

A photograph of two women and a black dog in a garden setting. The woman on the left is wearing a light pink jacket and a light blue skirt, and is smiling while petting the dog. The woman on the right is wearing a dark blue cardigan over a dark blue polka-dot blouse and skirt, and is also smiling. The dog is black and fluffy. They are standing in front of a green wooden fence. There are some plants and a stone path in the foreground.

Further Facts & Figures

Full-Year Report 2023
28th of February 2024



Inspired by **patients.**
Driven by **science.**

Disclaimer & safe harbor

This document contains forward-looking statements, including, without limitation, statements containing the words “potential”, “believes”, “anticipates”, “expects”, “intends”, “plans”, “seeks”, “estimates”, “may”, “will”, “continue” and similar expressions. These forward-looking statements are based on current plans, estimates and beliefs of management. All statements, other than statements of historical facts, are statements that could be deemed forward-looking statements, including estimates of revenues, operating margins, capital expenditures, cash, other financial information, expected legal, arbitration, political, regulatory or clinical results or practices and other such estimates and results. By their nature, such forward-looking statements are not guaranteeing future performance and are subject to known and unknown risks, uncertainties, and assumptions which might cause the actual results, financial condition, performance or achievements of UCB, or industry results, to be materially different from any future results, performance, or achievements expressed or implied by such forward-looking statements contained in this document.

Important factors that could result in such differences include but are not limited to: global spread and impacts of wars and pandemics, changes in general economic, business and competitive conditions, the inability to obtain necessary regulatory approvals or to obtain them on acceptable terms or within expected timing, costs associated with research and development, changes in the prospects for products in the pipeline or under development by UCB, effects of future judicial decisions or governmental investigations, safety, quality, data integrity or manufacturing issues; potential or actual data security and data privacy breaches, or disruptions of our information technology systems, product liability claims, challenges to patent protection for products or product candidates, competition from other products including biosimilars, changes in laws or regulations, exchange rate fluctuations, changes or uncertainties in tax laws or the administration of such laws, and hiring and retention of its employees. There is no guarantee that new product candidates will be discovered or identified in the pipeline, or that new indications for existing products will be developed and approved. Movement from concept to commercial product is uncertain; preclinical results do not guarantee safety and efficacy of product candidates in humans. So far, the complexity of the human body cannot be reproduced in computer models, cell culture systems or animal models. The length of the timing to complete clinical trials and to get regulatory approval for product marketing has varied in the past and UCB expects similar unpredictability going forward. Products or potential products which are the subject of partnerships, joint ventures or licensing collaborations may be subject to disputes between the partners or may prove to be not as safe, effective or commercially successful as UCB may have believed at the start of such partnership. UCB's efforts to acquire other products or companies and to integrate the operations of such acquired companies may not be as successful as UCB may have believed at the moment of acquisition. Also, UCB or others could discover safety, side effects or manufacturing problems with its products and/or devices after they are marketed. The discovery of significant problems with a product similar to one of UCB's products that implicate an entire class of products may have a material adverse effect on sales of the entire class of affected products. Moreover, sales may be impacted by international and domestic trends toward managed care and health care cost containment, including pricing pressure, political and public scrutiny, customer and prescriber patterns or practices, and the reimbursement policies imposed by third-party payers as well as legislation affecting biopharmaceutical pricing and reimbursement activities and outcomes. Finally, a breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of UCB's data and systems.

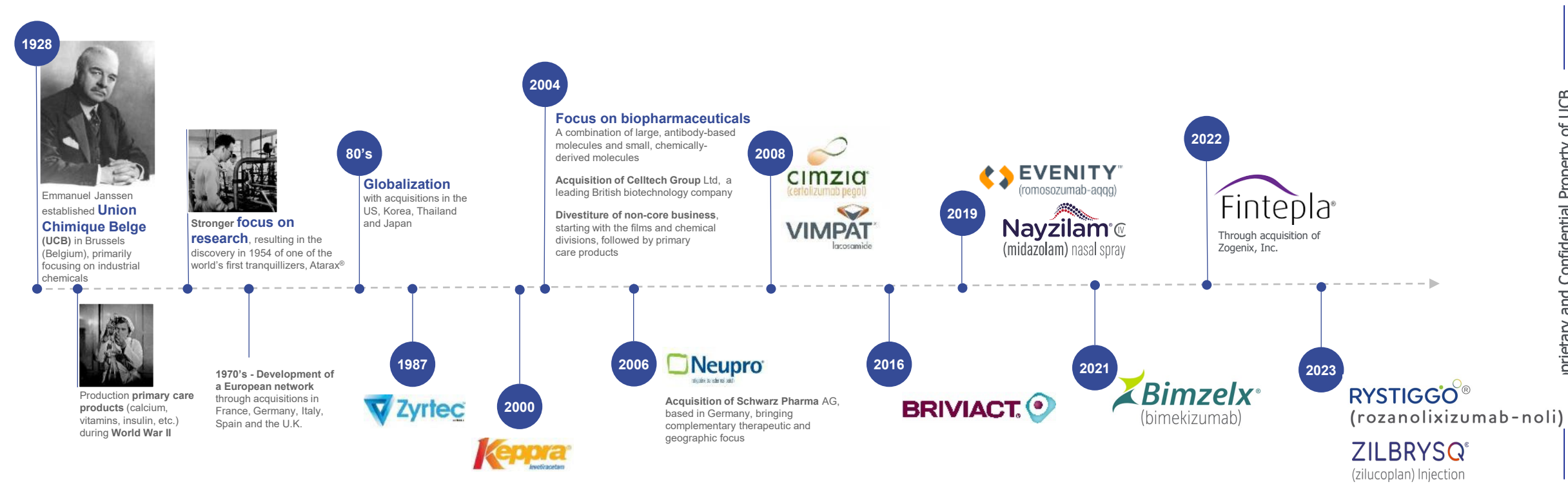
Given these uncertainties, you are cautioned not to place any undue reliance on such forward-looking statements. These forward-looking statements are made only as of the date of this document, and do not reflect any potential impacts from the evolving conflicts, wars, pandemics, as well as any other adversity, unless indicated otherwise. The company continues to follow the development diligently to assess the financial significance of these events, as the case may be, to UCB.

UCB expressly disclaims any obligation or duty to update any forward-looking statements in this document, either to confirm the actual results or to report or reflect any change in its forward-looking statements with regard thereto or any change in events, conditions or circumstances on which any such statement is based, unless such statement is required pursuant to applicable laws and regulations.

INTRODUCTION

UCB Story – Since 1928

Continuous adaptation to the changing ecosystem



UCB Patient Value Strategy

Sustained Company Growth – superior Shareholder Value

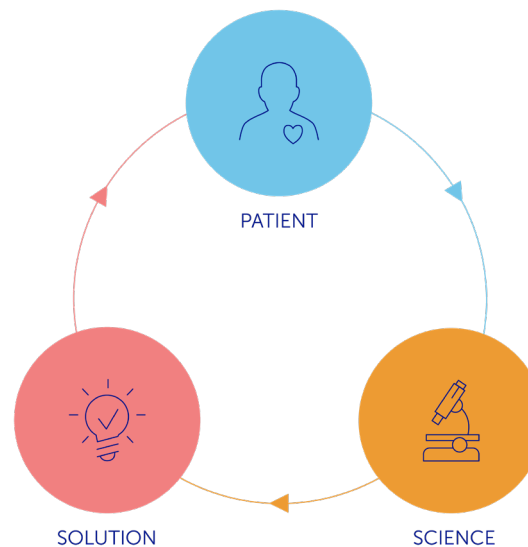
Creating Value For Patients

Our ambition is to be the patient-preferred biopharma leader, creating patient value for specific populations through unique outcomes, the best experience and improving as many of these lives as possible.

Global biopharmaceutical company with **95+ years of dedication** to our stakeholders: people living with severe diseases, employees, communities we live in, the planet, shareholders

>9000 employees world-wide*

Powered by scientific excellence and pioneering research



Key for UCB is innovation – relentless drive to bring innovative medicines. We bring our **portfolio of differentiated solutions** to people living with severe diseases

CIMZIA®	EVENITY®
VIMPAT®	FINTEPLA®
KEPPRA®	BIMZELX®
BRIVIACT®	RYSTIGGO®
NAYZILAM®	ZILBRYSQ®

UCB's Achievements – Innovation

Impressive Successes to date, based on Innovation, enabling Company Growth

UCB's innovative spirit is exemplified by an impressive tally of **10 + 2 positive phase 3 readouts**

External recognition as **2nd most innovative pharma company** in 2023¹

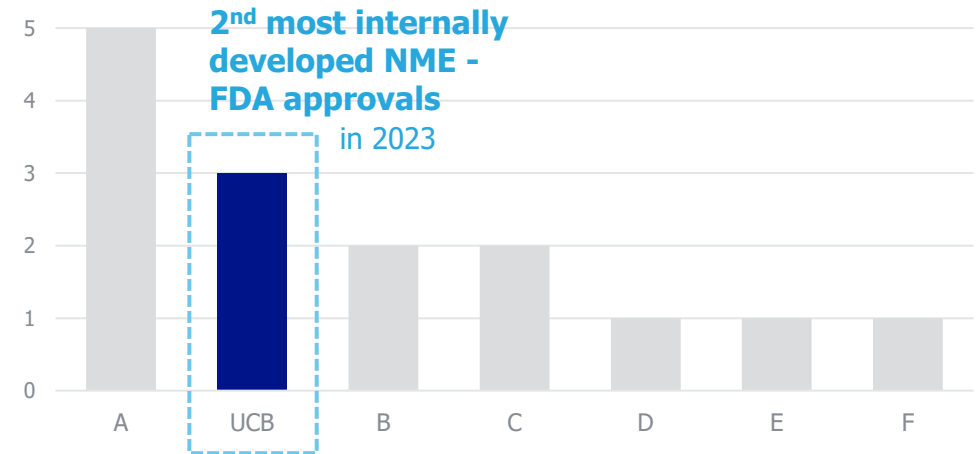
R&D productivity, with end-to-end success rates that soar to **three times higher** than the industry benchmark²

14 approvals in the last 14 months, across 6 patient populations, across 3 continents

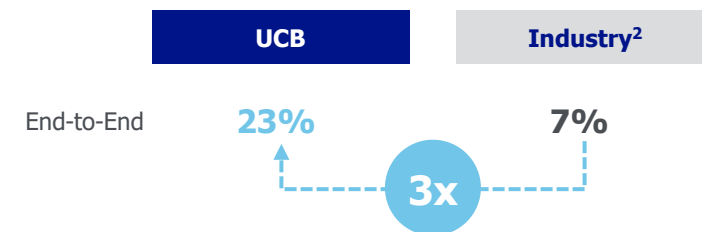
A clinical-stage pipeline of **10 unique assets** addressing well-defined **unmet patient needs**

Sustainability is our **business approach**, and we are committed to **sustainable growth**

2023 FDA Approvals for Major Pharma¹



Success rates lead indications (% , 2013-2022)



UCB's Portfolio 5 Unique and De-risked Growth Drivers

RYSTIGGO[®]
(rozanolixizumab-noli)

First agent for anti-AChR+ & anti-MuSK+


EVENITY[®]
(romosozumab-aqqg)
injection 105 mg/1.17 mL

First-in-class for Bone Builder

ZILBRYSQ[®]
(zilucoplan) Injection

First once-daily C5 inhibitor




Fintepla[®]
(fenfluramine)

Unique and dual mode of action


Bimzelx[®]
(bimekizumab)

First and only IL-17A & IL-17F inhibitor¹

UCB's Performance

Past **Inflection** Point and **Started a Decade+ of Growth**

2023 FINANCIAL and EXTRA-FINANCIAL

2023 financial guidance **delivered**

Inflection point at HY: **Back to growth since H2 2023: +3% revenue**

ESG Industry Top Rated by **Sustainalytics**

Strong performance of new launches

- ✓ EVENITY® +140%³
- ✓ FINTEPLA® +94%
- ✓ BIMZELX® +323%
- ✓ RYSTIGGO®

2023 MARKED BY

>3.2 million patients using UCB medicines¹,
40% of epilepsy treatments in US + EU (Japan 30%)
UCB generated

14 approvals since January 2023

BIMZELX® approved & launched

- ✓ US: PSO
- ✓ Europe & Japan: PsA and axSpA
>18k patients treated globally

RYSTIGGO® & ZILBRYSQ®
approved & launches ongoing/starting

- ✓ US, Japan & Europe

EVENITY®: worldwide sales of > \$1bn²

Q4 2023: Loss of exclusivity date for FINTEPLA®

2024 MARKED BY

Strong growth of EVENITY®, FINTEPLA®,
BIMZELX®, RYSTIGGO® and ZILBRYSQ®

Accelerated investment behind launches

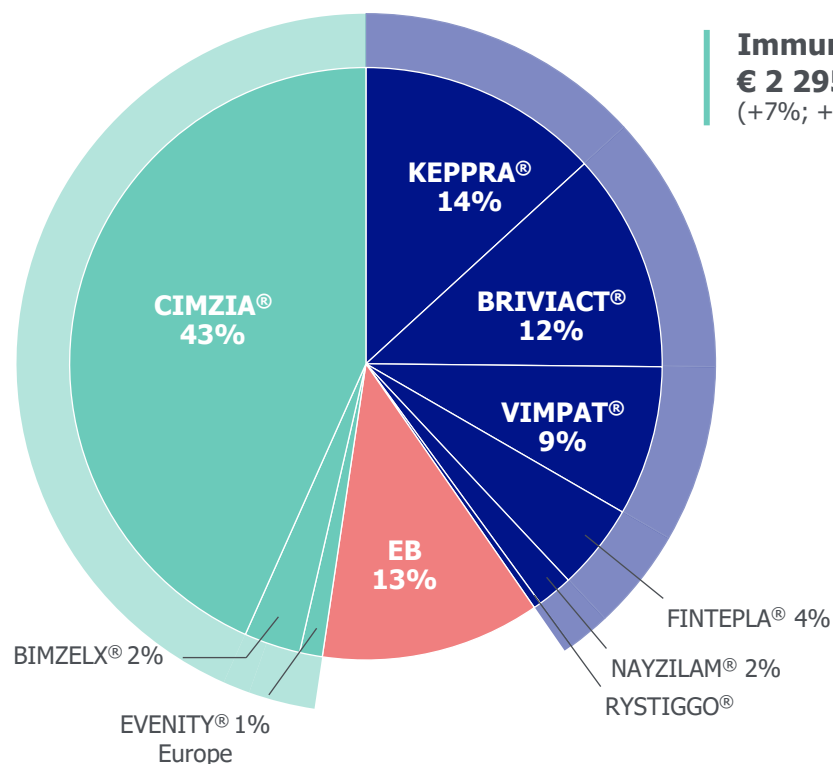
10 headline results from innovative
clinical pipeline

Product Portfolio: Solid foundation & five Growth Drivers

2023 FY Net Sales

€ 4 867 M¹

(-5%; -6% CER)



	€ M	ACT	CER	
CIMZIA®	€ 2 087	+0%	+3%	Stronger growth than the anti-TNF market based on differentiation: treatment option for women of childbearing age across 6 indications and for rheumatoid arthritis patients with high rheumatoid factor levels
KEPPRA®	€ 636	-13%	-8%	Generic competition in Japan since January 2022. Diminishing LOE effect
BRIVIACT®	€ 576	+19%	+21%	Continued double-digit growth, expected peak sales of € 600 M in 2026
VIMPAT®	€ 394	-65%	-63%	Generic erosion since March 2022 in the U.S., since September 2022 in Europe. Erosion bottomed out
FINTEPLA®	€ 226	+94%	+99%	Seizures associated with rare epileptic syndromes - Dravet Syndrome (DS) and Lennox-Gastaut Syndrome (LGS), acquired in March 2022, ongoing launches
BIMZELX®	€ 148	>100%	>100%	Approved for PSO globally, U.S. launch since mid-Nov. For PsA, AS + nr-axSpA in Europe since May and in Japan since December
NAYZILAM®	€ 94	+21%	+24%	Continued double-digit growth
EVENITY®	€ 60	>100%	>100%	Continued launches in Europe, worldwide net contribution of € 368 M (+53%) in "other operating income"
RYSTIGGO®	€ 19	n/a	n/a	Launched in the U.S. in July 2023
Established Brands (EB)	€ 577	-8%	-5%	Includes NEUPRO®, adjusted for product sale -3% - Impact in H1

Solid Foundation & Growth Drivers

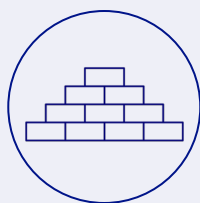
Growth Past Inflection Point

Growth Drivers



	Growth H2 vs. H1*	FY23 - M	ACT	CER	
FINTEPLA®	↑ +22%	€ 226	+94%	+99%	Seizures associated with rare epileptic syndromes - Dravet Syndrome (DS) and Lennox-Gastaut Syndrome (LGS), acquired in March 2022, ongoing launches
BIMZELX®	↑ +85%	€ 148	>100%	>100%	Approved for PSO globally, U.S. launch since mid-Nov. For PsA, AS + nr-axSpA in Europe since May and in Japan since Dec
EVENITY®	↑ +50%	€ 60	>100%	>100%	Continued launches in Europe, worldwide net earnings contribution of € 368 M (+53%) in "other operating income"
RYSTIGGO®	n/a	€ 19	n/a	n/a	Launched in the U.S. in July 2023

Solid Foundation



CIMZIA®	↑ +5%	€ 2 087	+0%	+3%	Stronger growth than the anti-TNF market based on differentiation: treatment option for women of childbearing age across 6 indications and for rheumatoid arthritis patients with high rheumatoid factor levels
KEPPRA®	↓ -11%	€ 636	-13%	-8%	Generic competition in Japan since January 2022. <u>Diminishing LOE effect</u>
BRIVIACT®	↑ +11%	€ 576	+19%	+21%	Continued double-digit growth, expected peak sales of € 600 M in 2026
VIMPAT®	↓ - 7%	€ 394	-65%	-63%	Generic erosion since March 2022 in the U.S., since September 2022 in Europe. <u>Erosion bottomed out</u>
NAYZILAM®	↑ +24%	€ 94	+21%	+24%	Continued double-digit growth
Established Brands (EB)	↓ -14 %	€ 577	-8%	-5%	Includes NEUPRO®, adjusted for product sale -3% <u>Impact of product sale in H1</u>




