Long-term Durability and Safety of the Targeted Oral Peptide Icotrokinra for High-Impact Site Psoriasis: 2-year Findings From the ICONIC-TOTAL Randomized Controlled Trial

Richard B. Warren,[1] Eingun James Song,[2] Edward Lain,[3] Joseph F. Merola,[4,5] Matthias Hoffmann,[6] Robert Bissonnette,[7] Yu-Huei Huang,[8] Amy Paller,[9] Jessica H. Rubens,[10] Melissa Larick,[11] Ming-Chun Hsu,[11] Shu Li,[11] Ya-Wen Yang,[12] Cynthia M. C. DeKlotz,[11] Melinda Gooderham[13,14,15]

[1]Dermatology Centre, Northern Care Alliance NHS Foundation Trust & Division of Musculoskeletal and Dermatological Sciences, Manchester NIHR Biomedical Research Centre, Manchester Academic Health Science Centre, University of Manchester, Manchester, UK; [2]Frontier Dermatology, Mill Creek, WA, USA; [3]Austin Institute for Clinical Research. Sanova Dermatology, Austin, TX, USA; [4]Department of Dermatology, UT Southwestern Medical Center and O'Donnell School of Public Health, Dallas, TX, USA; [5]Division of Rheumatology, Department of Medicine, UT Southwestern Medical Center and O'Donnell School of Public Health, Dallas, TX, USA; [6]Dermatology Practice Dr Matthias Hoffmann, Witten, Germany; [7]Innovaderm Research, Montreal, QC, Canada; [8]Department of Dermatology, Chang Gung Memorial Hospital and College of Medicine, Chang Gung University, Taoyuan City, Taiwan; [9]Department of Dermatology and Pediatrics, Northwestern University Feinberg School of Medicine, Chicago, IL, USA; [10]Johnson & Johnson, La Jolla, CA, USA; [11]Johnson & Johnson, Spring House, PA, USA; [12]Johnson & Johnson, Spring House/Horsham, PA, USA; [13]SKiN Centre for Dermatology, Peterborough, ON, Canada; [14]Department of Medicine, Queen's University, Kingston, ON, Canada; [15]Probity Medical Research, Waterloo, ON, Canada

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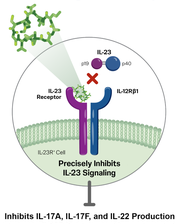
Key Takeaways

- **Through W112, among adults and adolescents with high-impact site PsO in the phase 3 ICONIC-TOTAL study, ICO demonstrated:**
  - **High and durable rates of overall and high-impact site PsO clearance**
  - **An AE profile similar to PBO through W16 with no new safety signals identified through W112**
- **The robust efficacy and favorable safety profile through 2 years support the use of the once-daily targeted oral peptide ICO for long-term management of high-impact site PsO**

Background

- Plaque psoriasis (PsO) is a chronic inflammatory disease that may involve high-impact sites, such as the scalp, genitals, hands/feet, and nails
  - High-impact site plaque PsO can be difficult to treat and has a significant impact on health-related quality of life[1]
- Icotrokinra (ICO) is the first and only targeted oral peptide that:
  - Precisely targets the interleukin (IL)-23 receptor and inhibits IL-23 pathway signaling[2]
  - Demonstrated robust efficacy and a favorable safety profile versus placebo (PBO) through Week (W) 16,[3,4] with consistent results through 1 year[5–8]
- **ICONIC-TOTAL (NCT06095102)**
  - Ongoing, phase 3, multicenter, randomized, double-blind, PBO-controlled trial in adult and adolescent participants (pts; ≥12 years of age)
  - Long-term data on durability of response and safety will help inform treatment decisions

Icotrokinra Blocks IL-23 From Binding to its Receptor



Inhibits IL-17A, IL-17F, and IL-22 Production

IL*=interleukin,* ***IL-12Rβ1****=interleukin-12 receptor beta 1,* ***IL-23R****=interleukin-23 receptor.*

Objective

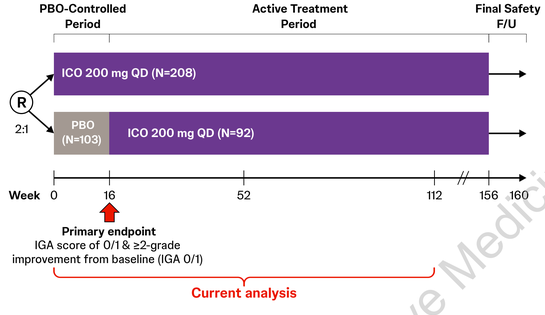
Report clinical response rates and safety of ICO through 2 years in ICONIC-TOTAL study pts with high-impact site plaque PsO

