	ARVINAS OPERATIONS
Date of FDA Approval	5/1/2026
Indication	**To treat estrogen receptorpositive, human epidermal growth factor receptor 2-negative, ESR1-mutated advanced or metastatic 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%	39.1%	123	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%	NA	NA	NA	**NA**

Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	1.8%	5	Decreased	**C**
Asian	6.3%	40.2%	122	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%	10.4%	29	Decreased	**C**

References: Phase 3 Pivotal Trial VERITAC-2 (C4891001); https://www.accessdata.fda.gov/drugsatfda_docs/nda/2026/219835Orig1s000MultidisciplineR.pdf pg 124; https://seer.cancer.gov/statistics-network/explorer/application.html?site=622&data_type=1&graph_type=2&compareBy=race&chk_race_6=6&chk_race_5=5&chk_race_4=4&chk_race_9=9&chk_race_8=8&rate_type=2&hdn_sex=3&age_range=1&stage=101&advopt_precision=1&advopt_show_ci=on; No PMR/PMC

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Idvynso**
Generic Name	doravirine and islatravir
Company	MSD
Date of FDA Approval	4/20/2026
Indication	**To treat HIV-1 infection (as a complete regimen) in adults to replace the current antiretroviral regimen**

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%	49.7%	354	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%	30.9%	226	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%	38.3%	277	Increased	**B**
Asian	6.3%	5.5%	38	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%	18.5%	127	Increased	**C**

References: Phase 3 Pivotal Trials P051,P052;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2026/216964s000MultidisciplineR.pdf pgs 45, 57;
https://www.hiv.gov/hiv-basics/overview/data-and-trends/statistics; No PMR/PMC

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Clinical Trial Demographic Scorecard

Drug	
Tradename	**Foundayo**
Generic Name	orforglipron
Company	ELI LILLY AND CO
Date of FDA Approval	4/1/2026
Indication	**To reduce excess body weight and maintain weight reduction long term in adults with obesity**

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%	13.0%	401	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%	58.4%	1860	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%	7.8%	263	Increased	**D**
Asian	6.3%	24.5%	784	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%	35.1%	1100	Similar	**A**

References: Phase 3 Pivotal Trials ATTAIN-1, ATTAIN-2;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2026/220934Orig1s000MultidisciplineR.pdf pg. 105,134;
https://www.cdc.gov/nchs/products/databriefs/db508.htm?utm_source=chatgpt.com#section_1;
https://www.niddk.nih.gov/health-information/health-statistics/overweight-obesity; No PMR/PMC

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Lynavoy**
Generic Name	linerixibat
Company	GSK
Date of FDA Approval	3/17/2026
Indication	**To treat cholestatic pruritus associated with 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%	25.2%	25	Increased	**C**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	95.0%	113	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%	0.8%	2	Decreased	**C**
Asian	6.3%	30.3%	35	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%	22.7%	33	Decreased	**A**

References: Phase 3 Pivotal Trial 212620 (GLISTEN)' https://www.accessdata.fda.gov/drugsatfda_docs/nda/2026/220295Orig1s000IntegratedR.pdf pg 37; 10.1097/HC9.0000000000000179; https://www.rarediseaseadvisor.com/disease-info-pages/primary-biliary-cholangitisepidemiology/; No PMR/PMC

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Icotyde**
Generic Name	icotrokinra
Company	JANSSEN BIOTECH
Date of FDA Approval	3/17/2026
Indication	**To treat moderate-to-severe plaque psoriasis**

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%	9.8%	125	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%	33.2%	438	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%	1.5%	21	Decreased	**C**
Asian	6.3%	20.4%	254	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%	13.2%	177	Decreased	**B**

References: Phase 3 Pivotal Trials PSO 3001, 3002, 3003, 3004;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2026/220149Orig1s000MultidisciplineR.pdf pgs 257-258;
https://www.psoriasis.org/prevalence-of-psoriasis/; No PMR/PMC

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Lifyorli**
Generic Name	relacorilant
Company	Corcept Therapeutics
Date of FDA Approval	3/25/2026
Indication	**To treat platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal 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%	39.9%	72	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%	NA	NA	NA	**NA**

Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	1.3%	3	Similar	**D**
Asian	6.3%	12.6%	22	Decreased	**A**

Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	8.7%	16	Similar	**D**

References: Pivotal Trial ROSELLA (556 (CORT125134-556) ;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2026/220641Orig1s000MultidisciplineR.pdf pg 123;
https://seer.cancer.gov/statfacts/html/ovary.html; https://doi.org/10.1016/j.ygyno.2017.02.025; No PMR/PMC

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**ADQUEY**
Generic Name	difamilast
Company	ACROTECH BIOPHARMA
Date of FDA Approval	2/12/2026
Indication	**To treat mild to moderate atopic dermatitis**

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%	0.3%	2	Increased	**F**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	49.2%	227	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%	5.3%	27	Increased	**F**
Asian	6.3%	80.1%	354	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%	1.6%	6	Similar	**D**

References: Pivotal trials 271-102-00007, 271-102-00008, and MEDI-MM36-301 ; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2026/219474Orig1s000MultidisciplineR.pdf pgs 121-2; 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/PMC

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Loargys**
Generic Name	pegzilarginase-nbln
Company	IMMEDICA PHARMA AB
Date of FDA Approval	2/23/2026
Indication	**To treat hyperarginemia in adults and pediatric patients two years and older with Arginase 1 Deficiency, in conjunction with dietary protein restriction (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%	40.6%	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%	6.2%	0	Increased	**F**
Asian	6.3%	18.8%	3	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%	28.1%	6	Increased	**C**

References: Pivotal Trial CAEB1102-300A; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2026/761211Orig1s000IntegratedR.pdf pgs 43-44; doi: 10.1186/s13023-022-02226-8; https://doi.org/10.1016/j.ymgme.2022.08.005; No PMR/PMC

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Clinical Trial Demographic Scorecard

Drug	
Tradename	**Zycubo**
Generic Name	copper histidinate
Company	SENTYNL THERAPS INC
Date of FDA Approval	1/12/2026
Indication	**To treat Menkes 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%	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%	1.6%	2	Decreased	**C**

Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	11.6%	15	Similar	**C**
Asian	6.3%	4.7%	6	Similar	**C**

Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	11.6%	15	Similar	**D**

References: Pivotal trials 0149, 0059;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2026/211241Orig1s000IntegratedR.pdf pg 91;
https://www.ncbi.nlm.nih.gov/books/NBK560917/?utm; No PMR/PMC