2023 Performance Highlights

Efficient Performance and Cost Management

		2023	Actual	CER
Revenue	Net Sales € 4 867M (-5%; -6% CER) strong growth of BRIVIACT®, FINTEPLA® and BIMZELX®, more than offset by the loss of exclusivity of 2 products, stable performance of CIMZIA®	€ 5 252 M	-5%	-6%
Adjusted Gross Profit	Well in-line with net sales performance, adjusted gross margin stable at 76.8%, underlying improvement compensated by impact of asset disposal	€ 4 033 M	-5%	-6%
Total Operating Expense € 2 888 M (-9%; -7% CER)	Marketing and selling expenses: Invest behind the launches of UCB's growth drivers	€ 1 594 M	+7%	+10%
	R&D expenses: 10 molecules in clinical development in 5 phase 3 + 7 POC (phase 2a) programs	€ 1 630 M	-2%	-1%
	General and administrative expenses: Inflation costs	€ 230 M	+2%	+3%
	Other operating income: € 368 M net contribution (+53%) from EVENITY®, € 145 million from the sale of a portfolio of established brands in Europe	€ 566 M	>100%	>100%
Adjusted EBITDA*	Adjusted EBITDA / revenue ratio 25.7 % after 22.8% in 2022	€ 1 349 M	+7%	-1%
Profit	Higher net financial expenses: higher interest rates and higher interest cost due to higher net debt after the acquisition of Zogenix in March 2022 Tax Rate 22% - lower earnings and earnings mix	€ 343 M	-18%	-34%
Core Earnings per Share	Based on 190 M weighted average shares outstanding** (2022: 190 M)	4.20€	-4%	-18%

Delivery on Social and Environmental Impact

As per UCB Sustainable Performance Goals

	Key Performance Indicator	2023	Δ 2022
 Value for Patient	Number of medicines in clinical development*	10	↑ 1
	Access Coverage Performance Index**	68%	↑ 24%
	Time to Access Index***	50%	↑ 22%
 Value for Planet	CO2 emissions we control (tons)	85,345	↑ 5.7%
	% of suppliers by emissions having Science-Based Targets	59.4%	↑ 98%
 Value for People	Health, Safety and Well-being Index	81.5%	↑ 1.4%
	Gender balance at executive level	38% / 62%	↔ stable
	Inclusion Index	70.3%	↓ -1%



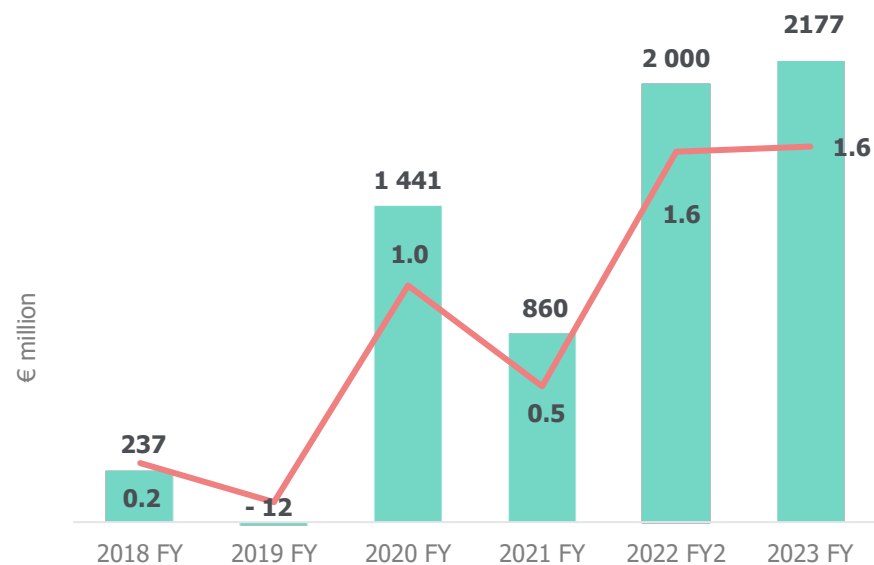
UCB ratings:
A- for climate change

*This number includes assets that have progressed to phase 1 and beyond;
Access Coverage Performance Index: tracks access of UCB's patented medicines in countries where we operate according to whether access is reimbursed; *Timely Access Index: measures the percentage of earlier positive decisions on reimbursement for UCB products than industry benchmark.
UCB - FY 2023 Facts & Figures, February 2024

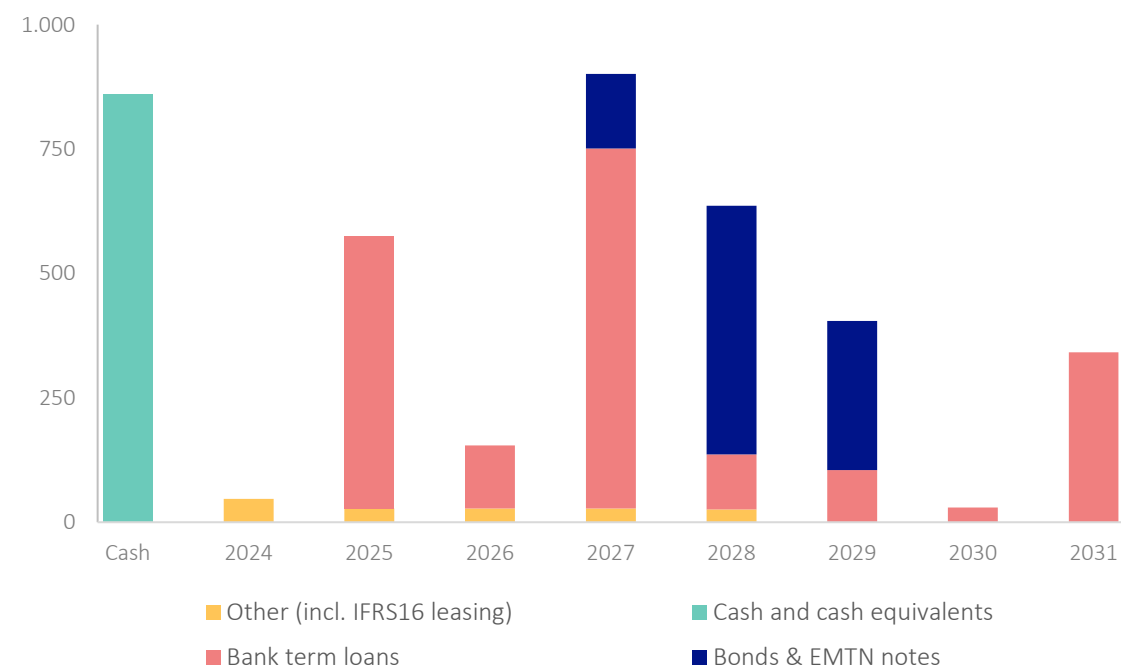


Net Debt & Debt Maturity Schedule

Net debt / adjusted EBITDA ratio

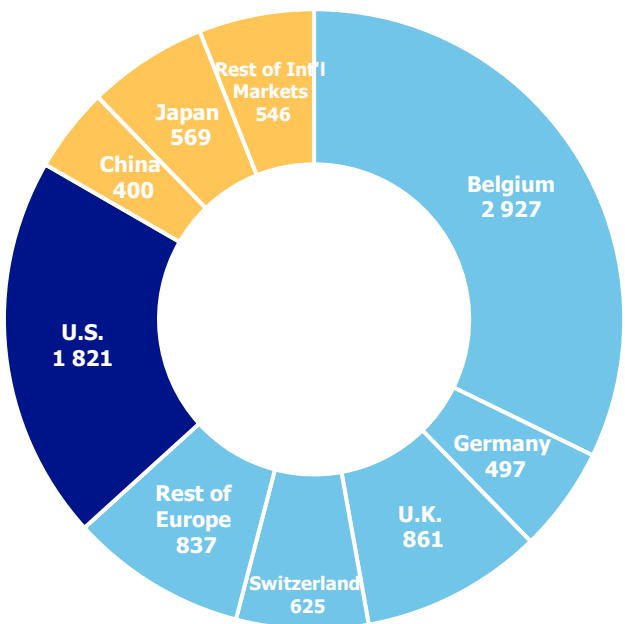
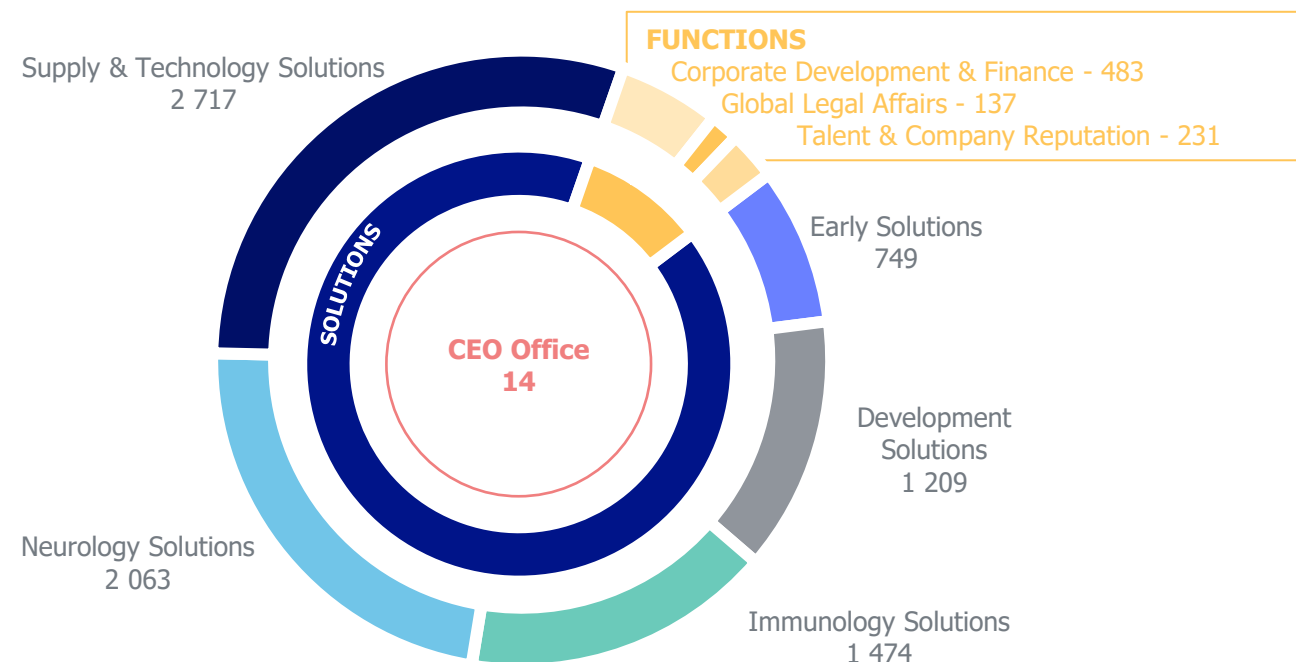


Debt Maturity Schedule (as of 31 Dec 2023, € million)



UCB's Organization

Our people are key to deliver on our ambition



9 083*
Employees Worldwide



51 / 49
Women / Men








1 209
New colleagues



8.3%
Employee turnover

OUR INNOVATION

UCB's Epilepsy solutions

	KEPPRA® (levetiracetam)	VIMPAT® (lacosamide)	BRIVIACT® (brivaracetam)	NAYZILAM® (midazolam)	FINTEPLA® (fenfluramine)
	Epilepsy POS Epilepsy PGTCs Epilepsy myoclonic seizures	Epilepsy POS (pediatric label extension in US, Oct. 2021, and EU CHMP positive opinion, Jan. 2022) POS down to 4 years in Japan and China Epilepsy PGTCs	Epilepsy POS Adj. therapy Monotherapy (US) pediatric label extension in US, Aug. 2021, and EU CHMP positive opinion, Jan. 2022)	Epilepsy seizure clusters (US - 2019) – orphan disease designation	Dravet-syndrome Approved and launched in US, EU, JPN; ODD in US, EU, JP Lennox-Gastaut syndrome Approved and launched in US, EU; ODD in US, EU, JP
	> 1.7 million patients globally*	> 500 000 patients globally*	>190 000 patients globally*	> 70 000 patients in the U.S*	> 3 000 patients globally**
	Otsuka (Japan – 2008-2020)	Daiichi Sankyo (Japan – 2014)		US only (in-licensed from Proximagen , 2018)	Acquisition of Zogenix, Inc. in 2022
	2008 (US) 2010 (EU) 2020 (Japan)	2022 (US & EU) 2024 (Japan)	2026 (US & EU)	2028 (US)	2033 (ODE US Dravet Syndrome) 2032 (ODE EU & Japan Dravet Syndrome)
	Peak sales: € 1.3 billion (2008)	Peak sales: € 1.5 billion (2021)	Peak sales guidance: € 600 million by 2026		Peak sales guidance: € 800 million by 2027

Focus on Epilepsy

>2.5 million*
epilepsy patients under care worldwide
in 2023

**UCB-originated epilepsy
medicines** touching the lives of
~40% of epilepsy patients in the
U.S. and Europe and of almost **~30%
of patients** in Japan

>250 interventional studies &
>25,000 patients enrolled
1 million compounds per drug
screening & **>6 targeted** projects in
early discovery pipeline

UCB's Portfolio of Epilepsy Solutions



Strategic Epilepsy Investments and Partnerships

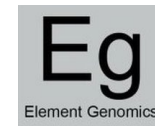
**Patient
Solution
Acquisitions**



**Drug
Discovery
Research**



Transcriptomic Big Data
Library in Epilepsy



**Digital
Health**



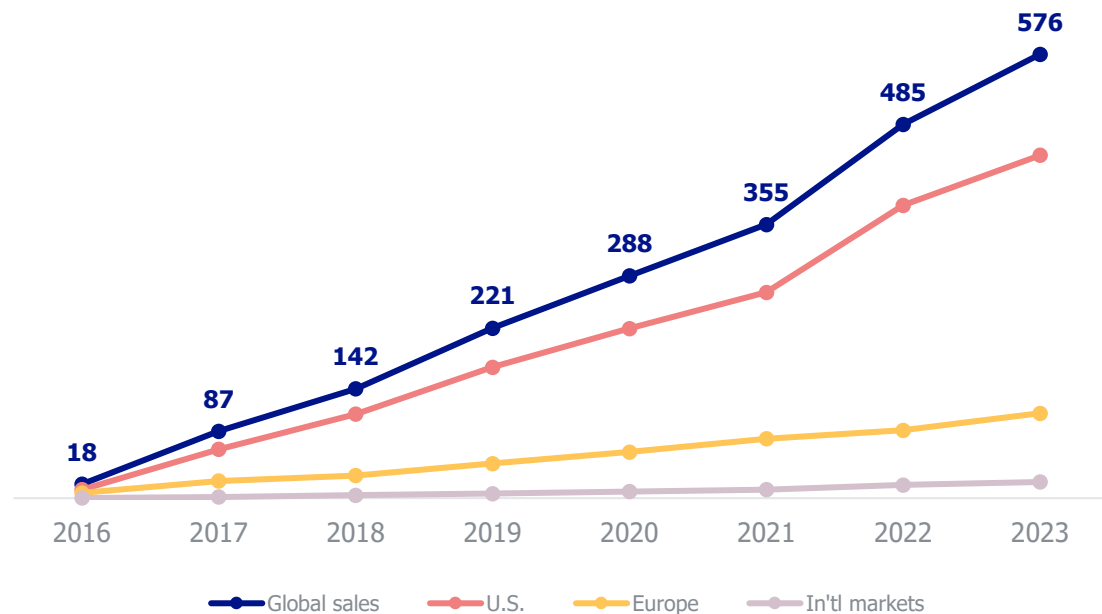
Focus on BRIVIACT®

Different mode of action from VIMPAT® and differentiates from KEPPRA®

Showed **significant growth** in all regions it is available to patients (19%; 21% CER)

Currently under **regulatory review** in Japan

BRIVIACT® Net Sales



Net sales in € million, FY numbers



Inspired by **patients.**
Driven by **science.**

UCB - FY 2023 Facts & Figures, February 2024

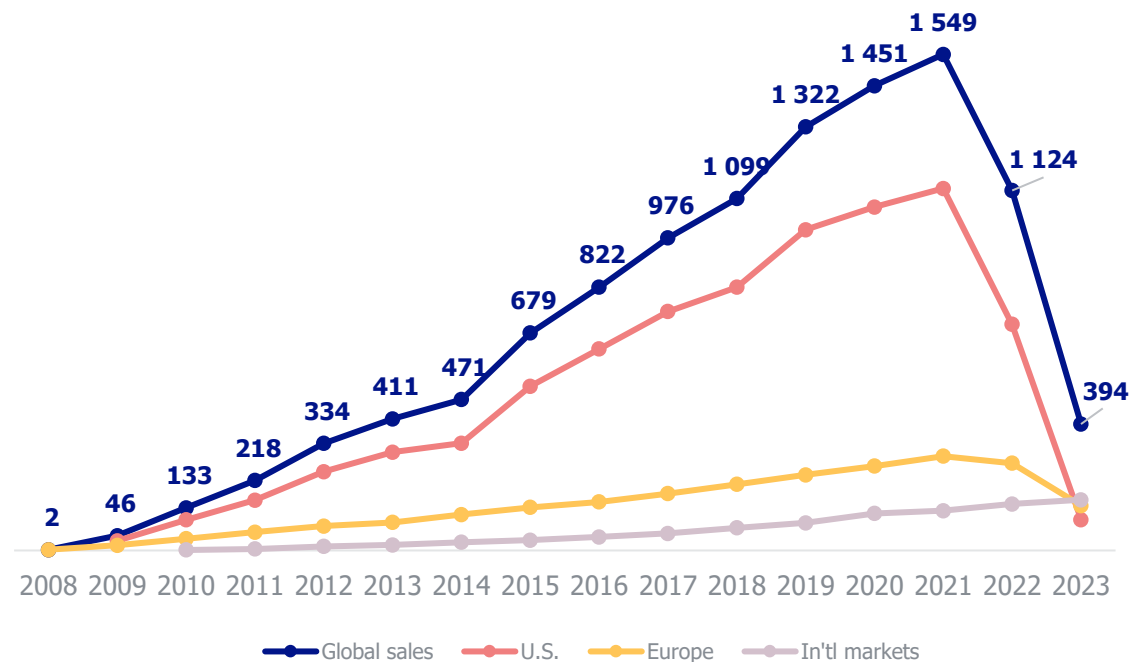
Focus on VIMPAT®

Experiencing **generic competition** since March **2022** in the U.S. and since September **2022** in Europe due to loss of exclusivity

Generic erosion has largely **bottomed** out in 2023

In **Japan**, the net sales show **continued growth**.