ICONIC-TOTAL Study Design

Adults and adolescents with plaque PsO involving high-impact sites (N=311)

Key inclusion criteria

- ≥12 years of age
- Plaque PsO for ≥26 weeks
- BSA ≥1% and IGA score ≥2
- At least moderate (score ≥3) high-impact PsO involving ≥1 site:
  - **Scalp:** ss-IGA
  - **Genital:** sPGA-G
  - **Hand/foot:** hf-PGA
- Candidate for phototherapy or systemic treatment for plaque PsO and failed ≥1 topical treatment



AE*=adverse event,* ***BSA****=body surface area,* ***F/U****=follow-up,* ***hf-PGA****=Physician's Global Assessment of hands and feet,* ***ICO****=icotrokinra,* ***IGA****=Investigator's Global Assessment,* ***mNAPSI****=modified Nail Psoriasis Severity Index,* ***PBO****=placebo,* ***PsO****=psoriasis,* ***pts****=participants,* ***PY****=patient-year,* ***QD****=once daily,* ***R****=randomization,* ***sPGA-G****=static Physician's Global Assessment of Genitalia,* ***ss-IGA****=scalp-specific Investigator's Global Assessment,* ***W****=week.*

Outcomes & Analyses

- **Overall PsO:** IGA 0/1 and 0[a]
- **Scalp PsO:** ss-IGA 0/1 and 0[a]
- **Genital PsO:** sPGA-G 0/1 and 0[a]
- **Hand/foot PsO:** hf-PGA 0/1 and 0[a]
- **Nail PsO:** mNAPSI % improvement[b] and mNAPSI=0[a]
- **AE:** Number (%) of pts and exposure-adjusted incidence rates (/100 PY)

[a]Through W52, nonresponder status assigned after pts discontinued study drug due to a lack of efficacy or an AE of worsening PsO or initiated prohibited medication that could impact PsO; observed data were used for pts who discontinued study agent for other reasons; pts with missing data were considered nonresponders. After W52, nonresponder status assigned after pts who discontinued study drug due to a lack of efficacy or an AE of worsening PsO. Missing data were imputed using multiple imputation. [b]Through W52, 0% improvement from baseline assigned after pts discontinued study drug due to a lack of efficacy or an AE of worsening PsO or initiated prohibited medication that could impact PsO; observed data were used for pts who discontinued study agent for other reasons. After W52, 0% improvement from baseline assigned after pts who discontinued study drug due to a lack of efficacy or an AE of worsening PsO. From W0–112, missing data were not imputed.

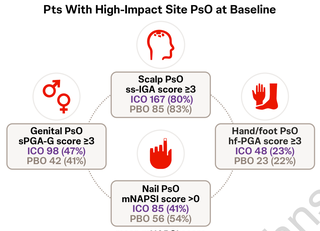
Results

Baseline demographics and PsO characteristics were generally balanced between groups

- Among pts with hand/foot PsO at baseline, greater proportions of ICO pts (35%) had severe hand/foot PsO (hf-PGA=4) compared with PBO (17%)

Baseline Characteristics		ICO (N=208)	PBO (N=103)
Demographics			
	Age, yrs	45.3 (14.6)	43.5 (13.8)
	Female	34%	39%
	Race, Asian/Black/White	20%/1%/77%	19%/0%/80%
	BMI, kg/m^2	29.0 (6.6)[a]	29.4 (8.1)[b]
Disease Characteristics			
	PsO disease duration, yrs	16.8 (13.3)	15.2 (10.5)
	% BSA with PsO	16.6 (13.5)	14.8 (11.7)
	IGA score		
	Moderate (3)	74%	71%
	Severe (4)	22%	21%
	PASI (0–72)	14.6 (7.6)	14.0 (7.0)
Prior PsO treatments			
	Phototherapy[c]	43%	31%
	Systemic therapy[d]	73%	73%
	Biologic therapy[e]	34%	31%

