



**ORUKA**  
THERAPEUTICS

# Corporate Overview

NASDAQ: ORKA

January 2026

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# On a mission to enable freedom from chronic skin disease

## Our goal

Help patients with chronic skin conditions experience the **greatest possible freedom from disease**

*Highest possible rates of disease clearance*



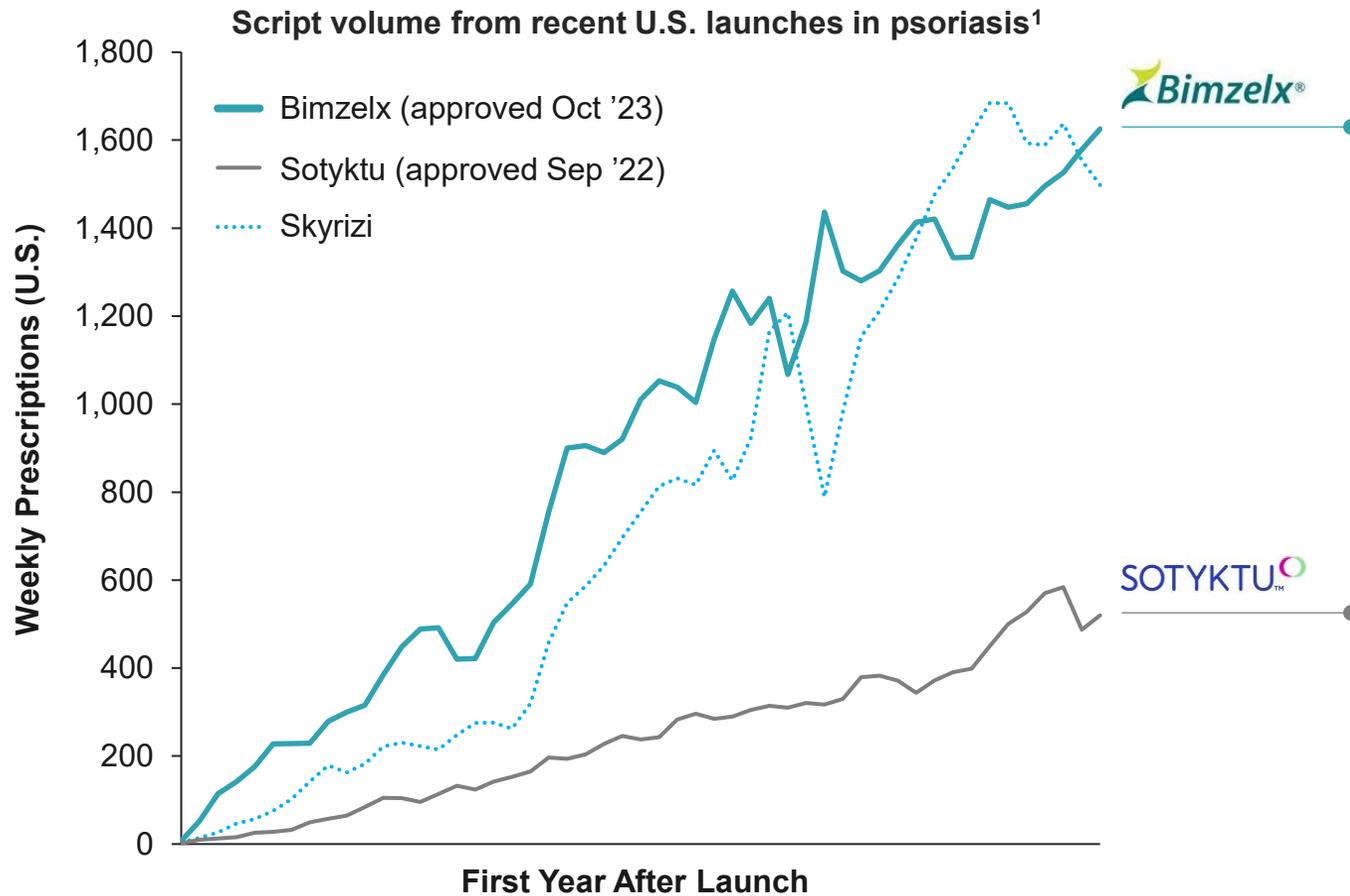
*Fewest number of doses*

## Our pipeline

PROGRAM	PRECLINICAL	PHASE 1	PHASE 2	INDICATIONS
ORKA-001	IL-23p19		Interim data 2H26	PsO
ORKA-002	IL-17A/F		PsO initiation 1H26 HS initiation 2H26	PsO, PsA, HS, others
ORKA-021		Sequential combination regimen of ORKA-002 and -001		
ORKA-003	Undisclosed			

# Bimzelx launch shows that better biologics will win in psoriasis

## Bimzelx versus Sotyktu performance validates our thesis



- **UCB's Bimzelx launch has exceeded expectations, driven by strong demand – ~\$2B annualized 2025 sales, with \$5B+ peak sales consensus**
- **Market underestimated the opportunity – UCB market cap ~\$15B pre-launch vs. ~\$50B two years later (>\$30B market cap created on Bimzelx alone)**
- **Strong launch driven by PsO in U.S. – proof point that smaller, non-incumbent company can effectively commercialize in PsO**
- **Sotyktu underperformed due to lack of demand – sub-optimal efficacy with JAK-like safety overhang**
- **Market access dynamics not meaningfully different from Bimzelx – not a major driver**

# The psoriasis market will continue to reward biologic innovation



Massive  