VIMPAT® Net Sales



Net sales in € million, FY numbers

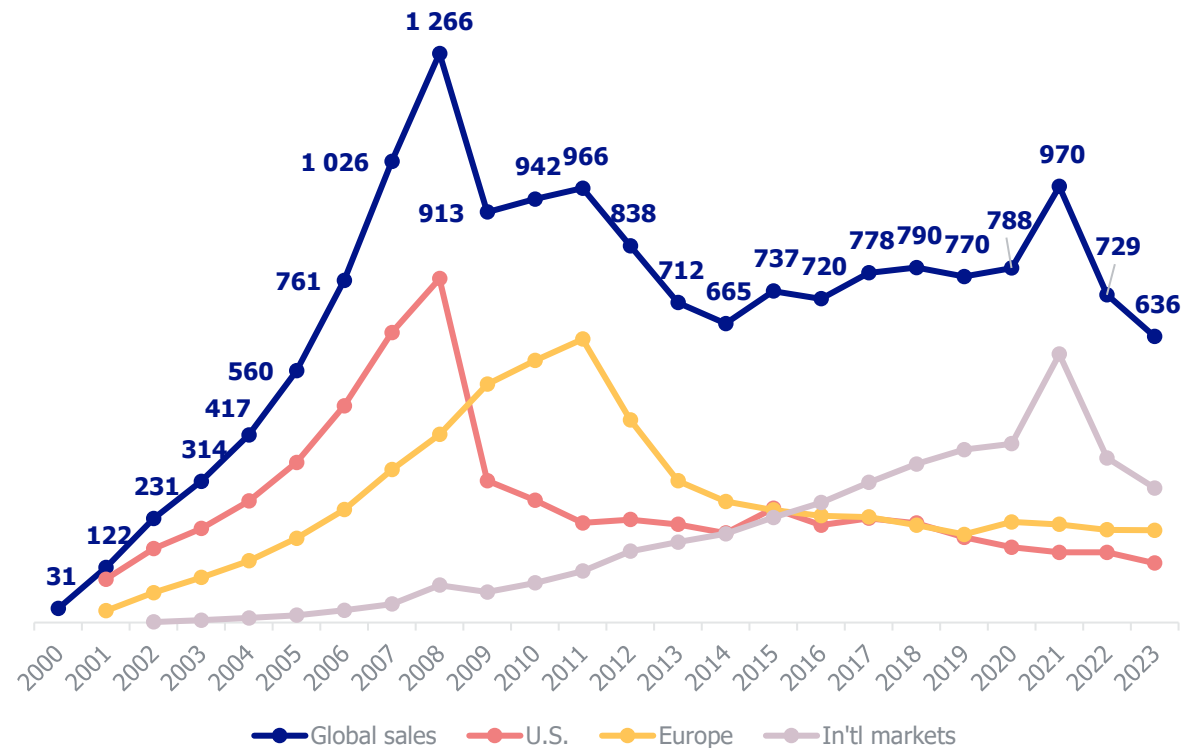
Focus on KEPPRA®

Inclusion of levetiracetam in the World Health Organization Model List of **Essential Medicines (WHO EML)**

KEPPRA® is **off patent** for **more than a decade** in markets other than Japan

Diminishing LOE effect in 2023

KEPPRA® Net Sales



Net sales in € million, FY numbers

Focus on FINTEPLA®

Unique and dual mode of action with antiseizure and non-seizure effects

New standards for Dravet syndrome and early treatment
Contributing to **strong heritage and leadership in epilepsy**

Following a settlement in a patent dispute, UCB is now considering **Q4 2033** as the loss of exclusivity in the U.S.

FINTEPLA® Indications

Dravet Syndrome (DS)

~12k - 15k

US, EU, JPN prevalence

>80% of patients remain uncontrolled on existing AED regimens

Premature childhood mortality, primarily SUDEP, of **~20%**

Standard of Care

Profound and sustained impact on seizures exceeding expectations of what could be possible in DS

Lennox-Gastaut Syndrome (LGS)

~60k - 100k






US, EU, JPN prevalence

Vast majority of patients on multi-drug treatment regimens of **2-5** ASMs as they experience multiple types of seizures, that change in type and frequency throughout life
Higher risk of status epilepticus and sudden death

The New Next Option

Proven efficacy on LGS's most challenging seizures proven efficacy as an adjunctive therapy

UCB's Immunology & Bone solutions

BIMZELX® (bimekizumab)	CIMZIA® (certolizumab pegol)	EVENITY® (romosozumab)
 <p>Psoriasis Approved in over 40 countries including US Psoriatic arthritis, radiographic and non-radiographic axial Spondyloarthritis Approved in EU in June 2023 and in Japan in December 2023 Under regulatory review in other geographies Hidradenitis suppurativa (HS) Submissions and regulatory reviews ongoing across geographies</p>	<p>For patients (including women of child-bearing age) living with</p> <ul style="list-style-type: none"> • Rheumatoid arthritis • Psoriatic arthritis • Psoriasis • (non-radiographic) axial Spondyloarthritis • Crohn's disease (US) 	<p>EU launch progressing Launched by Amgen and Astellas in Japan and by Amgen in US and ROW</p>
 <p>> 18 000 patients globally*</p>	<p>>180 000 patients globally**</p>	<p>> 600 000 patients since launch globally*</p>
	<p>Astellas (Japan – 2012) Cinkate (China – 2019)</p>	<p>Amgen (2020)</p>
 <p>2032 (US)*** 2036 (EU) 2037 (Japan)</p>	<p>2024 (US) 2024 (EU) 2026 (Japan)</p>	<p>2031 (EU & Japan) 2033 (US)</p>
 <p>Peak sales guidance: > € 4 billion</p>	<p>Peak sales guidance: > € 2 billion by 2024 – achieved already in 2022</p>	

Focus on BIMZELX®

Market leader in psoriasis **dynamic**
IL-17 markets

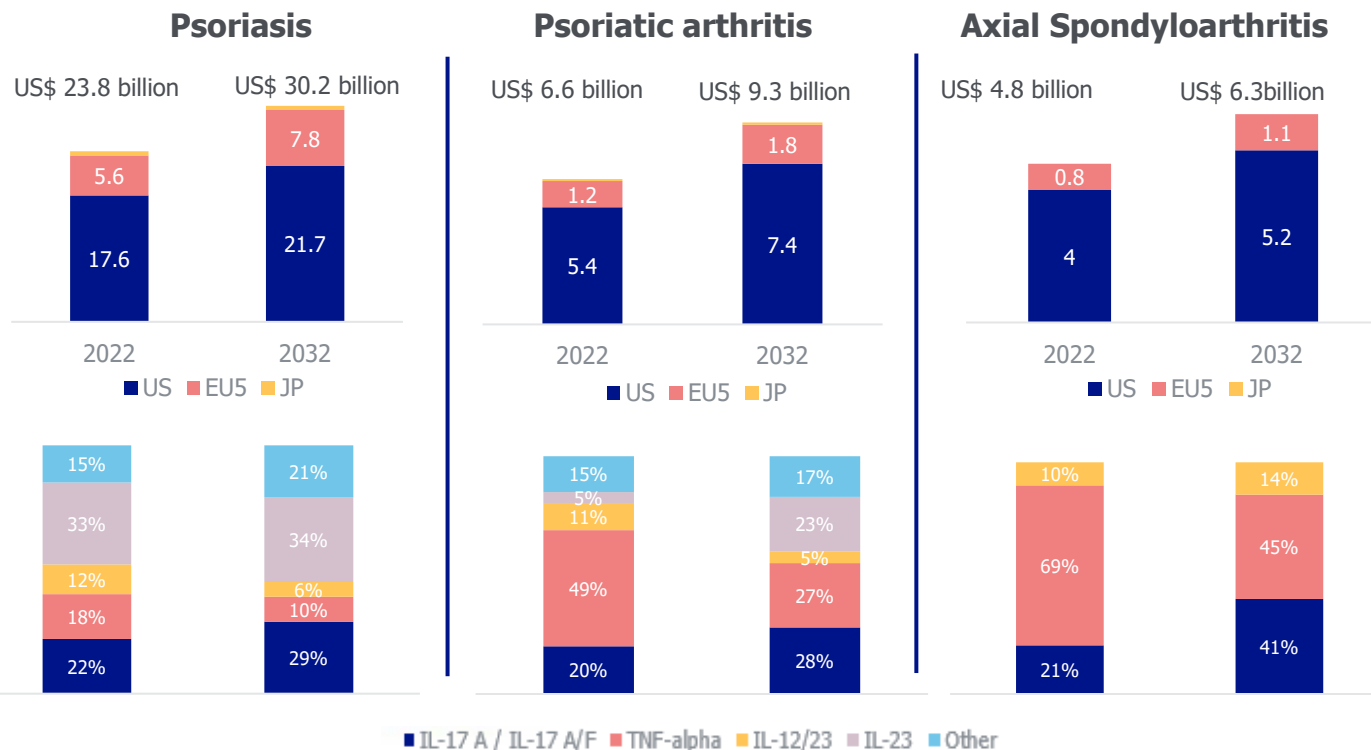


First and only IL-17A and IL-17F Delivers rapid, complete and maintained skin clearance from the first dose

Approved & launched in 2023

- ✓ US: PSO
- ✓ Europe & Japan: PsA and axSpA
- >18k patients** treated globally

Focusing On Growth Markets¹



BIMZELX® ex-U.S.

Accelerated Launch driven by Patient Experience and the Launch of PsA & axSpA

BIMZELX® Leading IL17 performance in PSO (excl. U.S.)
in less than 2 years

≥35%

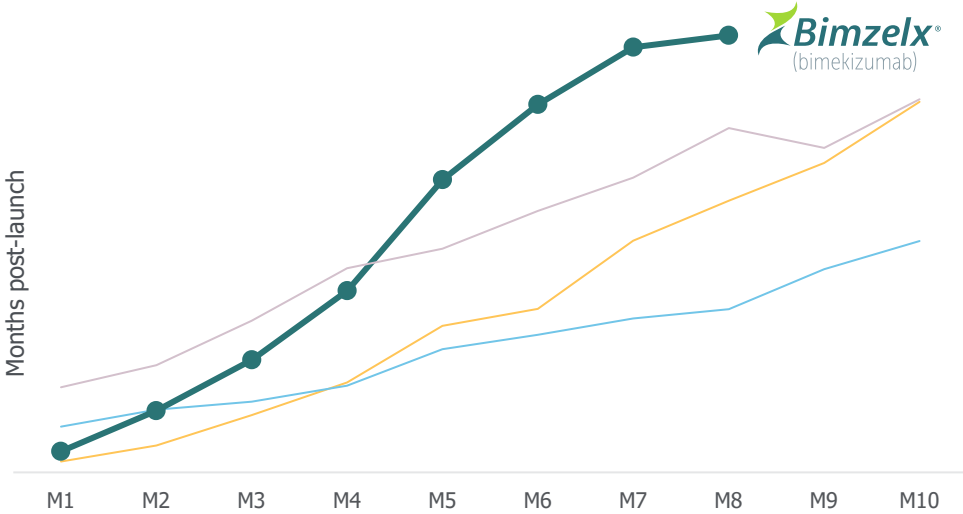
IL-17 Dynamic market share
at the end of 2023



Dynamic Share: Market share among switch and new patients. Source: IQVIA, UCB calculations based on internal and external sources

Number of patients using BIMZELX® in Europe
doubled over six months

BIMZELX® in Germany | PsA & axSpA
Launch Uptake vs. Analogues¹ (anti-interleukins)

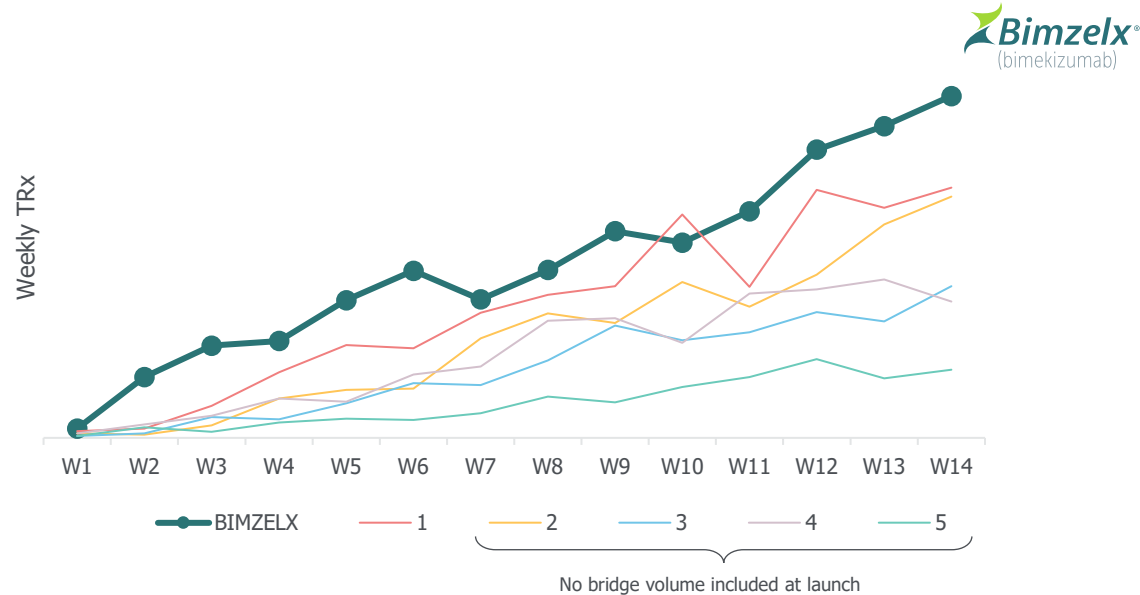


 **25%**
IL-17 dynamic market share in Germany
after **6 months**

BIMZELX® in U.S.

Strong start: Strategic Investment Behind the Launch

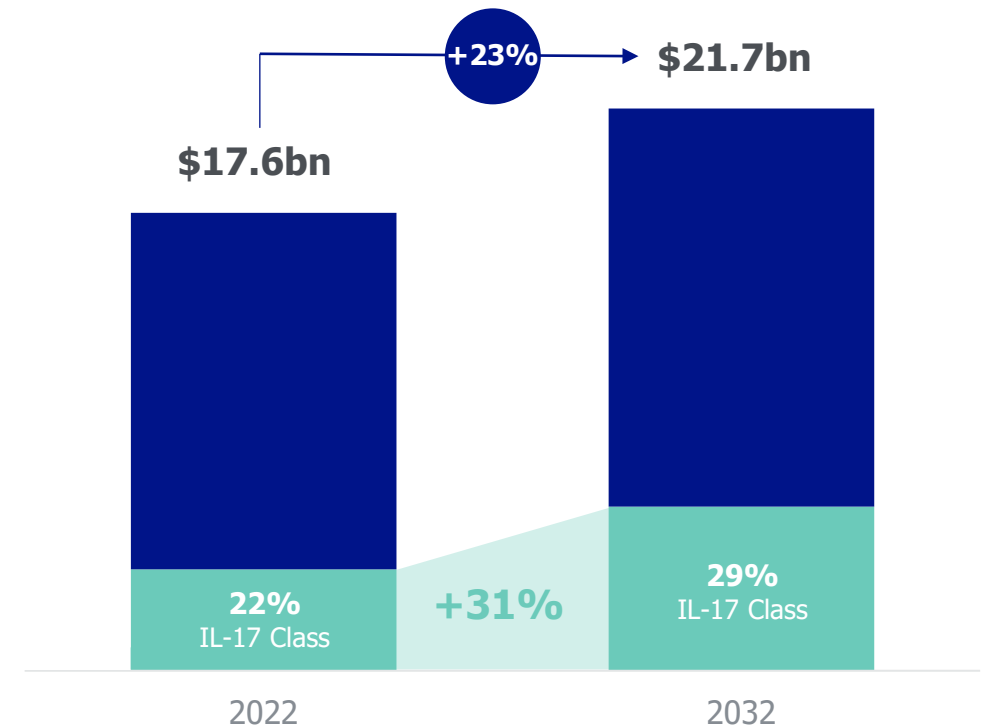
BIMZELX® in U.S. | Uptake in PSO
Psoriasis Launch Uptake vs. Analogues¹



Formulary access: BIMZELX® is covered and available for **6 out of 10 commercially insured lives**²

Paid to bridge ratio: already at 30%/70% with intent to increase to **50%/50% by Q4 2024**

Psoriasis U.S. Market Outlook³
BIMZELX® expected class leader³



Focus on CIMZIA®

Sustained growth for the last 16 years and reaching **€ 2bn** annual sales serving over **1.2 million** patients since launch

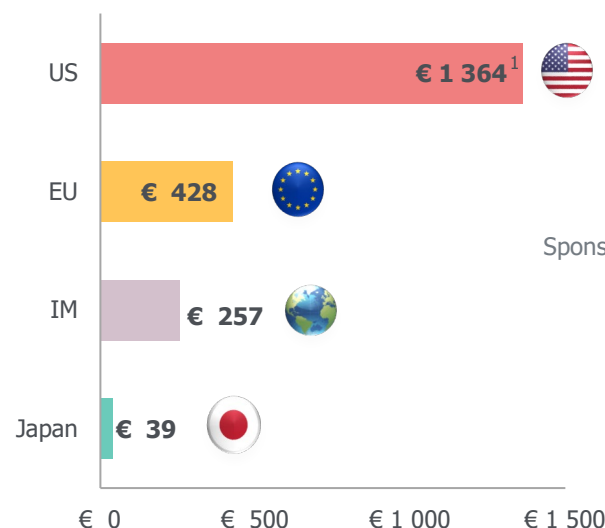
Continues to **grow** across all regions **faster** than **branded TNF-inhibitors** and the **anti-TNF market**

Unique Fc-free molecular structure drives personalized treatment for 2 targeted populations: **women of childbearing age** across indications and **RA** patients with high **RF** levels

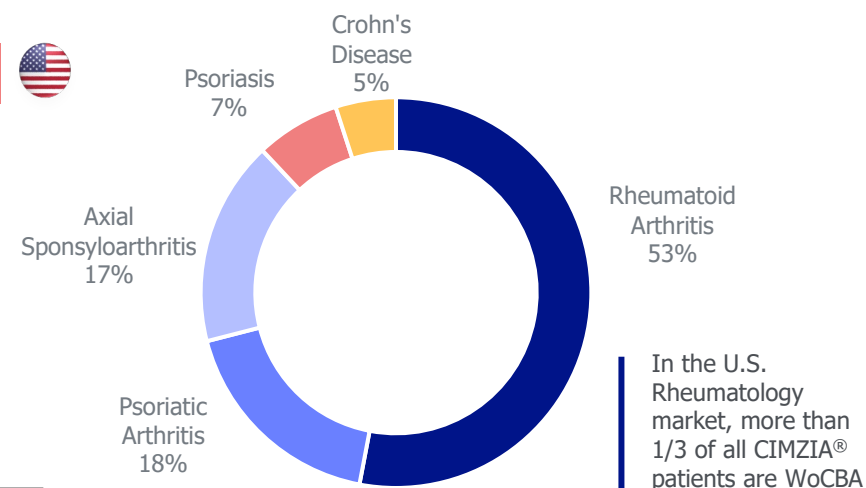
Expanded into **six indications**, including RA, ankylosing spondylitis (AS), also known as radiographic axial spondyloarthritis (r-axSpA), and non-radiographic axial spondyloarthritis (nr-axSpA), PsA, PSO, CD

CIMZIA®

Net Sales, by Region
€ 2 087M



Net Sales, by Segment



Focus on EVENITY®

First new osteoporosis approval since 2010

Market leader in the **bone-builder** market, annualizing at over **\$1bn**¹

Novel bone-forming agent with **dual effect** on bone, increasing bone formation and decreasing bone resorption