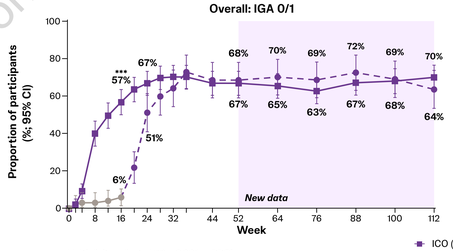
Pts With High-Impact Site PsO at Baseline



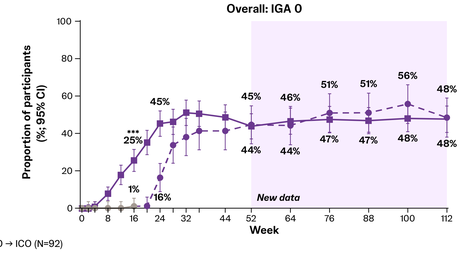
Overall PsO: IGA 0/1 response rates increased through W24 (67%) and remained stable through W112 (70%) among ICO-randomized pts

- IGA 0 response rates also increased through W24 (45%) and were consistent through W112 (48%) among ICO-randomized pts

Overall: IGA 0/1



Overall: IGA 0



ICO (N=208) PBO (N=103) PBO → ICO (N=92)

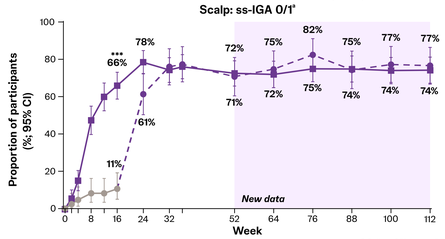
Multiplicity-adjusted ***$p<0.001$ vs PBO[a]

[a]p-values based on Cochran-Mantel-Haenszel chi-square test stratified by high-impact site involvement and BSA category. ***BSA****=body surface area,* ***CI****=confidence interval,* ***ICO****=icotrokinra,* ***IGA****=Investigator's Global Assessment,* ***PBO****=placebo.*

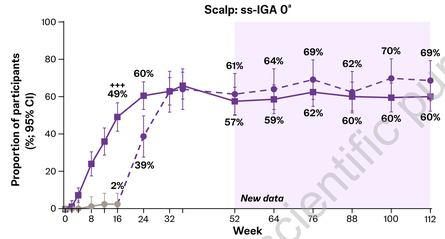
Scalp PsO: ss-IGA 0/1 response rates increased through W24 (78%) and remained stable through W112 (74%) among ICO-randomized pts

- ss-IGA 0 response rates also increased through W24 (60%) and were consistent through W112 (60%) among ICO-randomized pts

Scalp: ss-IGA 0/1[a]



Scalp: ss-IGA 0[a]



ICO (N=167) PBO (N=85) PBO → ICO (N=75)

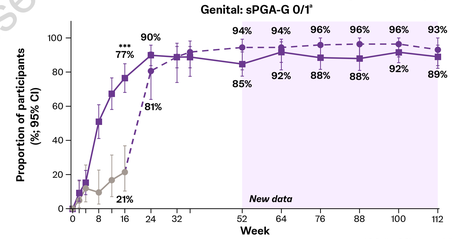
Multiplicity-adjusted ***$p<0.001$ vs PBO[b] **Nominal +++$p<0.001$ vs PBO[b,c]**

[a]Among pts with a baseline ss-IGA score ≥3. [b]p-values based on Cochran-Mantel-Haenszel chi-square test stratified by geographic region and BSA category. [c]Endpoint was not included in the hierarchical testing strategy. ***BSA****=body surface area,* ***CI****=confidence interval,* ***ICO****=icotrokinra,* ***PBO****=placebo,* ***pts****=participants,* ***ss-IGA****=scalp-specific Investigator's Global Assessment.*

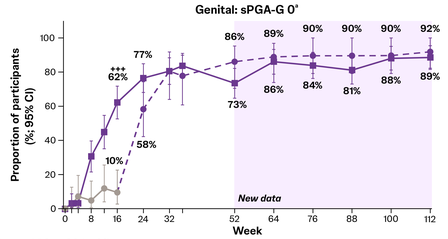
Genital PsO: sPGA-G 0/1 response rates increased through W24 (90%) and remained stable through W112 (89%) among ICO-randomized pts

- 89% of ICO-randomized pts achieved completely clear genital PsO (sPGA-G 0) at W112