market size

**\$30B+**

Growing moderate-to-severe psoriasis market, with further potential in mild-to-moderate disease



Continued pharma  
investment



nimbus  
THERAPEUTICS



DICE  
Therapeutics



Protagonist  
Therapeutics

Pharma has bet big on orals, sacrificing efficacy for perceived convenience



Better biologics  
continue to win

**\$5B+**  **Bimzelx<sup>®</sup>**  
(bimekizumab-bkzx)

**peak sales forecast**

Bimzelx launch shows non-incumbents can achieve access if they have a drug physicians want

# ORKA-001 & -002 complement each other to address all PsO/PsA

## ORKA-001

For patients with purely skin disease



Majority of dermatologists prefer an anti-IL-23p19

## ORKA-002

For patients with joint involvement, including PsA, or recalcitrant skin disease



Anti-IL-17 preferred, and IL-17A/F emerging as the best approach

## ORKA-021

Sequential combination of -002 and -001 – rapid response with ideal maintenance profile



Creates another way to "win" in defining the best possible regimen in PsO and PsA

# 1-2 doses per year is enough to win, but we are aiming far higher



Ultra-long dosing intervals with ORKA-001 and -002

## Greater efficacy

KNOCKOUT demonstrates potential for highest ever efficacy from higher IL-23 antibody exposure

## Off-treatment remission

High anti-IL-23 exposures could lead to immune reset and long-lasting disease clearance in some patients

## IL-17 to IL-23 combination

ORKA-021 could deliver rapid and deep responses with an ideal maintenance profile