First after Fracture²

Superior fracture risk reduction when used for 12 months followed by alendronate

Convenient: 2 auto-injectors, once a month, for 12 months

EVENITY® contribution to UCB's P&L

	UCB	Amgen	Astellas
+ Net sales	European sales	US & RoW sales + intercompany sales to Japan	In-market sales Japan
- Cost of goods	European sales	US & RoW sales + intercompany sales to Japan	Intercompany sales to Japan
- Operating expenses	European sales and costs for future UCB market launches	US & RoW sales and costs for future Amgen market launches	Japanese sales
+/- Other operating income/expense	50% of profit outside Europe minus 50% of EU profit/loss ³	↔ 50% of EU profit/loss ³ minus 50% of profit outside Europe	
= Adj. EBITDA includes	50% of worldwide profit	50% of worldwide profit	

Due to lower European sales compared to world-wide sales, EVENITY® over-proportionally contributes to UCB's adjusted EBITDA



Focus on EVENITY®

Leading in U.S., Japan, South Korea, Australia, Canada, Belgium¹

Worldwide



Reach

> **600 000**

patients at high risk of fracture reached since launch¹

Europe



Market Share

Biggest BB market share in Belgium, Denmark, Germany, Sweden and Switzerland; on trajectory towards BB leadership (+50%)

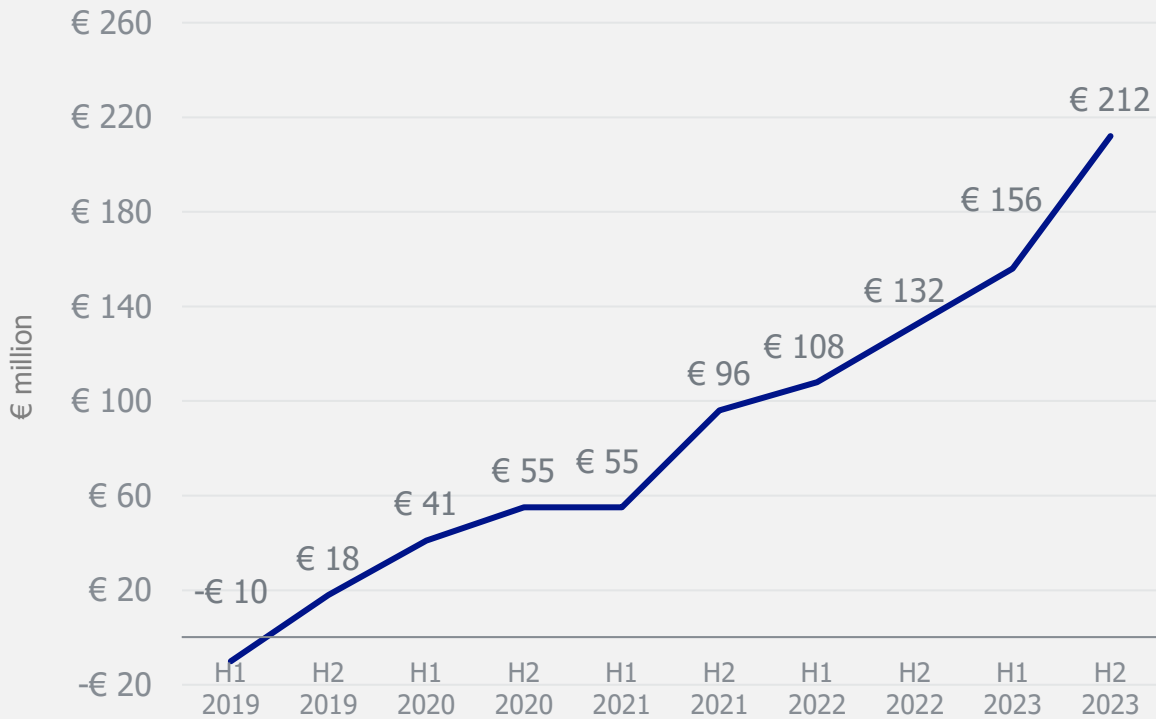
Net Sales

€ 60 M




sales in Europe in 2023

Amgen reported ex-EU sales 6 Feb 2024

Net Contribution from Amgen EVENITY® to UCB's P&L

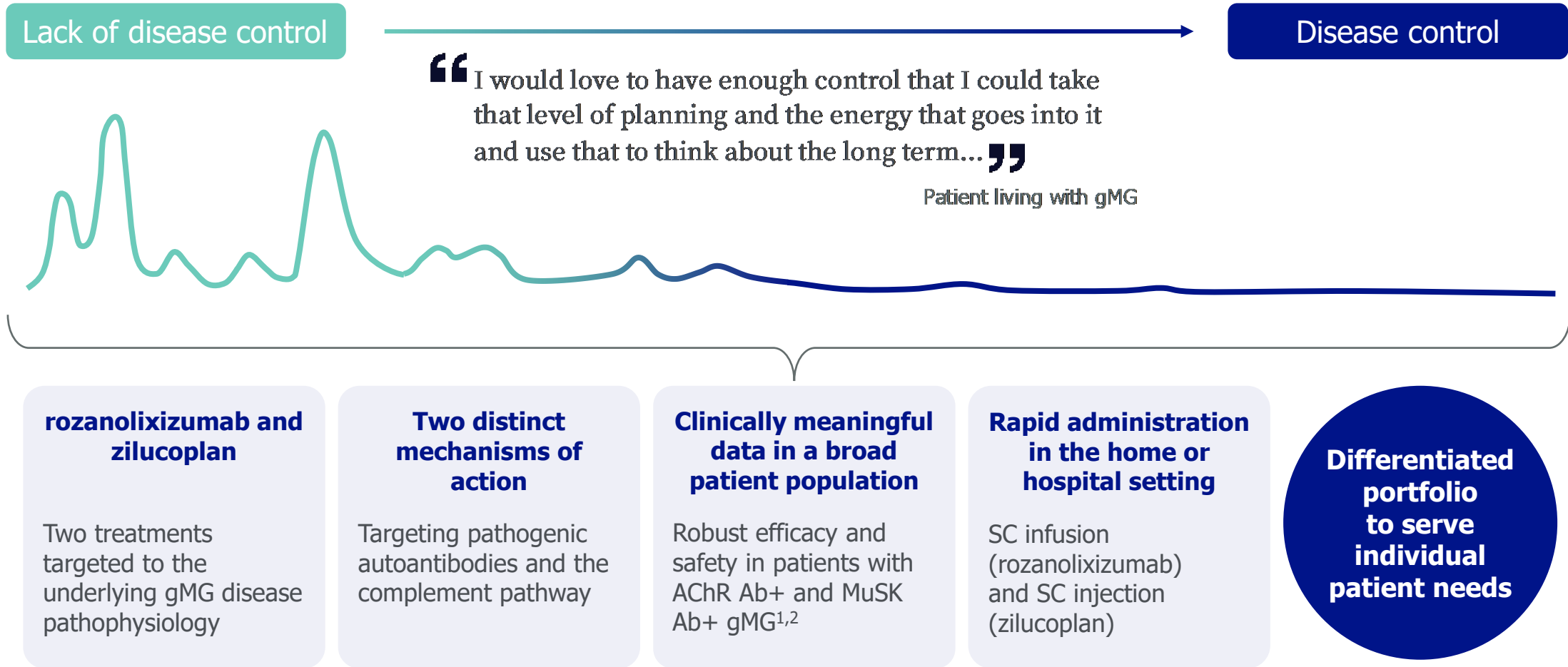


UCB's generalized Myasthenia Gravis solutions

RYSTIGGO® (rozanolixizumab)		ZILBRYSQ® (zilucoplan)	
	Anti-FcRn antibody to address pathogenic auto-antibodies AChR+ / MuSK+ patients SC, at-home self-admin cyclical therapy		Complement 5 inhibitor to address complement activation AChR+ patients SC, self-admin maintenance therapy
	In-house product		Acquired from Ra Pharma
	2033 (Japan)* 2034 (EU)* 2035 (US)*		2035 (US)* 2035 (EU)* 2035 (Japan)*

UCB in generalized Myasthenia Gravis (gMG)

Offering choice to patients living with an unpredictable and heterogenous disease to address individual needs



BIMZELX®

Bimekizumab: Clinical profile, Indications & Approvals

~6 000 patients included in clinical trials

Psoriasis (PSO)

3x superior
Superior levels of skin clearance compared to adalimumab, ustekinumab, and secukinumab in Ph3/3B trials. Responses achieved with bimekizumab were maintained for up to one year. Long-term data showed clinical responses were maintained in vast majority of patients through 4 years of bimekizumab treatment.

Approved in over 40 countries, other regulatory reviews ongoing

Psoriatic arthritis

Improvement in signs and symptoms were demonstrated with treatment in multiple aspects of PsA for both bDMARD-naïve patients and prior TNF α -inhibitor inadequate responders and sustained for up to 4.5 years

Approved in EU, GB, JP, SA and other regulatory reviews ongoing

Axial spondyloarthritis

(nr-axSpA & AS/r-axSpA)

Sustained efficacy across the full disease spectrum of axSpA in patients with AS up to 5 years and with nr-axSpA up to 2 years

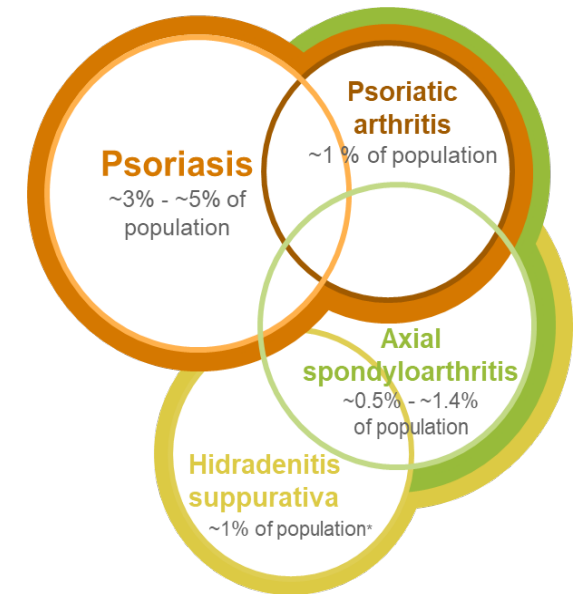
Approved in EU, GB, JP, SA, and other regulatory reviews ongoing

Hidradenitis suppurativa (HS)

Clinically meaningful improvements in HiSCR50 and more stringent endpoints of HiSCR75, HiSCR90, and HiSCR100 with improvements maintained or increased for patients from Week 16 through Week 48

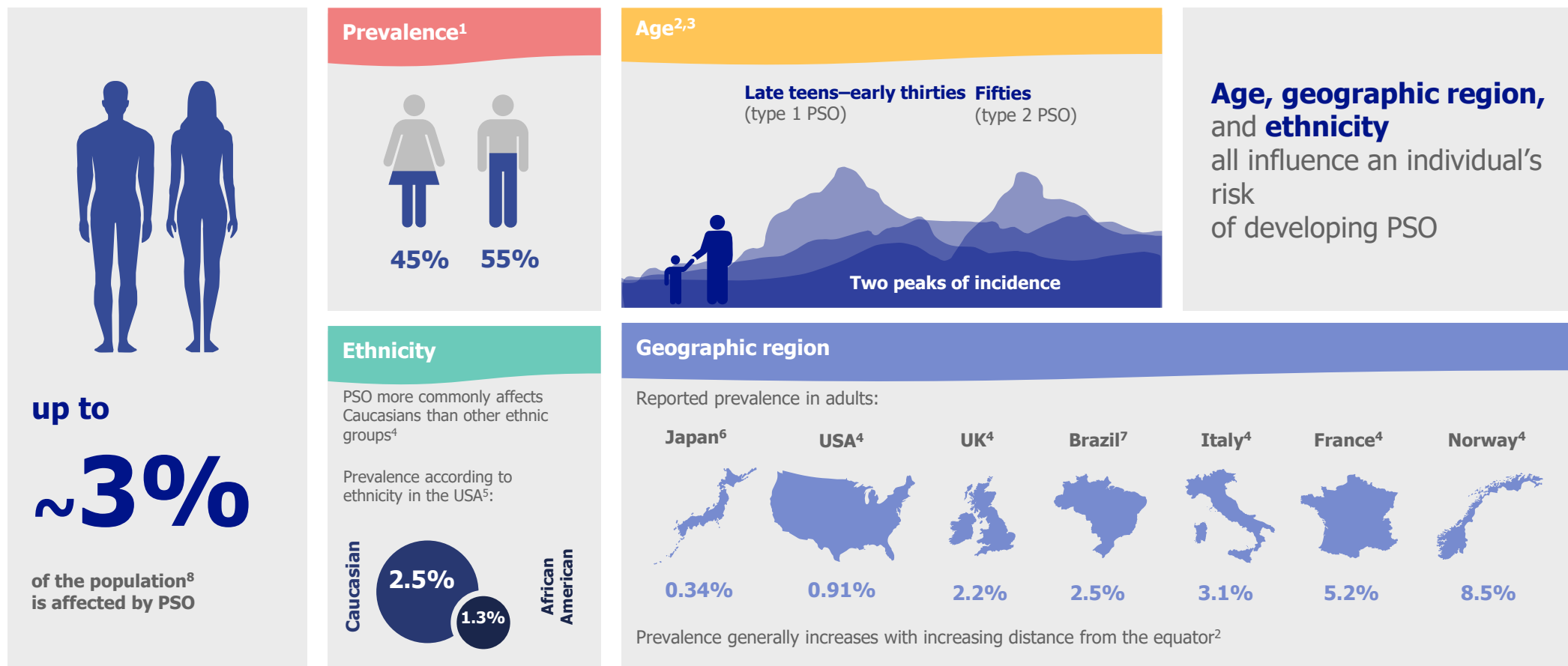
Submissions started Q3 2023

Spectrum of IL-17A+F-mediated diseases



Latest data can be found here: [Scientific Presentations, Abstracts, and Posters - Bimekizumab | UCB](#)

Psoriasis: High Prevalence Globally



Psoriatic Arthritis: High Unmet Need and Disease Burden

Psoriatic arthritis (PsA)

PsA is a complex disease with a **broad range of manifestations**, including swelling of the joints, entheses, and skin psoriasis¹⁻³

It is associated with **six key disease domains**⁴



Peripheral arthritis



Axial disease



Enthesitis



Dactylitis

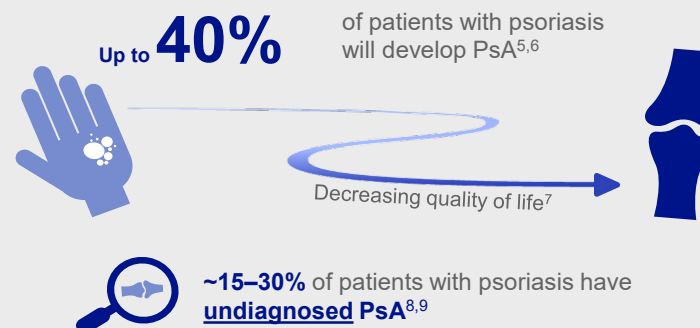


Skin



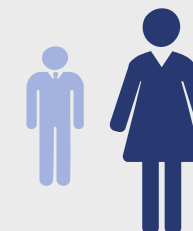
Nails

Disease progression

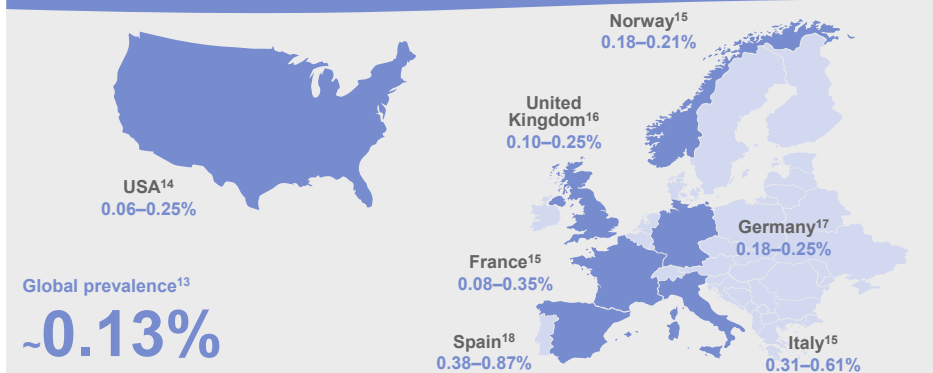


Gender differences

Diagnosis is delayed¹⁰ and outcomes are **worse in women**^{11,12}



Prevalence by geographic region



Burden of disease

Pain/swelling¹⁹



Itching⁷



Depression, anxiety and mental health^{11,20}



Difficulty with everyday activities²¹



Quality of life reduced^{20,21}



Approximately **1 in 3 patients** achieve **minimal disease activity criteria** in real-life studies with current treatments^{*22}





*Based on a study of patients in cross-sectional and cohort studies (n=39) fulfilling 5 out of the 7 MDA criteria: tender joint count (TJC) ≤1; swollen joint count (SJC) ≤1; psoriasis activity and severity index (PASI) ≤1 or body surface area (BSA) ≤3; patient pain visual analogue scale (pain VAS) score ≤15; patient global disease activity (global VAS) score ≤20; health assessment questionnaire (HAQ) score ≤0.5; and tender entheses points ≤16. 1. NHS. Psoriatic arthritis, 2019. Available at: <https://www.nhs.uk/conditions/psoriatic-arthritis/>. Accessed October 2020; 2 Ocampo DV et al. F1000Research. 2019;8:F1000 Faculty Rev-1665; 3 Gladman DD. F1000Research. 2016;5:2670-2670; 4 Coates LC et al. Arthritis Rheumatol. 2016;68(5):1060-1071; 5 Mease PJ and Armstrong AW. Drugs. 2014;74(4):423-441; 6 Gladman DD et al. Ann Rheum Dis. 2005;64 Suppl 2:ii14-17; 7 Kavanaugh A et al. Rheumatol Ther. 2016;3(1):91-102; 8 Villani et al. J Am Acad Dermatol. 2015;73:242-248; 9 Haroon M et al. Ann Rheum Dis. 2015;74(6):1045-1050; 10 Jovani V et al. PLoS One. 2018;13(10):e0205751; 11 Nas K et al. Ann Rheum Dis. 2019;78(Suppl 2):920-921; 12 Eder L et al. Ann Rheum Dis. 2013;72(4):578-582; 13 Scotti L et al. Semin Arthritis Rheum 2018;48(1):28-34; 14 Ogdie A and Weiss P. Rheum Dis Clin North Am 2015;41(4):545-568; 15 Alamanos Y et al. J Rheumatol. 2008;35:1354-1358; 16 Ogdie et al. Rheumatology. 2013;52(3):568-575; 17 Sewerin P et al. Ann Rheum Dis. 2019;78:286-287; 18 Pérez A et al. PLoS One. 2020;15(6):e0234556; 19 Lebwohl MG et al. J Am Acad Dermatol. 2014;70(5):871-881; 20 Salaffi F et al. Health Qual Life Outcomes. 2009;7:25; 21 Picchianti-Diamanti A et al. Qual Life Res. 2010;19:821-826; 22 Zardin-Moraes M et al. J Rheumatol. 2020;47(6):839-846.