Genital: sPGA-G 0/1[a]



Genital: sPGA-G 0[a]



ICO (N=98) PBO (N=42) PBO → ICO (N=36)

Multiplicity-adjusted ***$p<0.001$ vs PBO[b] **Nominal +++$p<0.001$ vs PBO[b,c]**

[a]Among pts with a baseline sPGA-G score ≥3. [b]p-values based on Cochran-Mantel-Haenszel chi-square test stratified BSA category. [c]Endpoint was not included in the hierarchical testing strategy. ***BSA****=body surface area,* ***CI****=confidence interval,* ***ICO****=icotrokinra,* ***PBO****=placebo,* ***pts****=participants,* ***sPGA-G****=static Physician's Global Assessment of Genitalia.*

Exposure-adjusted AE rates were consistent across treatment groups and study phases through W112

- ICO AE profile was similar to PBO through W16, with no increases in exposure-adjusted rates through 2 years of treatment

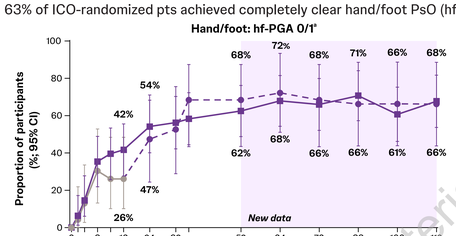
AEs Through W112	PBO-controlled (W0–16) ICO (N=208)	PBO-controlled (W0–16) PBO (N=103)	W0–52 ICO Combined[a] (N=300)	W0–112 ICO Combined[a] (N=300)
Mean weeks / total PY of follow-up	15.9 / 63.3	15.5 / 30.6	45.0 / 258.9	98.1 / 563.9
Any AE	105 (50%)	46 (45%)	206 (69%)	240 (80%)
Incidence/100PY (95% CI)[b]	232 (188, 277)	219 (156, 282)	160 (138, 182)	122 (106, 137)
SAE	1 (<1%)	2 (2%)	7 (2%)	15 (5%)
Incidence/100PY (95% CI)[b]	2 (0, 9)	7 (1, 24)	3 (1, 6)	3 (1, 4)
AE leading to D/C	6 (3%)	4 (4%)	7 (2%)	10 (3%)
Incidence/100PY (95% CI)[c]	10 (4, 21)	13 (4, 34)	3 (1, 6)	2 (1, 3)
Infection	59 (28%)	23 (22%)	146 (49%)	180 (60%)
Incidence/100PY (95% CI)[b]	110 (82, 138)	89 (53, 126)	82 (69, 95)	58 (50, 67)
Serious infection	0 (0%)	1 (1%)	0 (0%)	2 (1%)
Incidence/100PY (95% CI)[b]	0 (0, 5)	3 (<1, 18)	0 (0, 1)	<1 (0, 1)
GI AE	15 (7%)	8 (8%)	28 (9%)	49 (16%)
Incidence/100PY (95% CI)[b]	25 (12, 38)	27 (12, 54)	12 (7, 16)	10 (7, 12)
Malignancy[d]	1 (<1%)	0 (0%)	2 (1%)	6 (2%)
Incidence/100PY (95% CI)[b]	2 (0, 9)	0 (0, 10)	1 (<1, 3)	1 (<1, 2)

Data shown are n (%) unless otherwise noted. [a]Includes data for ICO-randomized pts through W52 and for PBO → ICO pts from W16 through W52/W112. [b]CI is based on the normal approximation or an exact method following a Poisson distribution if the number of pts with events is <10. [c]Includes one of basal cell carcinoma, chronic lymphocytic leukemia, malignant melanoma stage 0, prostate cancer, squamous cell carcinoma and squamous cell carcinoma of the cervix. ***AE****=adverse event,* ***CI****=confidence interval,* ***D/C****=discontinuation,* ***GI****=gastrointestinal,* ***ICO****=icotrokinra,* ***PBO****=placebo,* ***PY****=patient-year,* ***SAE****=serious adverse event,* ***W****=week.*

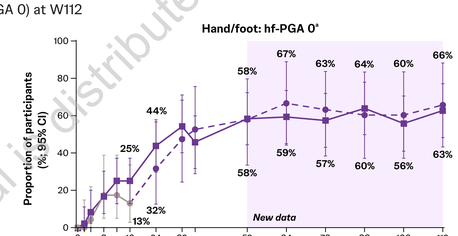
Hand/foot PsO: hf-PGA 0/1 response rates increased through W24 (54%) and remained stable through W112 (68%) among ICO-randomized pts