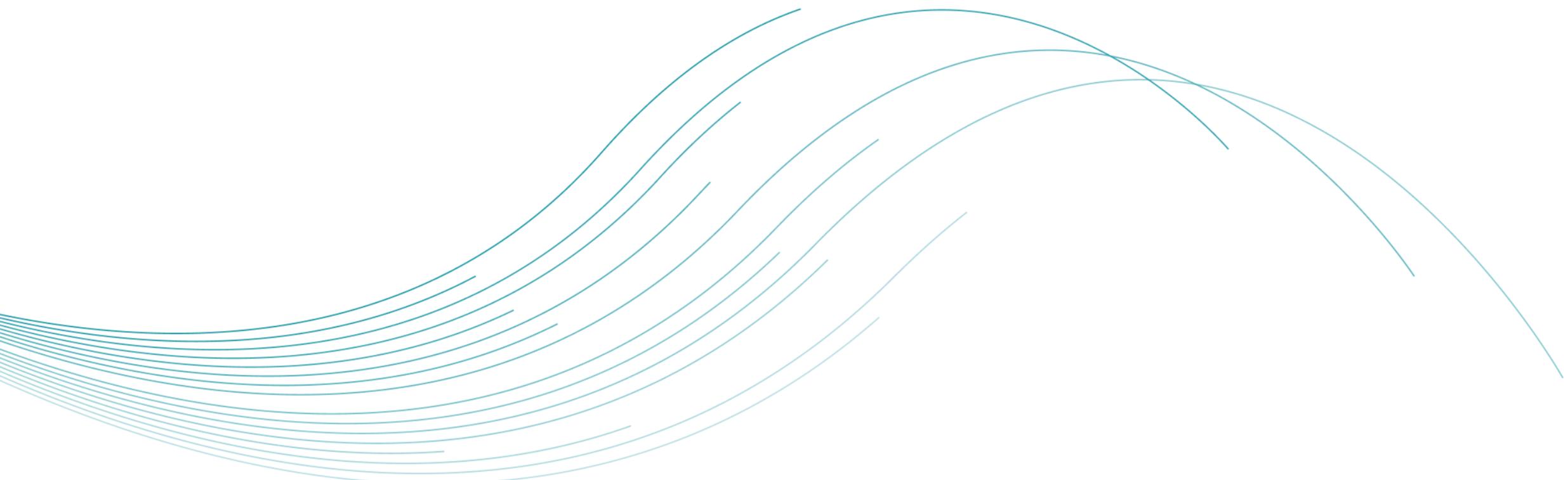


Maximizes odds of having a strong value proposition to achieve preferred access and price for innovation

# Advancing co-leads rapidly towards multiple clinical data catalysts

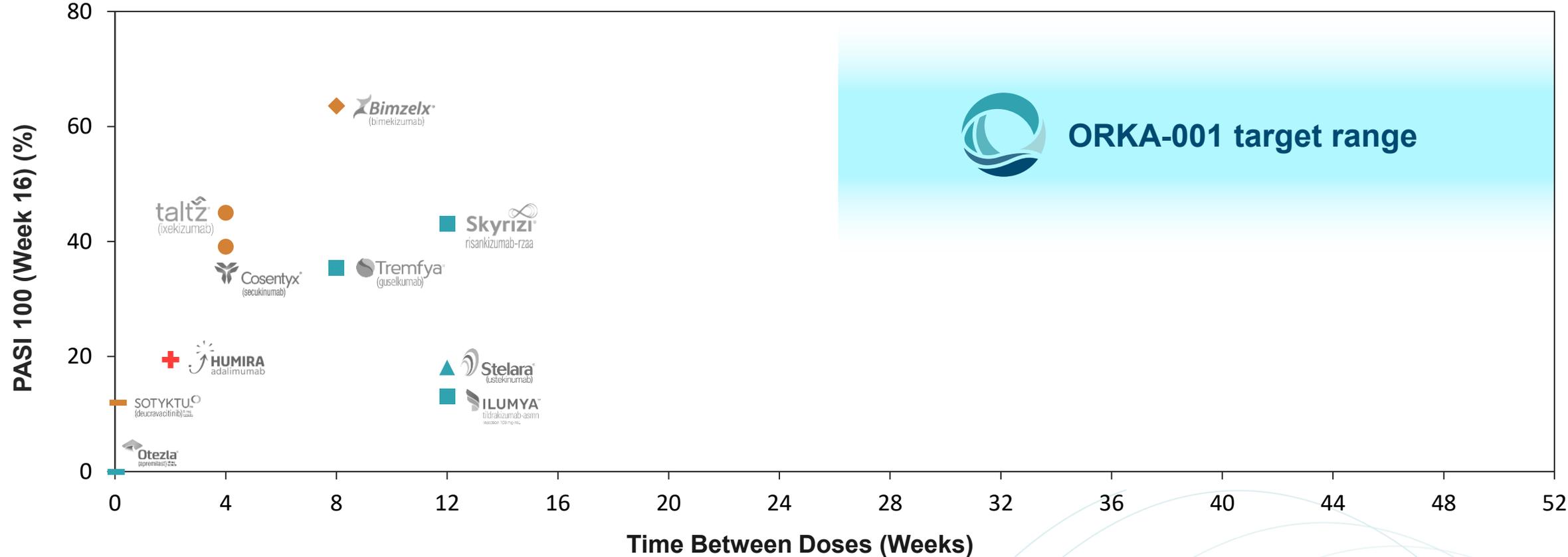
	2025		2026	
ORKA-001	<p><b>FIH Ph1</b> Q4 2024</p>	<p><b>Interim PK in HVs</b> EVERLAST-A initiation</p>	<p>EVERLAST-B initiation</p>	<p><b>EVERLAST-A:</b> PASI 100 rates &amp; response duration</p>
ORKA-002	<p><b>FIH Ph1</b> <i>Ahead of schedule</i></p>	<p><b>Interim PK in HVs</b></p>	<p>Ph2 initiation in PsO (ORCA-SURGE)</p>	<p>Ph2 initiation in HS</p>