What is Axial Spondyloarthritis (axSpA)?

axSpA is a **chronic, immune-mediated, inflammatory rheumatic disease** affecting the **sacroiliac joints (SIJ)** and **spine**¹⁻³

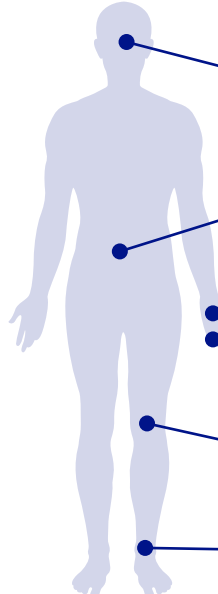
Key **patient** symptoms:¹

**Chronic back pain**

**Morning stiffness**

**Fatigue**

Key **non-axial** symptoms:⁴⁻⁸

**Uveitis**
30–40%

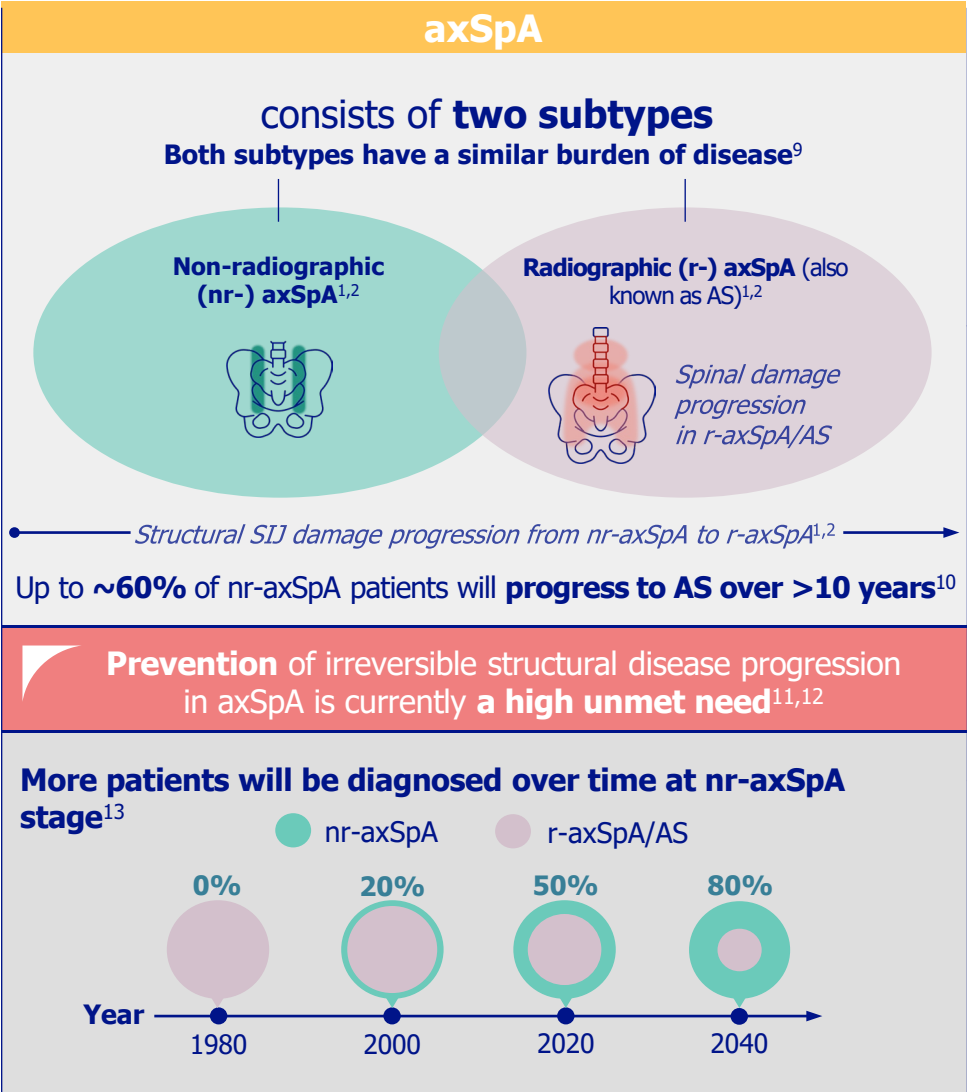
Inflammatory bowel disease (IBD)
5–10%

Psoriasis
~10–27%

Dactylitis
~6%

Peripheral arthritis
~40%

Enthesitis
~25%



Patients experience disease onset **before the age of 45**¹⁴

Average age of symptom onset is **28 years**¹⁵ — Patients typically have a delay in diagnosis of **8.5 years**¹⁴

axSpA affects **~20 million people globally**^{*2,16,17}

0.5–1.5% of adult population have axSpA, similar to Rheumatoid Arthritis¹⁸

There are **limited treatment options**

1st line: NSAIDs¹⁹

2nd/3rd line: TNF inhibitors, IL-17 inhibitors, and JAK inhibitors¹⁹

Hidradenitis Suppurativa (HS)

Under-recognized inflammatory disease with severe impact on people living with this disease



Hidradenitis suppurativa (HS)

A debilitating, chronic, inflammatory skin disease of the hair follicle that presents with painful, inflamed lesions in the armpits, genital area, groin, buttocks/anus, and breasts resulting in painful, inflamed lesions, lumps, cysts, scarring

DIAGNOSIS



Not Understood

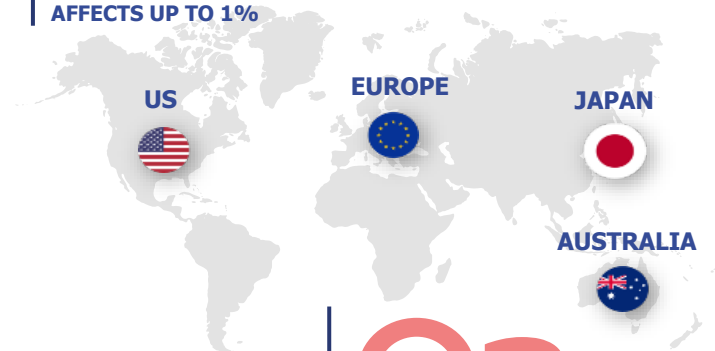
Significant delays in diagnosis ranging from

3.7–23.7 yrs.

Resulting in intense pain, progressive scarring, and psychological damage

PREVALENCE

AFFECTS UP TO 1%



♀ 3x

more **common in women** than men

SEVERE IMPACT ON QOL



MULTIPLE CO-MORBIDITIES



Inflammatory Bowel Disease (IBD)



Acne Vulgaris (AV)



Diabetes



Axial Spondyloarthritis (axSpA)

OTHER CO-MORBIDITIES


















Psychological Disorders
Metabolic Syndrome
Squamous Cell Carcinoma
Down Syndrome

REGULATORY & PIPELINE UPDATE

Cutting-edge Innovation Delivering Unprecedented Tally of Approvals

Approvals and Submissions

14 approvals
since January 2023

H1 2023		H2 2023		H1 2024
 FINTEPLA®  LGS EU	 BIMZELX®  PsA EU	 ZILBRYSQ®  gMG Japan	 BIMZELX®  PsA Japan	 RYSTIGGO®  gMG EU
 RYSTIGGO®  gMG US	 BIMZELX®  axSpA EU	 RYSTIGGO®  gMG Japan	 BIMZELX®  (nr)-axSpA, AS Japan	
	 E KEPPRA®  Young children Japan	 BIMZELX®  PSO U.S.	 ZILBRYSQ®  gMG  U.S., EU	

8 ongoing
regulatory reviews

H1 2023		H2 2023		H1 2024
 bimekizumab HS EU	 fenfluramine LGS Japan	 brivaracetam Japan	 bimekizumab HS Japan	 bimekizumab PsA, nr-axSpA, AS, HS

Cutting-edge Innovation Delivering Industry-leading Pipeline

- ✓ 8 new solutions
- ✓ 10 patient populations
- ✓ 12 clinical programs
- 11 news flows in 2024

		PHASE 1	PHASE 2	PHASE 3	TOPLINE RESULTS
	rozanolixizumab (FcRn inhibitor)				
	MOG-antibody disease				H2 2024
	Autoimmune encephalitis		Ph-2a		H1 2024
	Severe fibromyalgia syndrome		Ph-2a		H2 2024
	fenfluramine (5-HT agonist)				
	CDKL5 deficiency disorder				H2 2024
To improve survival and daily activity	doxecitine and doxribtimine (nucleoside therapy)				
	TK2 deficiency disorder				Submissions to begin mid-2024
To address the multiple manifestations of SLE	dapirolizumab pegol (anti-CD40L antibody)				
	Systemic lupus erythematosus*				Mid-2024
Major advances in epilepsy research ¹	STACCATO® alprazolam (benzodiazepine)				
	Stereotypical prolonged seizures				H1 2024
Potential first-in-class & best-in-class	bepranemab (anti-tau antibody)				
	Alzheimer's disease**		Ph-2a		H2 2024
Potential first-in-class & best-in-class	minzasolmin (α-syn-misfolding inhibitor)				
	Parkinson's disease***		Ph-2a		H2 2024
New pipeline addition	UCB0022 (D1 receptor positive allosteric modulators)				
	Parkinson's disease		Ph-2a		H1 2025
	UCB9741				
	Atopic dermatitis		Ph-2a		H2 2024
	UCB1381				
	Atopic dermatitis		Ph-2a		H2 2024

*In partnership with Biogen; 1st phase 3 study; **In partnership with Roche / Genentech; ***In partnership with Novartis; 5-HT = 5-hydroxytryptamin or serotonin; α-syn = alpha-synuclein; CD40L = CD40 ligand; C5 = complement component 5; CDKL5 = cyclin-dependent kinase-like 5; H = half-year; IL = interleukin; FcRn = Neonatal Fragment Crystallizable Receptor; MOG = Myelin Oligodendrocyte Glycoprotein; TK2 = Thymidine Kinase 2; ¹www.thelancet.com/neurology Vol 23 January 2024; Assets not currently approved by any regulatory authority

UCB - FY 2023 Facts & Figures, February 2024

UCB in Oncology

In partnership with Cancer Research UK (announcement in March 2023)

UCB6114 (ginisortamab)



Phase 2



Advanced malignancies



IgG4P monoclonal antibody that binds to grem-1



Post 2027

UCB4594



Phase 1 / 2



Advanced malignancies



Antibody targeting the immune checkpoint, human leukocyte antigen G, also known as HLA-G

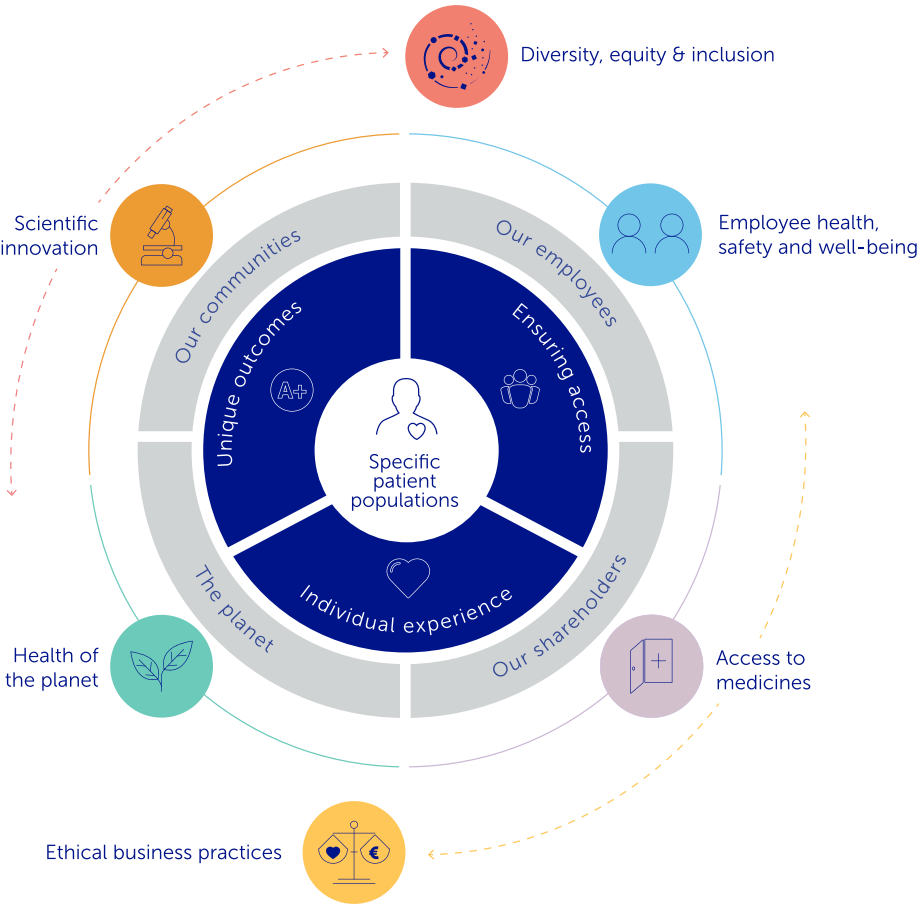


Post 2028

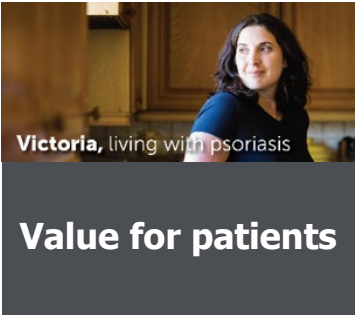
Oncology is outside of UCB’s core therapeutic areas of focus, which are neurology and immunology. However, UCB’s commitment to scientific innovation combined with UCB’s world-leading antibody discovery and development capabilities, has enabled UCB to take these programs forward in oncology. UCB now works with Cancer Research UK as UCB believes they provide the best possible way to progress these assets to patients.

SUSTAINABLE BUSINESS APPROACH

We See Sustainability as an Approach for Business Growth and Societal Impact



Our goals



Victoria, living with psoriasis

Value for patients

We aim to bring to patients **differentiated solutions with higher predictability of response and in 2030, all patients who need these solutions shall have access to them in a way which is viable for patients, society and UCB.**



Véronique, UCB

Value for people at UCB and our communities

We are creating the right conditions for **all UCB employees to thrive.**

We support **vulnerable populations** in the countries where we operate.



Value the planet

By 2030, we will be carbon neutral and we will have reduced our water consumption and waste production by respectively 20% and 25%.



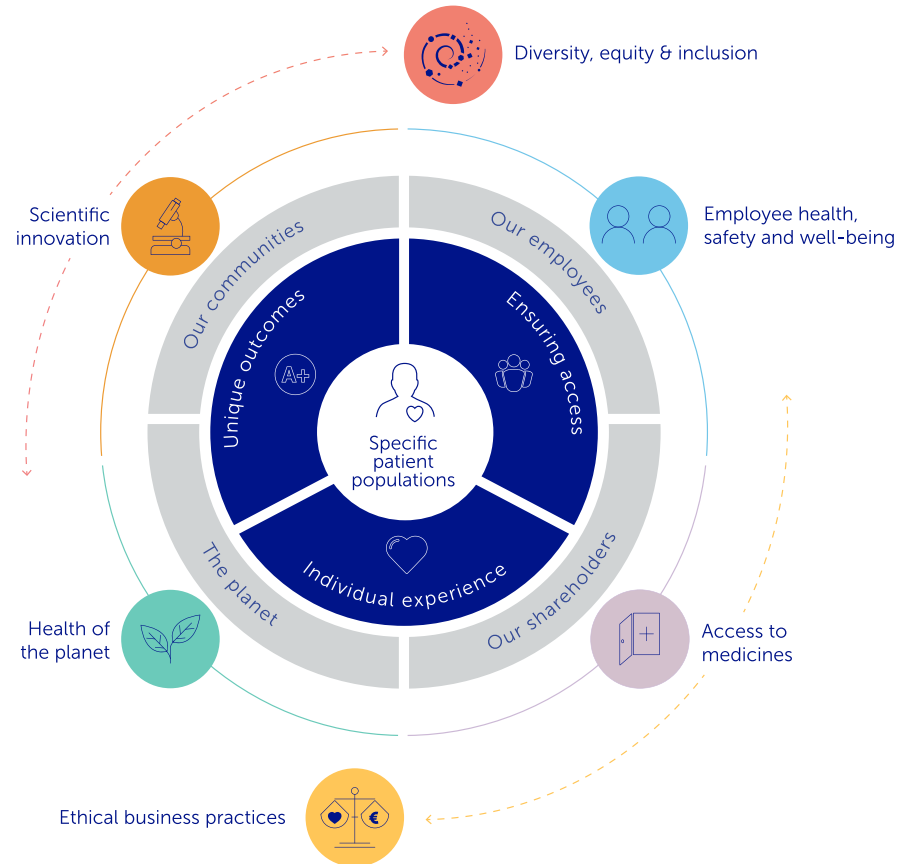
Value for shareholders

By 2025, we will lead in 5 specific patient populations

Our revenue are expected to reach of at **least € 6 billion** and our **adj. EBITDA margin to be in the low to mid-thirties.**

We will have **improved significantly our ESG rating performance.**

Driving Sustained Growth while making a Positive Impact on Society¹



Value for patients

- ✓ **>3.2 M** patients
- ✓ **68%** reimbursement coverage achieved for UCB medicines
- ✓ **50%** earlier positive decisions on reimbursement than industry benchmark



Value for people at UCB

- ✓ **81.5%** for our Health, Safety and Wellbeing index
- ✓ **38%** women at executive level
- ✓ **70.3%** inclusion index results



Value for our communities

- ✓ **>160** global academic non-commercial partnerships
- ✓ **210** publications
- ✓ **€9 million** distributed to 204 projects supported by the UCB Community Health Fund since 2020



Value the planet

- ✓ **-55%** CO2 emissions we directly control vs. 2015
- ✓ **59.4%** emissions by our suppliers with Science-Based-Targets alike



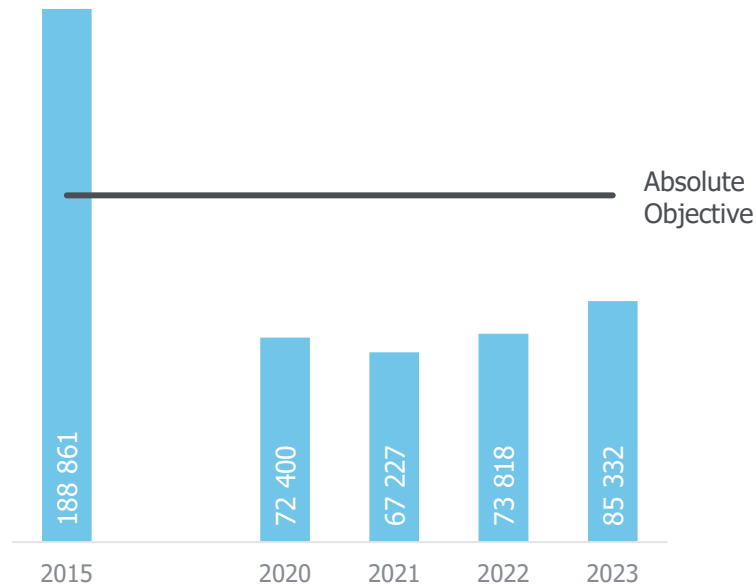
Value for shareholders – 2023 results

- ✓ **€ 5.25 bn** revenues
- ✓ **€ 1.35 bn** adjusted EBITDA
- ✓ **17.3** as Sustainalytics rating (low risk)