- 63% of ICO-randomized pts achieved completely clear hand/foot PsO (hf-PGA 0) at W112

Hand/foot: hf-PGA 0/1[a]



Hand/foot: hf-PGA 0[a]



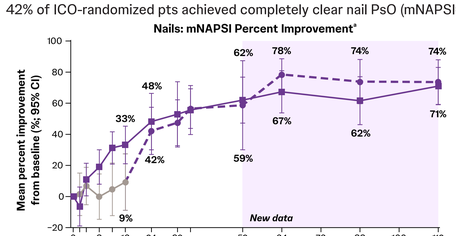
ICO (N=48) PBO (N=23) PBO → ICO (N=19)

[a]Among pts with a baseline hf-PGA score ≥3. ***CI****=confidence interval,* ***hf-PGA****=Physician's Global Assessment of hands and feet,* ***ICO****=icotrokinra,* ***PBO****=placebo,* ***pts****=participants.*

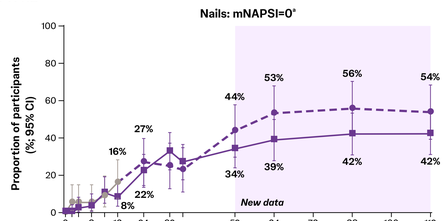
Nail PsO: ICO demonstrated increasing improvements through W64 (67%), which were consistent through W112 (71%)

- 42% of ICO-randomized pts achieved completely clear nail PsO (mNAPSI=0) at W112

Nails: mNAPSI Percent Improvement[a]



Nails: mNAPSI=0[a]



ICO (N=73–81) PBO (N=52–54) PBO → ICO (N=45–46) ICO (N=85) PBO (N=56) PBO → ICO (N=48)

[a]Among pts with a baseline mNAPSI score >0. ***CI****=confidence interval,* ***ICO****=icotrokinra,* ***mNAPSI****=modified Nail Psoriasis Severity Index,* ***PBO****=placebo,* ***pts****=participants.*