**Strong cash position provides runway >1 year beyond three major readouts: EVERLAST-A Ph2a in 2H 2026, EVERLAST-B Ph2b in 2027, and ORCA-SURGE Ph2 in 2027**



**ORKA-001:  
potentially best-in-class anti-IL-23p19**

# Biologics have raised the bar on standard of care in PsO, but there is ample room for improvement



 **ORKA-001 target range**

- Anti-IL-23
- ◆ Anti-IL-17A/F
- + Anti-TNF
- Highly safe; no AEs / SAEs of note
- Black box warning / significant safety concerns
- ▲ Anti-IL-12/23
- Anti-IL-17A
- Oral (various mechanisms)
- Mixed safety results; some AEs / SAEs of note



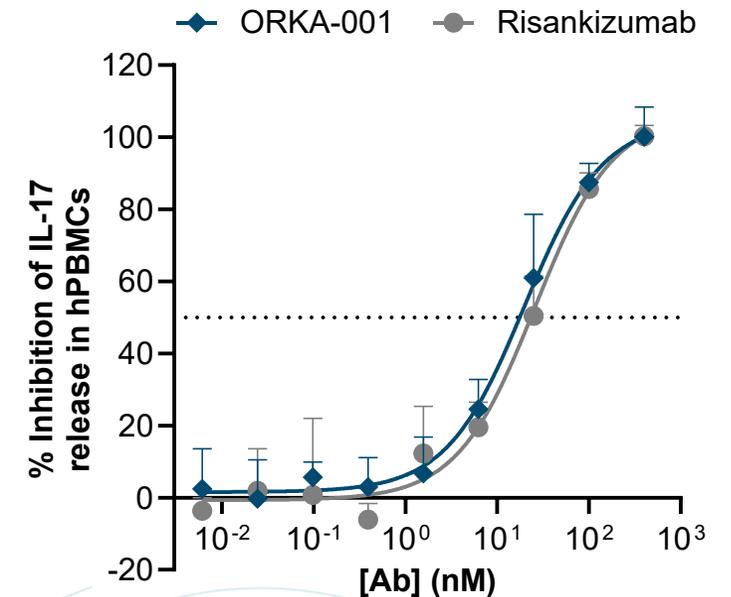
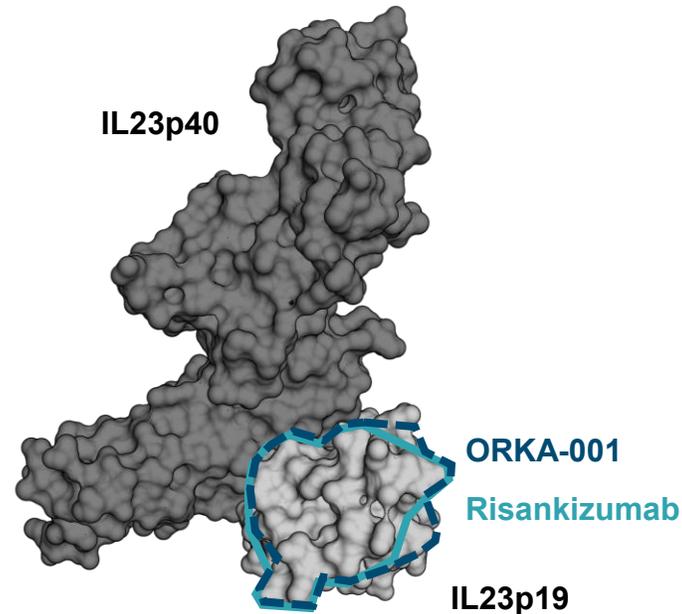
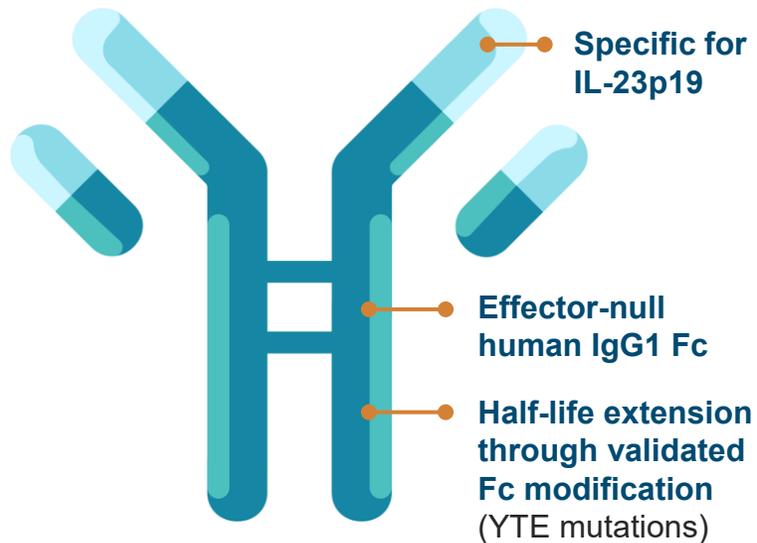
Notes & Sources: FDA Approval Labels and publications of Phase 3 trials supporting approval; W16 PASI 100 not reported for Ilumya (W12 data shown), Otezla (W16 data shown from comparator arm in Sotyktu label), or Stelara (W16 data shown from comparator arm in Skyrizi UltimMa-1/2 trials)

# ORKA-001 targets validated biology with significantly extended PK

ORKA-001 could be the last word in IL-23p19 inhibitors

Binds a nearly identical epitope to risankizumab

Comparable potency to risankizumab across a variety of assays



ORKA-001 is designed to match the validated biology of Skyrizi (risankizumab), but with a dramatically extended half-life

# ORKA-001 Phase 1 results set the stage for a step-change in PsO

## Phase 1 results

- Half-life of ~100 days
- $C_{max}$  and AUC that enable “KNOCKOUT” exposures
- PD biomarkers linking antibody PK to target engagement
- Safety and tolerability consistent with the IL-23 class