UCB Green Strategy

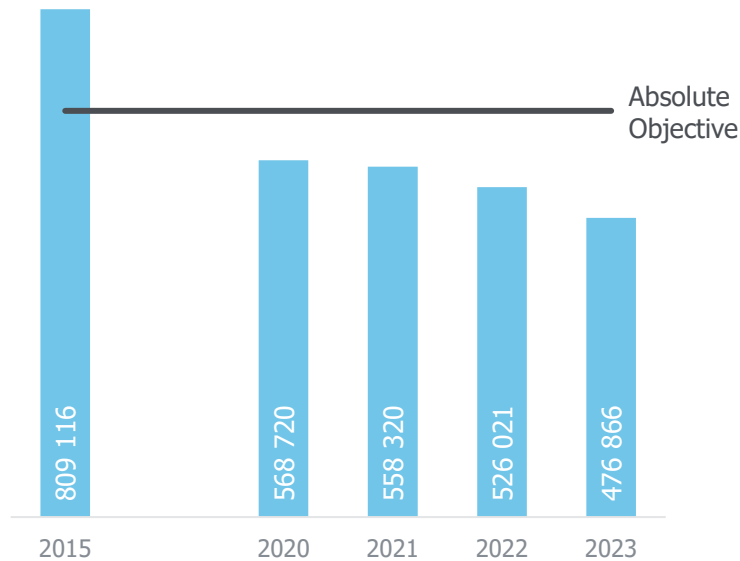
Our environmental targets by 2030
Reductions in absolute numbers against 2015 baseline

CO₂ emissions - 55% since 2015



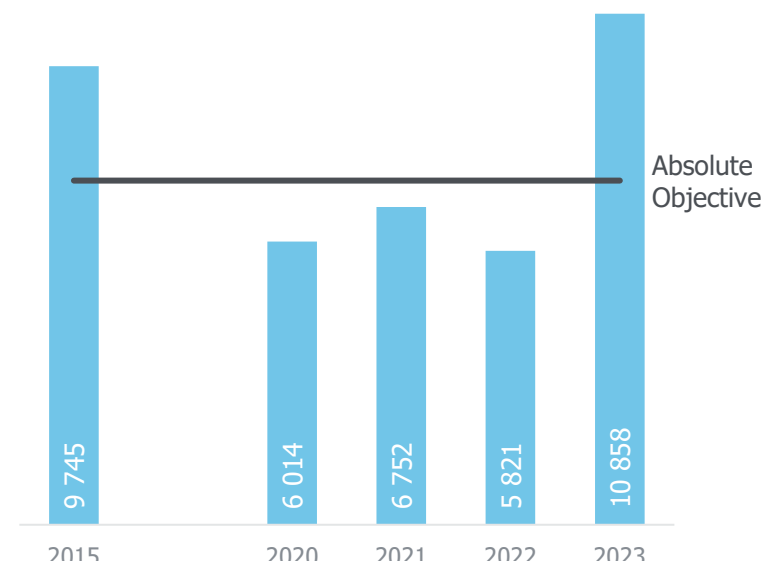
CO₂e emissions (tons)
2030 Objective -35%

Water consumption -41% since 2015



Water consumption (m³)
2030 Objective -20%

Waste production +11% since 2015



Waste production (tons)
2030 Objective -25%

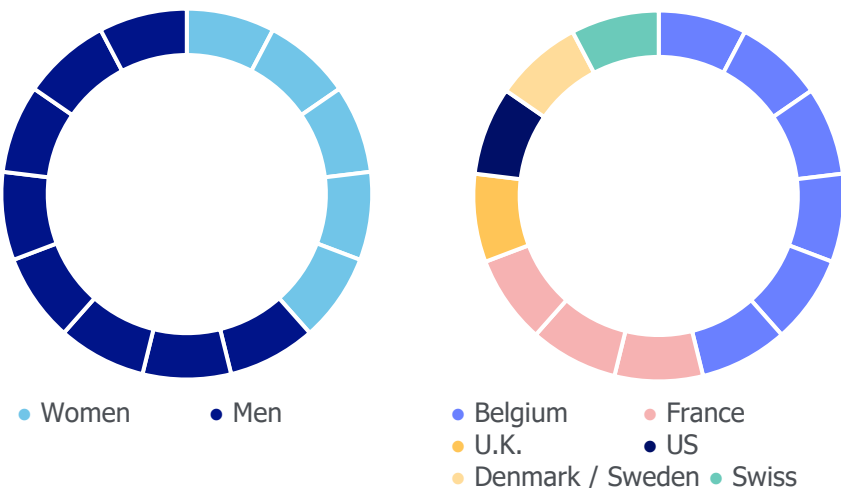
GOVERNANCE & SHAREHOLDING

Corporate Governance

Board of directors & Executive committee

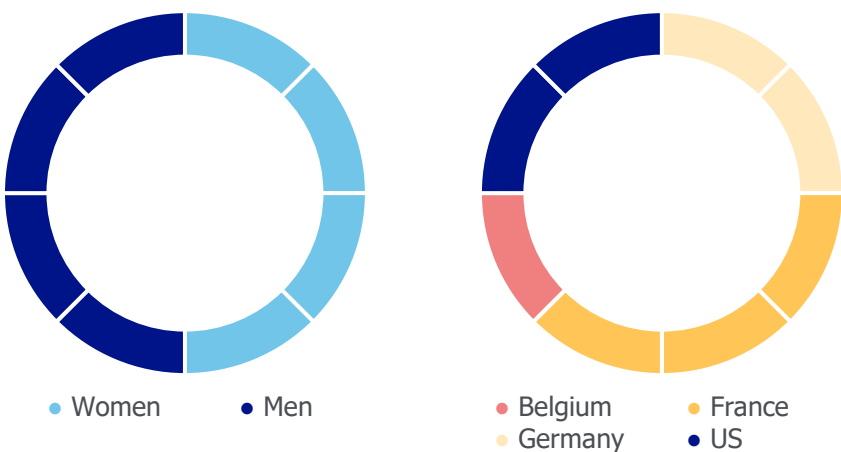
Board of directors

- **13 members**
 - Mandate: 4 year
 - Age limit: 70
- **5 women (38%)**
- **7 independent directors (54%)**
- **6 nationalities**



Executive committee

- **8 members**
 - Jean-Christophe Tellier, CEO since 2015
- **4 women (50%)**
- **4 nationalities**



Corporate Governance

Executive committee headed by Jean-Christoph Tellier

- **8 members**
- **4 women (50%)**
- **4 nationalities**



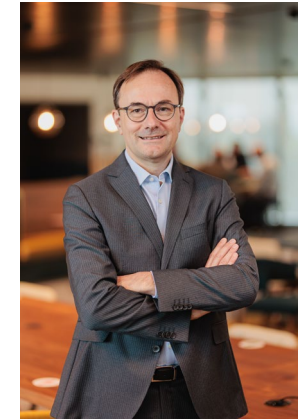
JL Fleurial,
CHRO



S. Dufour,
CFO



D. Waynick Johnson
General Counsel



E. Caeymaex,
Immunology Solutions &
Head of U.S



JC Tellier,
CEO*



D. Patel,
CSO



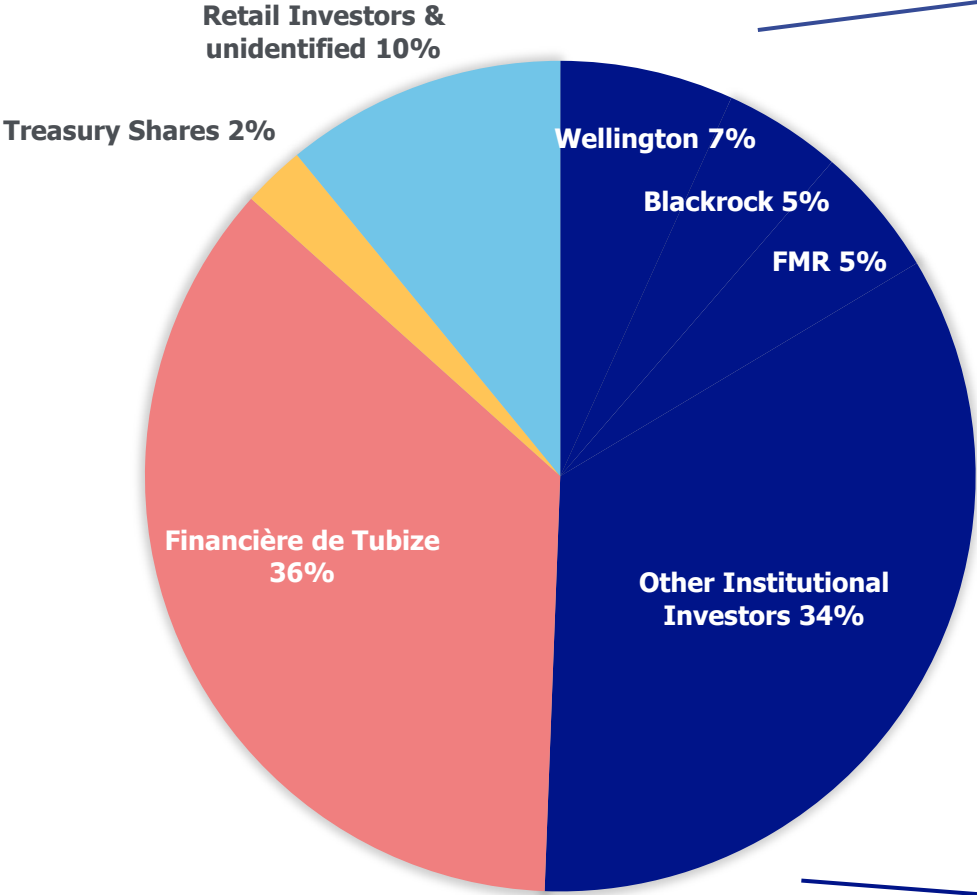
I. Loew-Friedrich,
CMO



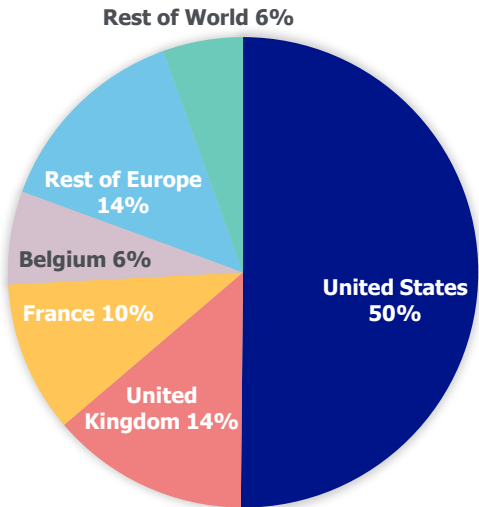
K. Lund-Jurgensen,
Supply & Technology
Solutions

*Ad interim: JC Tellier,
Neurology Solutions &
Head of EU / International

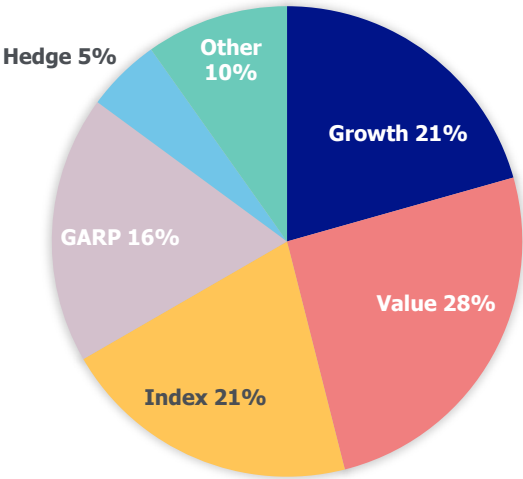
Shareholder Distribution



Institutional investors:
geographic distribution



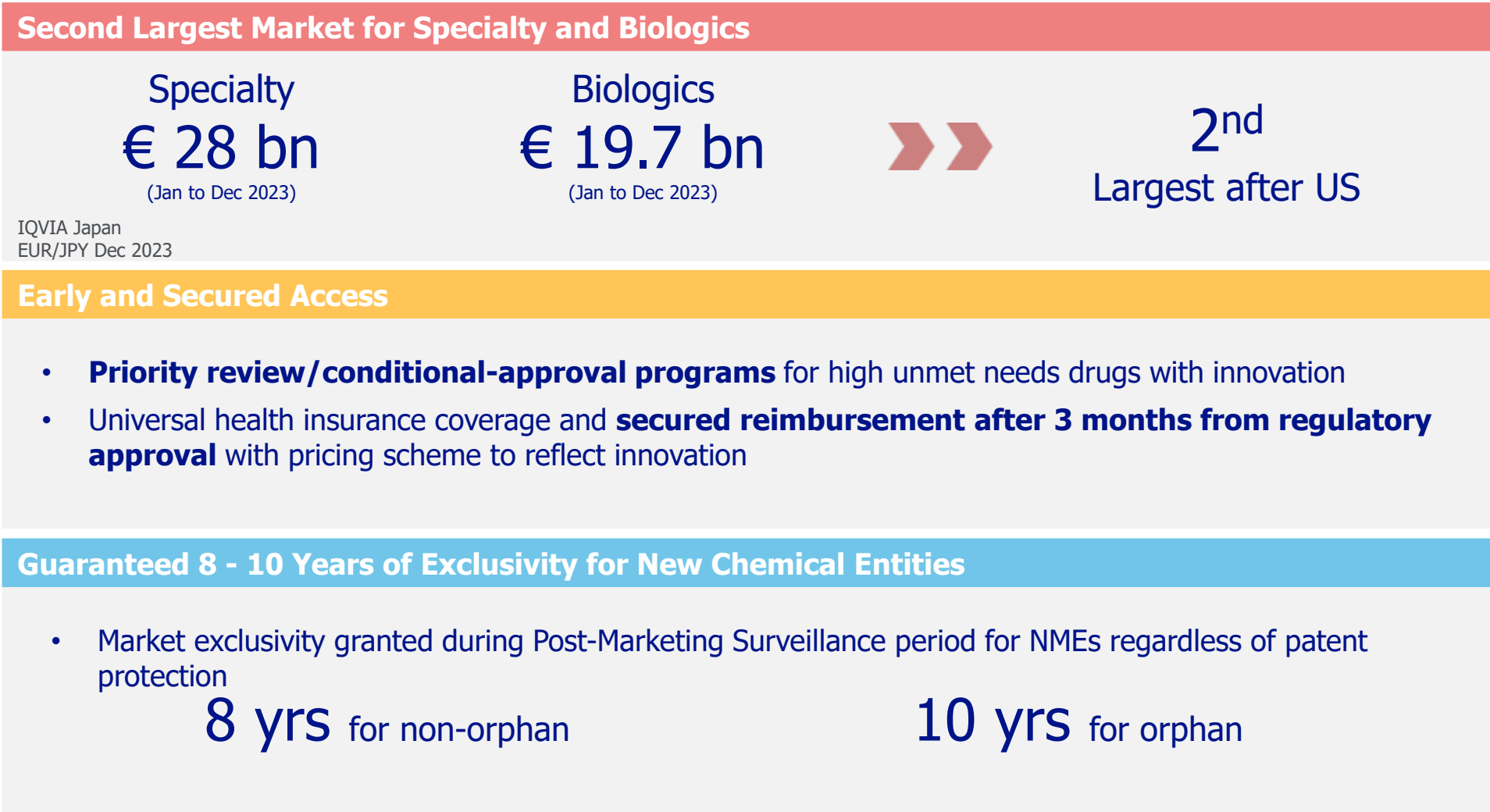
Institutional investors:
investment style



FOCUS ON JAPAN

Japan Market Environment for Innovation

Large specialty and biologics market, early and secured access, and guaranteed market exclusivity



UCB Japan – 7 Launches

Evolution in organization & commercial capabilities

Growth in Size and Diversity

Employees (as of Dec 2023)

580
6.4% of Global UCB
x1.4 in 5 yrs

% Female Manager (Expected March 2024)

21%
vs. industry average 13.5%

x1.5 in 3 yrs
50% female newly hired managers Jan 2024 – Mar 2024

Transformation to Solo Business

Shift **from partnering to solo business** started in 2020

End-to-end **capability and business process** established





- Sales and Marketing
- Manufacturing and Supply Chain Management
- Distribution
- IT infrastructure
- Data and Analytics

Overview of approvals & launches

Product	Approval	Launch
ZILBRYSQ®	Sep 2023	Q1 2024
RYSTIGGO®	Sep 2023	Nov 2024
BIMZELX® – PsA	Dec 2023	Dec 2023
BIMZELX® – axSpA	Dec 2023	Dec 2023
FINTEPLA® – LGS	Reviews ongoing, expected feedback 2024	
BRIVIACT®		
BIMZELX® – HS		

DEEP-DIVE CLINICAL PIPELINE & DISEASE AREAS

Rozanolixizumab: Potential in Multiple IgG Autoantibody-Mediated Diseases With High Unmet Medical Need

	Myelin oligodendrocyte glycoprotein (MOG)-antibody disease	Autoimmune encephalitis (AIE)	Severe fibromyalgia
	<ul style="list-style-type: none"> Auto-antibodies targeting MOG leading to inflammatory demyelination in the CNS 	<ul style="list-style-type: none"> Auto-antibodies targeting the LGI1 protein on healthy cells in the CNS leading to localized swelling and inflammation 	<ul style="list-style-type: none"> Pathogenic IgG accumulation in dorsal root ganglia recently associated with severe fibromyalgia
	<ul style="list-style-type: none"> Monophasic or relapsing course of neurological dysfunction including optic neuritis (ON), transverse myelitis (TM), and acute disseminated encephalomyelitis (ADEM) Temporary and residual permanent disability (in particular, blindness, reduced visual acuity and limited mobility, as well as residual permanent bladder issues, bowel and erectile dysfunction) 	<ul style="list-style-type: none"> Cognitive impairment Seizures (including faciobrachial dystonic seizures, other focal seizures, and tonic-clonic seizures) Hyponatremia Sleep disorders 	<ul style="list-style-type: none"> Chronic (>3months) and widespread pain Hypersensitivity to pain stimuli Chronic fatigue Sleep disturbance Cognitive impairment
	~ 1 - 4 / 100 000	~ 0.7 / 100 000	~ 200 cases / 100 000 (diagnosed severe fibromyalgia)
	<ul style="list-style-type: none"> No approved therapy No formal treatment guidelines established 	<ul style="list-style-type: none"> Immunotherapy and symptomatic therapy including antiseizure medications PEX, IVIg 	<ul style="list-style-type: none"> US: pregabalin, duloxetine and milnacipran JPN&CHN : pregabalin EU: nil approved <p>G7 off-label: antidepressants, ASMs, IVIg, PLEX</p>

Systemic Lupus Erythematosus (SLE)

Lupus is a chronic **disease** that can cause **inflammation** in any part of your body. It's an autoimmune disease, which means that the immune system attacks healthy tissue instead of fighting infections. Lupus most commonly affects: **skin, joints, internal organs**, like your **kidneys and heart**. Because lupus affects many parts of the body, it can cause a lot of different symptoms¹.