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PRESENTED BY: Santiago Munoz at The Society of Dermatology Physician Associates (SDPA) Annual Fall Dermatology Conference, November 11–15, 2026; Hollywood, FL, USA. **REFERENCES: 1.** Merola JF. *Dermatol Ther.* 2018;31:e12589. **2.** Fourie AM. *Sci Rep.* 2024;14:17515. **3.** Bissonnette, R. *N Engl J Med.* 2025. 393:1784–1795. **4.** Gooderham, M. *NEJM Evid.* 2025. EVIDoa2500155. **5.** Warren, RB. *J Eur Acad Dermatol Venereol.* 2026. 40:1502–1514. doi: 101111/jdv70471 **6.** Soung, J. *J Am Acad Dermatol.* 2026. doi:101016/j.jaad.2026.05.048. **7.** Soung, J. *J Am Acad Dermatol.* 2026. doi:101016/j.jaad.2026.05.035. **8.** Stein Gold, L. *Br J Dermatol.* 2026. doi:101093/bjd/ljaq264. **ACKNOWLEDGMENTS:** Medical writing support was provided by JSS Medical Research under the direction of the authors in accordance with Good Publication Practice guidelines (*Ann Intern Med.* 2022;175:1298–1304). Layout design and formatting for this encore presentation was provided by Amit Kavle (SIRO Medical Writing Pvt. Ltd., India). This presentation was sponsored by Johnson & Johnson. **DISCLOSURES: RBW:** Consultant and/or speaker for AbbVie, Almirall, Alumis, Amgen, Apogee, Arena Pharmaceuticals, Astellas, Avillion, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, DICE Therapeutics, Eli Lilly, Galderma, GSK, Johnson & Johnson, LEO Pharma, Meiji Pharma, Nektar; Novartis, Pfizer, RAPT Pharmaceuticals, Sanofi, Sitryx, Sun Pharma, UCB, and UNION. Received research grants from AbbVie, Almirall, Amgen, Celgene, Eli Lilly, Johnson & Johnson, LEO Pharma, Novartis, Pfizer, and UCB. **EJS:** Served as an investigator, consultant, and/or speaker for AbbVie, Acelyrin, Alphyn, Alumis, Amgen, Apogee, Arcutis, ASLAN, Boehringer Ingelheim, Bristol Myers Squibb, Celldex, CorEvitas, Dermavant, DermTovrit, Eli Lilly, Galderma, Incyte, Johnson & Johnson, LEO Pharma, MoonLake, Novartis, Pfizer, Regeneron, Sanofi, Genzyme, Sun Pharma, TARGET PharmaSolutions, TIMBER, UCB, and Zura Bio. **ELs** Speaker, consultant, advisory board member, or principal investigator for AbbVie, Aslan Pharmaceuticals, Biofrontera, Cellvey, Cassiopea, Castle Biosciences, Celldex Therapeutics, Concert Pharmaceuticals, Eli Lilly, Evommune, Galderma, Incyte, Johnson & Johnson, L'Oreal, Nielsen BioSciences, Peregrine Ophthalmic, Pfizer, Regeneron, RegenX Science, Sanofi, Symatese, Takeda, Teoxane, UCB, Verademics, and Vyne. **JFM:** Served as a consultant and/or investigator for AbbVie, Amgen, AstraZeneca, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant, Eli Lilly, Galderma, Johnson & Johnson, Moonlake, Novartis, Oruka, Pfizer, Regeneron, Sanofi, Sun Pharma, and UCB. **MH:** Served as an advisory board member, consultant, speaker and/or investigator for and/or received honoraria and/or grants from AbbVie, Almirall, Biofrontera, Bristol Myers Squibb, Dermapharm, Dermasence, Eli Lilly, Forward, Galderma, Incyte, Johnson & Johnson, Kiniksa, LEO Pharma, L'Oreal, MSD, Nektar Therapeutics, Novartis, Pierre Fabre, Pfizer, Sanofi, Schering-Plough, Smerud Medical Research, Stallergenes Greer, Viatris, and UCB. **RBs:** Served as an advisory board member, consultant, speaker and/or investigator for and received honoraria and/or grants from AbbVie, Alumis, Amgen, AnaptysBio, Arcutis, Bristol Myers Squibb/Celgene, Dermavant, Eli Lilly, Johnson & Johnson, LEO Pharma, Nimbus Therapeutics, Oruka, Takeda, UCB, Ventyx Biosciences, Vyne Therapeutics, Xencor, Zai Lab, and Zura Bio; Employee and shareholder of Innoaderm Research. **Y-HH:** Conducted clinical trials for or received honoraria as a consultant for AbbVie, Bristol Myers Squibb, Celgene, Johnson & Johnson, Novartis, and Pfizer. **AP:** Served as an investigator: AbbVie, Biomedics, Dermavant, Eli Lilly, Incyte, Johnson & Johnson Innovative Medicine, Moonlake, Ouoin, Regeneron, TheraClean, TWI, and UCB. Served as a consultant: Abbvie, Abeona Therapeutics, Aegle Therapeutics Corporation, Apogee Therapeutics, Applied Pharma Research, Arcutis Biotherapeutics, Biocryst, Biomedics LLC, BIORAY Pharmaceutical, BlueFin Therapeutics, Eli Lilly, Galderma, Gedeon Richter, Genzyme, Johnson & Johnson, Kamari Pharma, Kymera, LEO Pharma, Novartis, Palvella Pharmaceuticals, Pelthos, Pfizer, Quoin Pharmaceuticals, Sanofi, and Sato. Data safety monitoring board: AbbVie, Abeona, Biocryst, Galderma, and Takeda. **JHR, ML, M-CH, SL, Y-WY, CMCD:** Employees of Johnson & Johnson; may own stock/stock options in Johnson & Johnson. **MG:** Speaker, investigator or advisory board member for AbbVie, Acelyrin, Alumis , Amgen, Akros, AnaptysBio, Apogee, Arcutis, Bausch Health, Boehringer Ingelheim, Bristol Myers Squibb, Coherus, Dermavant, Dermira, Eli Lilly, Galderma, GSK, Incyte, Inmagene, JAMP Pharma, Johnson & Johnson, Kyowa Kirin, LEO Pharma, L'Oréal, Medimmune, Merck, Moonlake, Nimbus, Novartis, Organon, Pfizer, Regeneron, Relstone, Sanofi Genzyme, Sun Pharma, Tarsus, Takeda, UCB, and Vyne.
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