## Three major “ways to win”

### Annual dosing

**Once per year dosing**, with a Q6M option if needed for hard-to-treat patients

### Best-in-class efficacy

“**KNOCKOUT**” antibody exposures could lead to **highest anti-IL-23 efficacy**

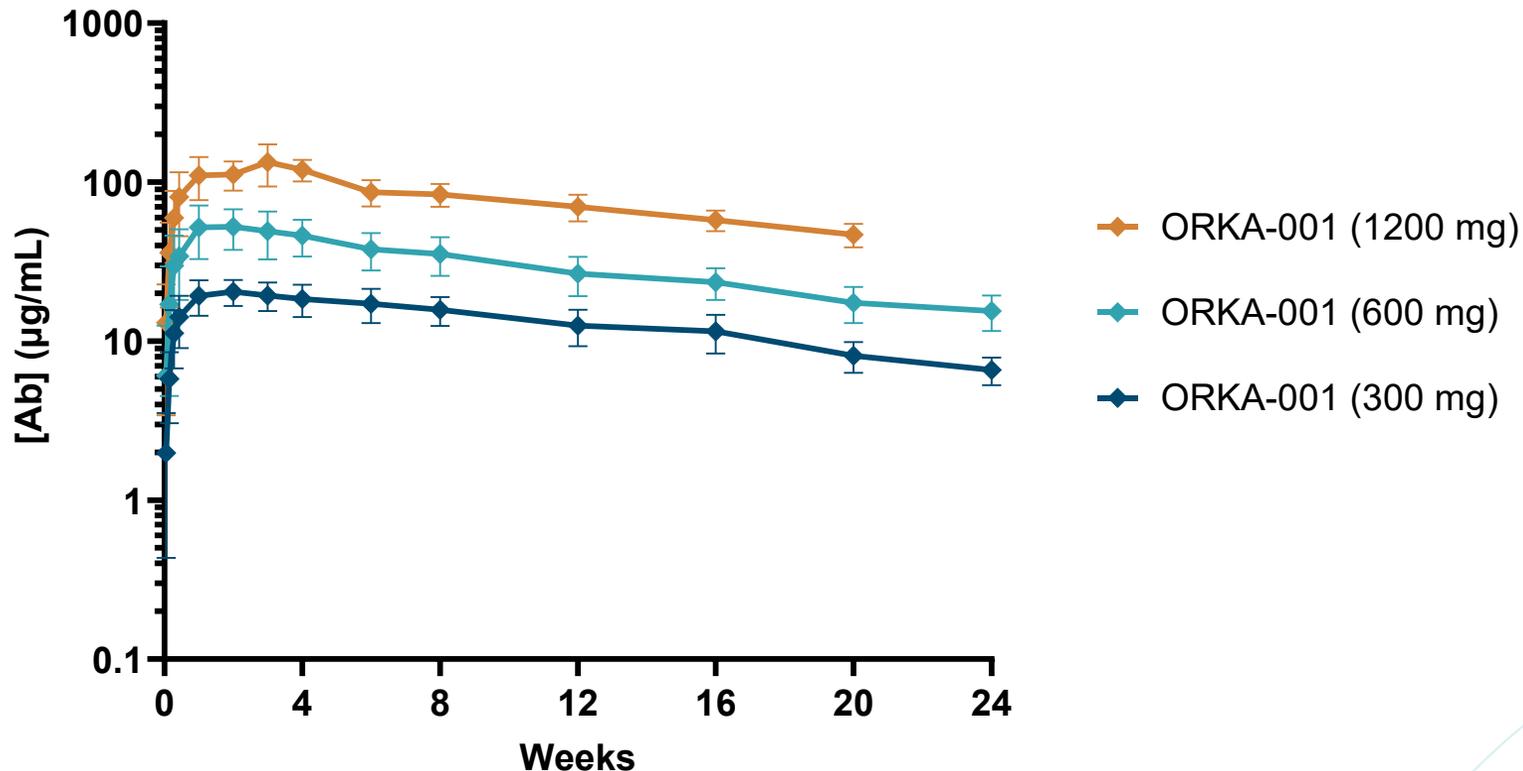
### Off-treatment remission

**Multi-year off-treatment remissions** for some patients – **a first in PsO** and a potential paradigm change

Ongoing EVERLAST-A Phase 2a trial in PsO will validate this potential – efficacy data expected in 2H 2026