Mortality & Life expectancy

SLE is the **#1 cause of death** among autoimmune diseases **in women aged 15 –24** in the US²

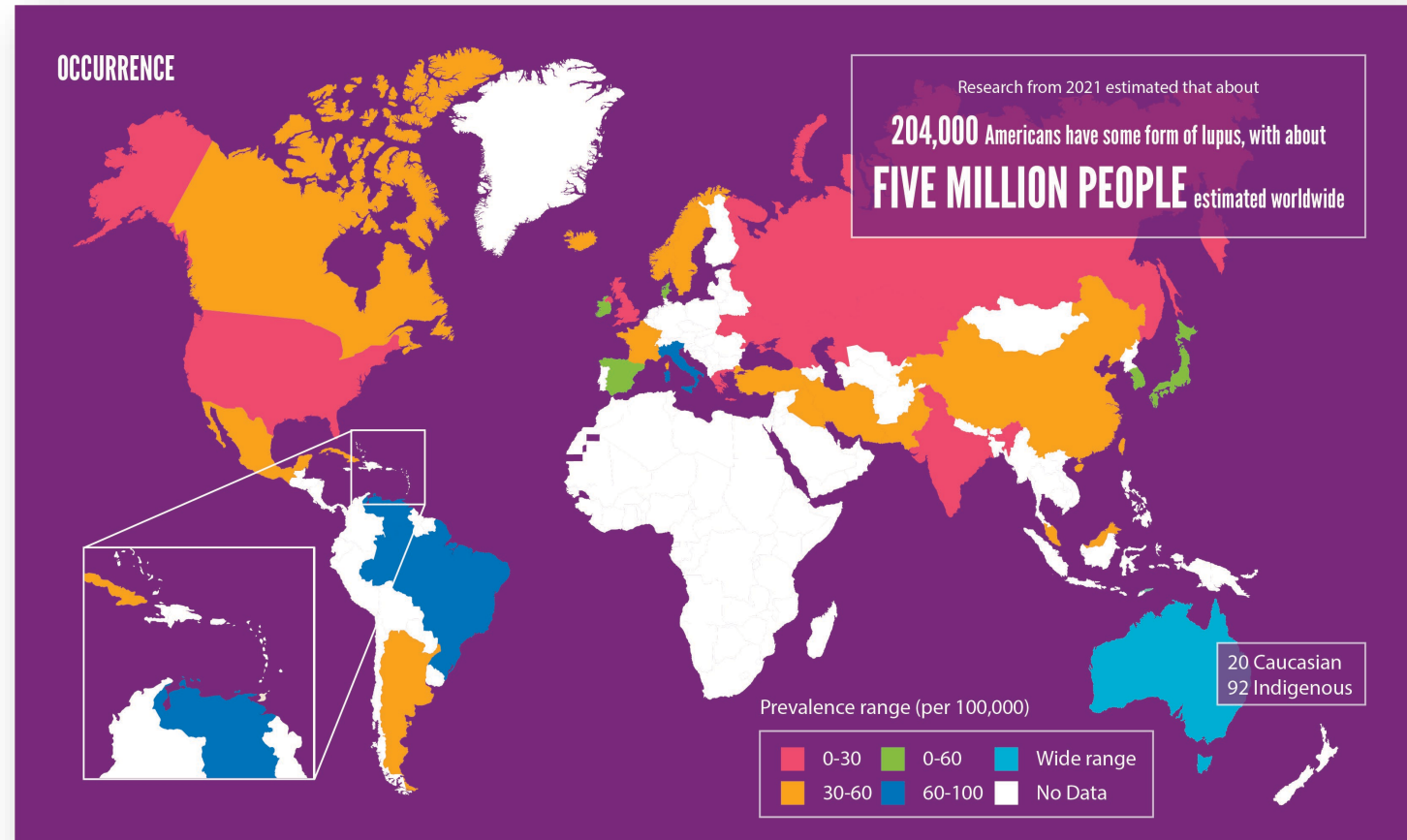
However, due to **improved** diagnosis and **disease management**, most people with lupus can expect to **live a normal life span**

High unmet medical need

Focus on underserved patient population

Minorities:

- often have more severe disease
- are underrepresented in clinical research
- experience unique challenges accessing health care



SLE Disproportionately affects Underserved Populations

Epidemiology

Anyone can develop lupus. However, certain people are at higher risk, including:

Women

90% are women, of those, 50% are women of childbearing age¹ between 15 – 45

Certain racial/ethnic groups

two to three times more prevalent among people who are African American, Asian American, Hispanic/Latino, Native American, or Pacific Islander

20 % of people with lupus will have a **parent** or **sibling** who already has lupus or may develop lupus. About **5% of the children born to individuals with lupus** will develop the illness.

5 million

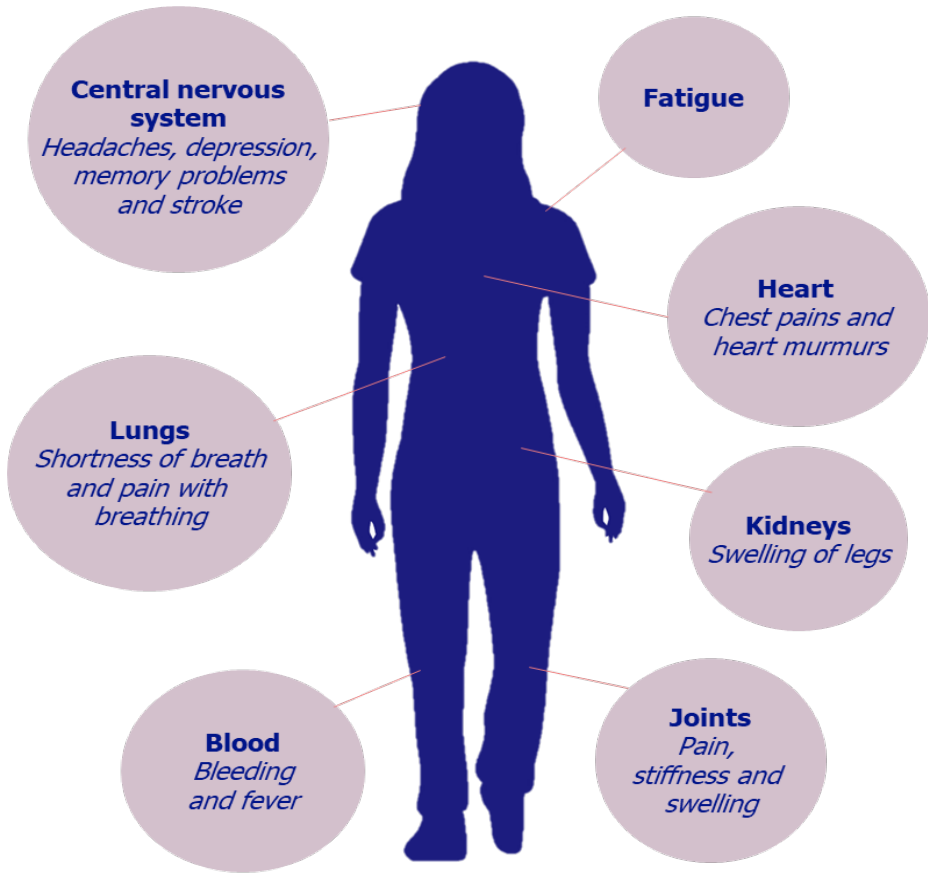
People affected by SLE globally

1 in 3

Lupus patients suffer from multiple autoimmune diseases

90% of people with SLE are women¹

Common Symptoms of SLE²



Dapirolizumab Pegol Phase 3 Clinical Development Program

50/50 partnership with Biogen; topline results of 1st Phase 3 study mid-year 2024

PHOENYCS GO

(SL0043)

[NCT04294667](#)

312 patients

1 dosing regimen
(dose not
disclosed) vs.
placebo



Primary endpoint: BICLA response @ week 48
To evaluate the ability of DZP as an add-on treatment to SOC medication to achieve clinically relevant long-term improvement of moderate to severe disease activity

Partnership With Novartis Leverages UCB Sciences

Sharing high-risk, high-reward, and investments needed for disease-modifying therapies in **Parkinson's disease**



Minzasolmin

Potential first-in-class, small molecule, alpha-synuclein, misfolding inhibitor

Partnered with Novartis²
(December 2021)



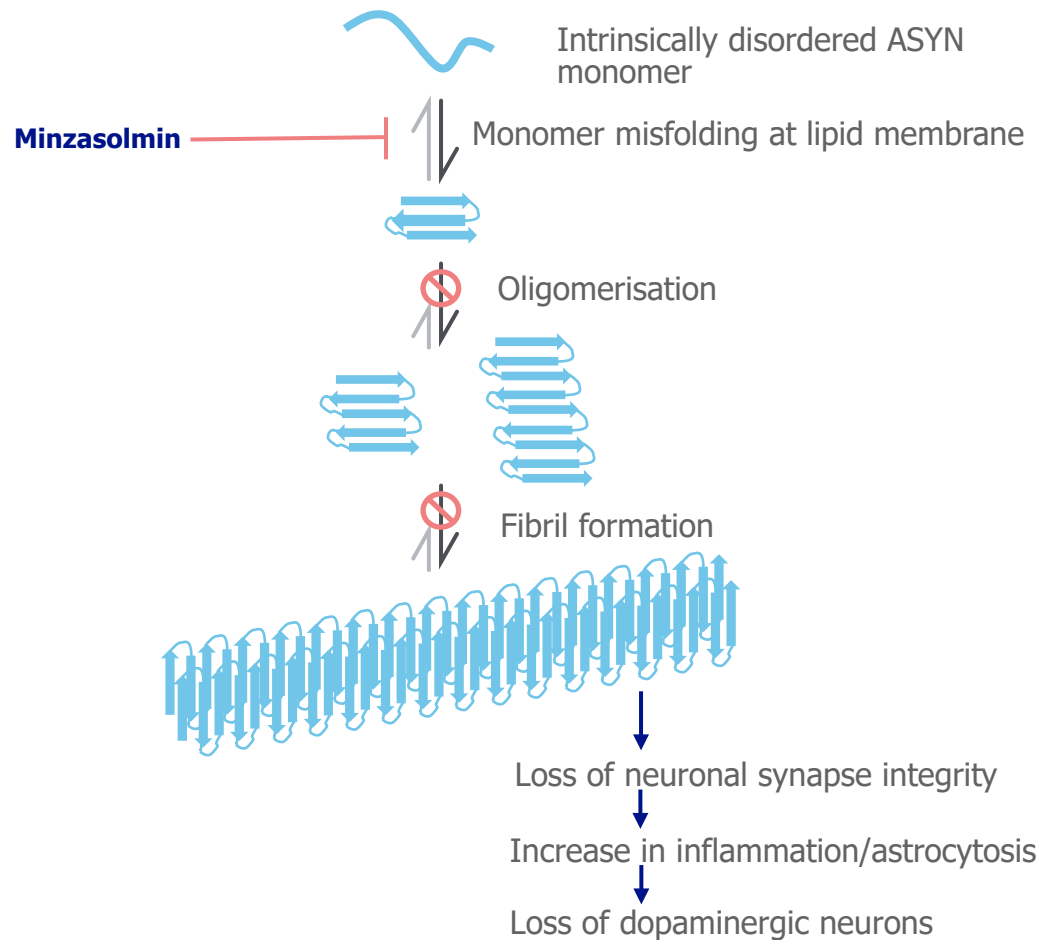
10m people are living with **Parkinson's Disease (PD)** worldwide¹

High unmet need given lack of disease-modifying therapies



- UCB received **upfront payment** (US\$150m) and is eligible to receive further potential payments with a total consideration approaching **US\$1.5 bn³**
- If approved, **commercial responsibilities** will be **split**, with UCB being the marketing authorization holder and commercial lead in **Europe** and **Japan**, and Novartis in the US and all other territories

Minzasolmin is an Oral Small Molecule Inhibitor of ASYN Misfolding



Minzasolmin

- Minzasolmin is an oral small molecule that **binds to ASYN early** in the pathological aggregation process^{1,2}
- Minzasolmin is thought to **prevent the initial misfolding of ASYN** that leads to fibril formation and consequent progression of PD¹⁻⁵
- A **Phase 2** study is underway to evaluate the efficacy of Minzasolmin in slowing **disease progression** in patients with early-stage Parkinson's disease (ORCHESTRA study; PD0053; NCT04658186)⁶⁻⁸

ASYN = α -synuclein; PD = Parkinson's disease;

¹ Genius. Poster P8476 at the 73rd Annual Meeting of the AAN, Virtual Conference, 17–22 April 2021; ² Maguire. Oral presentation OPP-093 at the 7th Congress of the EAN, Virtual, 19–22 June 2021; ³ Chen et al. PNAS. 2015; 112: E1994–E2003; ⁴ Cardinale et al. Int J Mol Sci. 2021; 22: 6517; ⁵ UCB Data on File, Investigator's Brochure, Sep 2020. ⁶ ClinicalTrials.gov

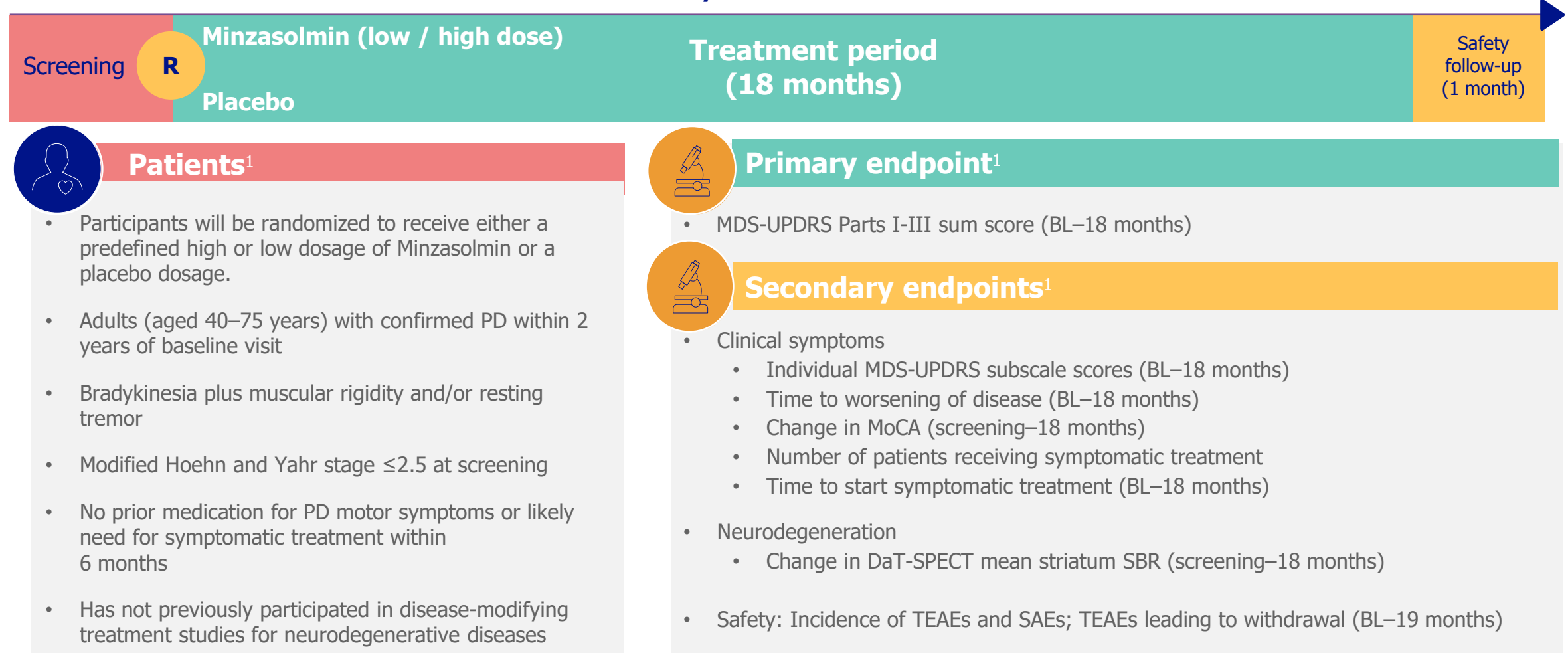
<https://clinicaltrials.gov/ct2/show/study/NCT04658186#studydesign>; ⁷ ORCHESTRA Study <https://orchestra-study.com/en-uk/about-clinical-studies/>; ⁸ UCB Clinical Trial PD0053

<https://www.ucb.com/clinical-studies/Clinical-Trials?studyId=PD0053>; Minzasolmin is an investigational product currently in clinical development and has not been approved by any health authorities worldwide.

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A Phase 2, Proof-Of-Concept Study of Minzasolmin in Early Parkinson's Disease (The Orchestra Study; PD0053) is Underway

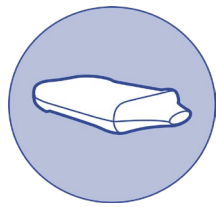
NCT04658186¹ / EudraCT 2020-003265-19²



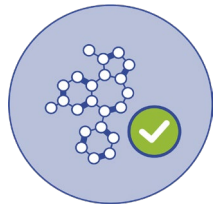
BL = baseline; DaT-SPECT = Dopamine Transporter Imaging with Single Photon Emission Computed Tomography; EU = European Union; MDS-UPDRS = Movement Disorder Society Unified Parkinson's Disease Rating Scale; MoCA = Montreal Cognitive Assessments; PD = Parkinson's disease; R = randomised; SAEs = Serious Adverse Events; SBR = Specific Binding Ratios; TEAEs = Treatment-emergent Adverse Events;
¹ ClinicalTrials.gov <https://clinicaltrials.gov/ct2/show/study/NCT04658186>; ² EU Clinical Trials Register <https://www.clinicaltrialsregister.eu/ctr-search/search?query=2020-003265-19>; Minzasolmin is an investigational product currently in clinical development and has not been approved by any health authorities worldwide.

Developing STACCATO® *alprazolam* for Rapid Cessation of an Ongoing Seizure in Patients With Stereotypical Prolonged Seizures

STACCATO® *alprazolam* is a drug-device combination for inhalation of alprazolam, administered by a patient or care giver in an out-patient setting, to rapidly terminate (within 90 seconds) an ongoing seizure.



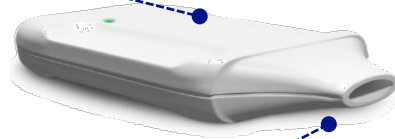
STACCATO® delivery technology:
FDA- and EMA-approved^{1,2}



***alprazolam*:**
a well-known benzodiazepine³



Delivers *alprazolam*
with a single, normal breath, to potentially terminate an ongoing seizure in <90 seconds²



Potential to deliver on-demand, rapid seizure termination for **20 - 30% of people** living with epilepsy



The STACCATO® system rapidly vaporizes alprazolam to form an aerosol, with particle size designed for deep lung delivery to produce a rapid, systemic effect



Phase 2b clinical trial completed (end 2019); **Phase 3 started Q4 2021; topline results in H1 2024**



UCB to perform further clinical development, regulatory filings, launch and commercialization

STACCATO® *alprazolam* is an investigational product and is not approved for any indication by any regulatory authority in the world. STACCATO® *alprazolam* requires additional studies before any conclusions for safety and efficacy can be made. Image is for illustrative purposes only. EMA, European Medicines Agency; FDA Food and Drug Administration.

¹ Alexza Pharmaceuticals. Staccato® One Breath Technology. Available at <https://staccatoobt.com> (accessed November 2020); ² UCB. Data on file. Engage Therapeutics. It's About Time: Finding The Power to Terminate Epileptic Seizures. April 2020. Confidential Overview; ³ French JA, et al. *Epilepsia* 2019;60:1602-609. UCB - FY 2023 Facts & Figures, February 2024

STACCATO® *alprazolam* Phase 3 Clinical Development Program

STACCATO® *alprazolam* is an orally inhaled investigational therapy with the potential to rapidly terminate an ongoing seizure.

EP0162 / [NCT05077904](#)

A Study to Test the Efficacy and Safety of STACCATO® alprazolam in Study Participants 12 Years of Age and Older With Stereotypical Prolonged Seizures

Maximum of 250 participants randomized to a single dose of STACCATO® *alprazolam* or placebo

Primary outcome measures:

- Treatment success for the treated seizure within 90 seconds after investigational medicinal product administration
- Treatment success for the treated seizure with no recurrence after 2 hours

EP0165 / [NCT05076617](#)

A Study to Test the Safety and Tolerability of STACCATO® alprazolam in Study Participants 12 Years of Age and Older With Stereotypical Prolonged Seizures

Approximately 250 participants will be treated with STACCATO® *alprazolam*

Primary Safety objective:

- Frequency of adverse events (all adverse events, serious and those leading to discontinuation)

EP0162 Study Periods:



Fenfluramine Offers New Hope for Individuals and Families Living with Challenging Developmental Epileptic Encephalopathies (DEEs)

CDKL5 Deficiency Disorder (CDD)	
~4k - 5k US, EU, JP prevalence	
Nearly three-quarters of individuals with CDD take 2 or more ASMs simultaneously	
>70% of patients experience daily seizures	
Many individuals at high risk of SUDEP	
Phase 3 trial ongoing	Topline results H2 2024
Novel, complementary MOA with demonstrated impact on refractory seizure disorders	

CDKL5 Deficiency Disorder (CDD)

An ultra-rare, severe developmental epileptic encephalopathy with onset in early infancy, high unmet need, and limited treatment options ^{1,2,3}

Cyclin-dependent kinase like-5 (CDKL5) deficiency disorder (CDD)

CDD can manifest in a broad, complex range of clinical symptoms and severity.³ The hallmarks are early-onset epilepsy and neurodevelopmental delay impacting cognitive, motor, speech, and visual function. In 90% of patients, early onset of seizures are observed in the first year of life, usually at six weeks of age.⁴ The highly refractory nature of epilepsy in CDD puts many individuals with CDD at **high risk for SUDEP** (Sudden Unexpected Death in Epilepsy).¹⁰

DIAGNOSIS Not Understood

The cause of CDD is not known at this time. CDKL5 gene mutations have been found in children diagnosed with Infantile Spasms, West Syndrome, Lennox-Gastaut syndrome, Rett Syndrome, cerebral palsy, autism, and intractable epilepsy of unknown origin.⁴

CDD by the Numbers

- 2.36 estimated incidence per 100,000 live births
- <1,000 individuals with CDD in the world are known to patient registries
- >80% of children experience daily seizures
- 6 weeks median age at onset of seizures, 90% by 12 months of age ^{5,7,9}

♀ 4x
more common in girls than boys

Types of Seizures

- Most common initial seizure type at onset was tonic seizures, followed by infantile (or epileptic) spasms and generalized tonic-clonic seizures, and focal seizures
- Over time, epileptic spasms, followed by tonic, myoclonic, and then generalized tonic-clonic are the most common seizure types

Severe impact on QOL



Seizures

- 56% of individuals have between one and five seizures per day
- 15% of individuals have more than five per day⁵



Cortical visual impairment



Gross motor, fine motor, and communication skills are extremely impaired



Sleep and gastrointestinal disturbances reported in 87% of patients



Respiratory symptoms like aspiration and lower respiratory tract infections



Musculoskeletal problems, such as scoliosis, can also occur⁵

Impact on Caregivers

- Increasing child sleep disturbances also have a negative impact on caregiver emotional wellbeing⁵
- Caregivers often give up their careers in order to provide their children a wide range of treatment and multidisciplinary care to manage the symptoms of CDD⁷
- The broad range of symptoms and health conditions, diagnosis, and access to syndrome-specific family support can be considerably delayed, adversely affecting caregiver wellbeing and possibly also the family quality of life⁸

- Infantile (epileptic) spasms, abnormal waves, irregular spikes, and developmental regression are more commonly seen in CDD (and West Syndrome) than in other early-life genetic epilepsies⁹

¹ NIH. CDKL5 deficiency disorder. <https://medlineplus.gov/genetics/condition/cdkl5-deficiency-disorder/#frequency>. Accessed May 2022; ² NORD. CDKL5 Deficiency Disorder. <https://rarediseases.org/rare-diseases/cdkl5>. Accessed May 2022; ³ International Foundation for CDKL5 Research. About CDKL5. www.cdkl5.com/about-cdkl5. Accessed March 2022; ⁴ IFCR and Loulou Foundation. The Voice of the Patient Report: CDKL5 Deficiency Disorder (CDD). <https://www.cdkl5.com/wp-content/uploads/2020/06/CDD-VoP-REPORT.pdf>. Accessed May 2022; ⁵ Mori, Y., Downs, J., Wong, K. et al. Impacts of caring for a child with the CDKL5 disorder on parental wellbeing and family quality of life. Orphanet J Rare Dis 12, 16 (2017). OR Linggen M, Albers L, Borchers M, et al. Obtaining a genetic diagnosis in a child with disability: impact on parental quality of life. Clin Genet. 2016; 89(2):258-266; ⁶ Olson HE, Demarest ST, Pestana-Knight EM, et al. Cyclin-Dependent Kinase-Like 5 Deficiency Disorder: Clinical Review. Pediatr Neurol. 2019; 97:18-25; ⁷ IFCR and Loulou Foundation. The Voice of the Patient Report: CDKL5 Deficiency Disorder (CDD). <https://www.cdkl5.com/wp-content/uploads/2020/06/CDD-VoP-REPORT.pdf>. Accessed May 2022; ⁸ Mori, Y., Downs, J., Wong, K. et al. Impacts of caring for a child with the CDKL5 disorder on parental wellbeing and family quality of life. Orphanet J Rare Dis 12, 16 (2017). OR Linggen M, Albers L, Borchers M, et al. Obtaining a genetic diagnosis in a child with disability: impact on parental quality of life. Clin Genet. 2016; 89(2):258-266; ⁹ Olson HE, Demarest ST, Pestana-Knight EM, et al. Cyclin-Dependent Kinase-Like 5 Deficiency Disorder: Clinical Review. Pediatr Neurol. 2019;97:18-25; ¹⁰ William Hong et al., CDKL5 Deficiency Disorder-Related Epilepsy: A Review of Current and Emerging Treatment. CNS Drugs (2022) 36:591–604. Fenfluramine is an investigational product and is not approved for the indication by any regulatory authority in the world.

Bepranemab (UCB0107, Anti-Tau Antibody)

- In July 2020, UCB entered a worldwide, exclusive license agreement with Roche and Genentech (a member of the Roche group) for the global development and commercialisation of *bepranemab* in Alzheimer's disease (AD)
- UCB will fund and perform a proof-of-concept study in AD and upon availability of the results Genentech will progress with the development of *bepranemab* or return full rights back to UCB



In AD, amyloid β peptides form plaques and pathological tau proteins misfold and form intracellular aggregates, which accumulate within the brain leading to neurodegeneration.^{1,2} Clinical progression is closely linked to the progressive spread of tau pathology throughout the brain.¹



Pathological **tau aggregates** or '**seeds**' can spread between neurons propagating disease^{3,4}



Bepranemab is a fully humanised, full-length IgG4 **monoclonal anti-tau antibody**⁵ that is currently under investigation for the treatment of AD⁶



Bepranemab aims to **reduce the progression of disease** by binding extracellular pathological tau and **slowing down or halting the spread of tau neuropathology**^{1,3,5}

AD = Alzheimer's disease; IgG = immunoglobulin G.; ¹ Courade JP, *et al. Acta Neuropathol.* 2018;136:729–45; ² Bloom G. *JAMA Neurol.* 2014;71:505–8; ³ Albert M, *et al. Brain.* 2019;142:1736–50; ⁴ Colin M, *et al. Acta Neuropathol.* 2020;139:3–25; ⁵ Buchanan T, *et al.* Presented at the International Congress of Parkinson's Disease and Movement Disorders, 2019: Abstract LBA3; ⁶ NCT04867616. Available at: <https://clinicaltrials.gov/ct2/show/NCT04867616> (Accessed September 2021). bepranemab is an investigational product and is not approved for any indication by any regulatory authority in the world. Bepranemab requires additional studies before any conclusions for safety and efficacy can be made.

Together (AH0003): Overview and Study Design

A Phase 2 study in people living with AD – Recruitment for this study was completed, topline results Q4 2024



Objective

- To evaluate the efficacy, safety, and tolerability of bepranemab in people with prodromal and mild AD¹

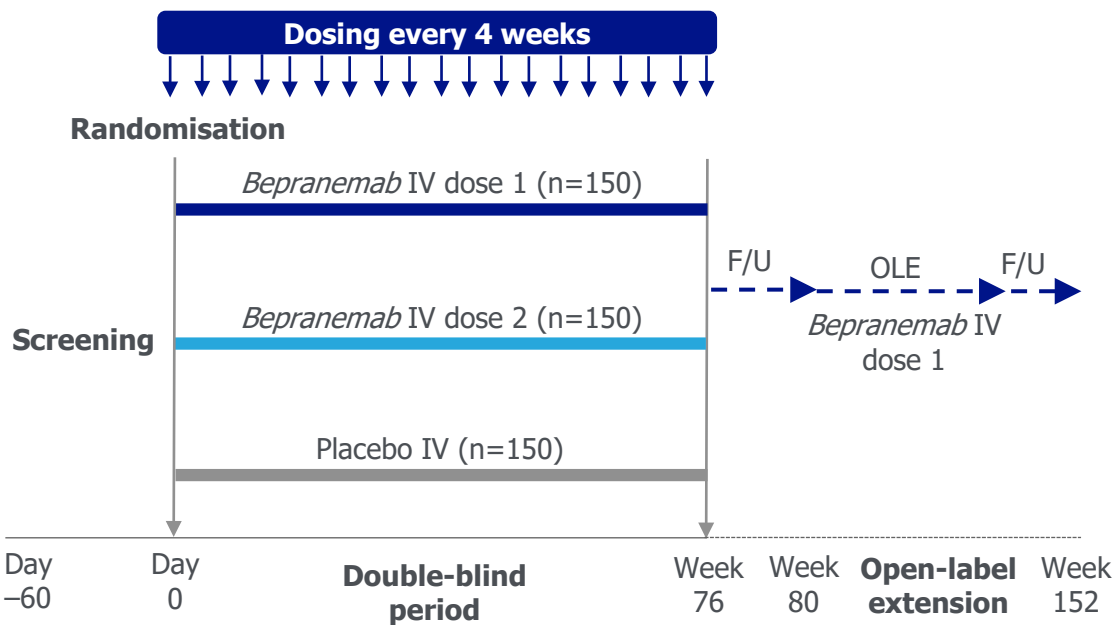


Inclusion criteria

- Prodromal or mild AD*
- MMSE score ≥ 20 to ≤ 30
- A β biomarker-positive (CSF or PET)
- If receiving an AD symptomatic treatment, must be stable for at least 3 months prior to screening



Design



Endpoints

Primary:

- Change from baseline in CDR-SB at Week 80

Key secondary:

- Safety and tolerability of bepranemab
- Effect on tau PET imaging at Wk 56 and Wk 80
- Change from baseline in cognitive clinical measures
- Pharmacokinetics

Thymidine Kinase 2 Deficiency

An ultra-rare debilitating and life-threatening (often fatal) genetic mitochondrial disorder

Thymidine Kinase 2 deficiency (TK2d)

Is a rare, inherited, debilitating, and life-threatening mitochondrial disorder that causes severe and progressive muscle weakness. Patients lose the ability to walk, eat and breathe independently

Treatment

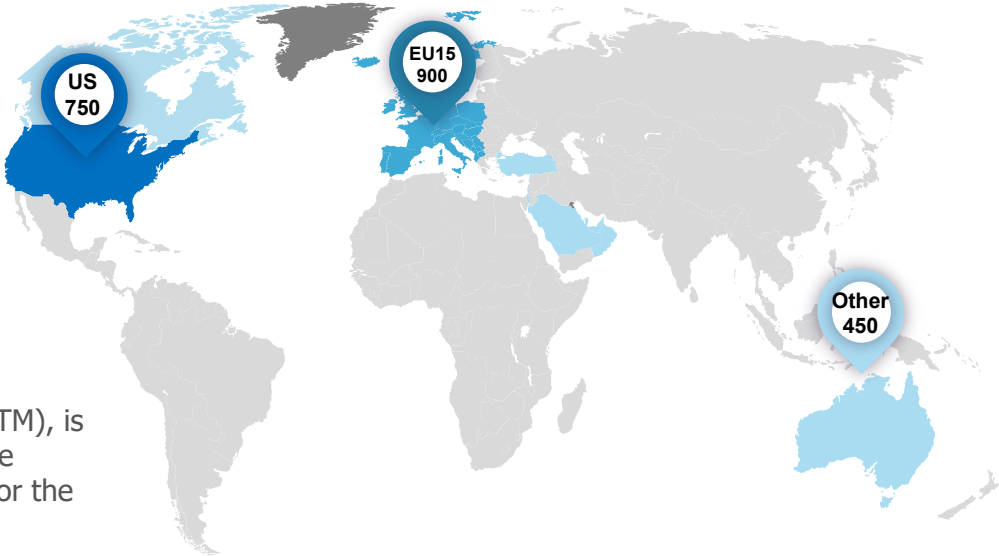
There are no medicinal products approved for the treatment of Tk2d. Standard of Care is limited to supportive and palliative care aimed at preserving motor functions and preventing respiratory failure

Prevalence

There are an estimated ~2,100 TK2d patients in the targeted geographies¹

Mechanism of Action

Doxecitine and doxribtimine (doxTM), is an investigational deoxynucleoside substrate enhancement therapy for the treatment of TK2d



Management Goals



Infants

- Extremely poor prognosis and often fatal within a few years
- Require palliative care such as mechanical ventilation, feeding tubes and sedation
- Psychological support for parents



Children

- Ultimate goal is to prolong life to help reach developmental milestones (e.g. able to sit up, crawl, talk, walk)
- Ensure adequate respiratory support (if/when needed)
- Support psychological development



Adults

- Ultimate goal is to maintain independence for as long as possible
- Preserve muscle and respiratory function
- Ensure adequate respiratory support (if/when needed)
- Provide psychological support when needed (depression and anxiety very common)

UCB9741 - Atopic Dermatitis (AtD)

A Phase 2a study in people living with AtD – Results in H2 2024

A Multicenter, Double-blind, Placebo-controlled, Randomized Study



Objective

- Evaluate the safety, PK and efficacy following repeat dosing of UCB9741 in study participants with moderate to severe AtD



Inclusion criteria

- Participants with atopic dermatitis (AtD) aged 18-65
- Moderate or severe AtD present for at least 12 months
- Recent history of inadequate response to treatment with topical medications or topical treatments are confirmed to be otherwise medically inadvisable



Design

Participant Group/Arm	Intervention/Treatment
Experimental: - Intravenous UCB9741 arm. Participants receive pre-specified intravenous doses of UCB9741	Drug: UCB9741 – Participants receive repeat dose UCB9741 during the Treatment Period
Placebo Comparator - Intravenous Placebo arm. Participants receive intravenous Placebo to maintain the blinding	Drug: Intravenous Placebo – Participants receive repeat dose Placebo during the Treatment Period



Endpoints

Primary:

- Incidents of TEAEs and TSEAEs from Baseline through the EOS Visit (Week 18)
- ≥75% improvement vs Baseline in EASI score (EASI75) at Week 12

Key secondary:

- PK parameters from Baseline through Week 12
- Percent change from Baseline in EASI score at Week 12
- ≥50% improvements vs Baseline in EASI score (EASI50) at Week 12
- ≥90% improvements vs Baseline in EASI score (EASI90) at Week 12



Inspired by patients.
Driven by science.

Note: This is a Phase 1/2a study – this slide details Part B of study (2a). Refer to [ClinicalTrials.Gov](https://clinicaltrials.gov) for Part A details.
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UCB1381 - Atopic Dermatitis (AtD)

A Phase 2a study in people living with AtD – Results in H2 2024

A Multicenter, Double-blind, Placebo-controlled, Randomized Study



Objective

- Evaluate the safety, PK and efficacy following repeat dosing of UCB1381 in study participants with moderate to severe AtD



Inclusion criteria

- Participants with atopic dermatitis (AtD) aged 18-65
- Moderate or severe AtD present for at least 12 months
- Recent history of inadequate response to treatment with topical medications or topical treatments are confirmed to be otherwise medically inadvisable



Design

Participant Group/Arm	Intervention/Treatment
Experimental: - Intravenous UCB1381 arm. Participants receive pre-specified intravenous doses of UCB1381	Drug: UCB1381 – Participants receive repeat dose UCB1381 during the Treatment Period
Placebo Comparator - Intravenous Placebo arm. Participants receive intravenous Placebo to maintain the blinding	Drug: Intravenous Placebo – Participants receive repeat dose Placebo during the Treatment Period



Endpoints

Primary:

- Incidents of TEAEs and TSEAEs from Baseline through the EOS Visit (Week 22)
- ≥75% improvement vs Baseline in EASI score (EASI75) at Week 12

Key secondary:

- PK parameters from Baseline through Week 12
- Percent change from Baseline in EASI score at Week 12
- ≥50% improvements vs Baseline in EASI score (EASI50) at Week 12
- ≥90% improvements vs Baseline in EASI score (EASI90) at Week 12



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