# ORKA-001's 100-day half-life and high AUC derisks upside case

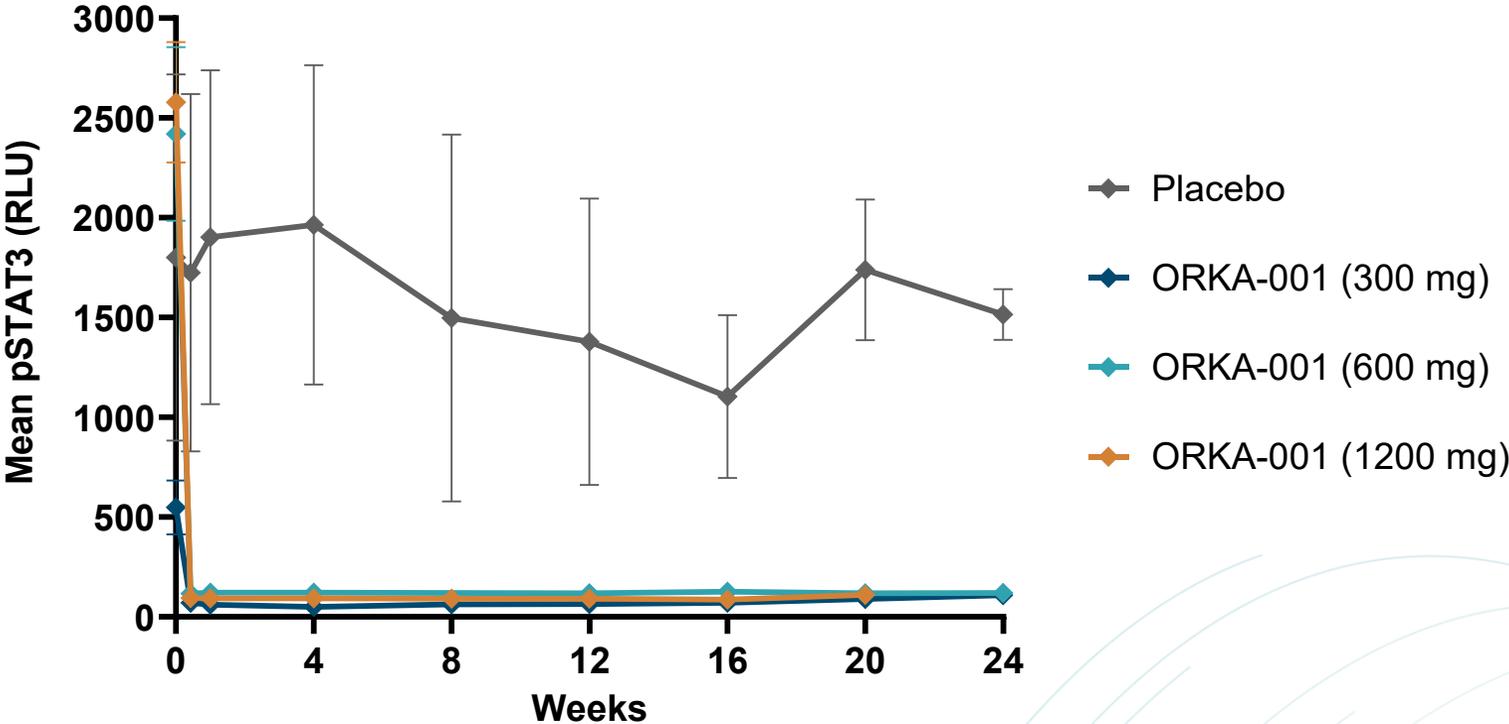
## Pharmacokinetic profile of a single subcutaneous dose of ORKA-001



- **~100-day half-life** in humans, >3x longer than risankizumab
- $C_{max}$  exceeds risankizumab's at an equivalent dose<sup>1</sup>, suggesting ORKA-001 has **high bioavailability**
- High AUC confirms ability to achieve **exposures matching or exceeding KNOCKOUT**
- Individual PK profiles **show no indication of ADAs**

# ORKA-001 demonstrated deep and sustained inhibition of STAT3 signaling, a downstream marker of IL-23 activity, through 24 weeks

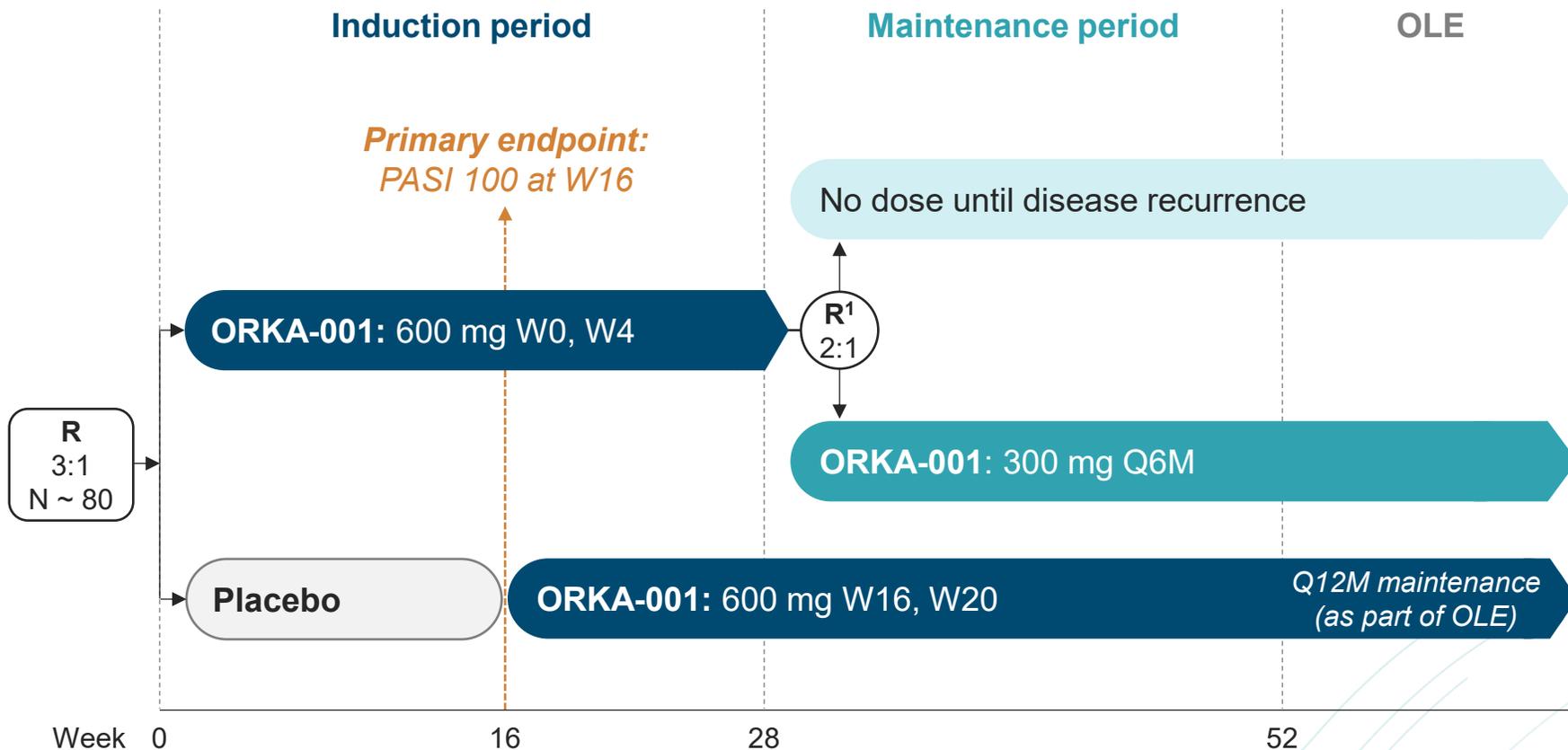
ORKA-001 from serum inhibits STAT3 phosphorylation following *ex vivo* IL-23 stimulation



# EVERLAST-A Phase 2a – a potential game changer in PsO



## EVERLAST-A Phase 2a proof-of-concept trial in moderate-to-severe psoriasis (NCT07090330)



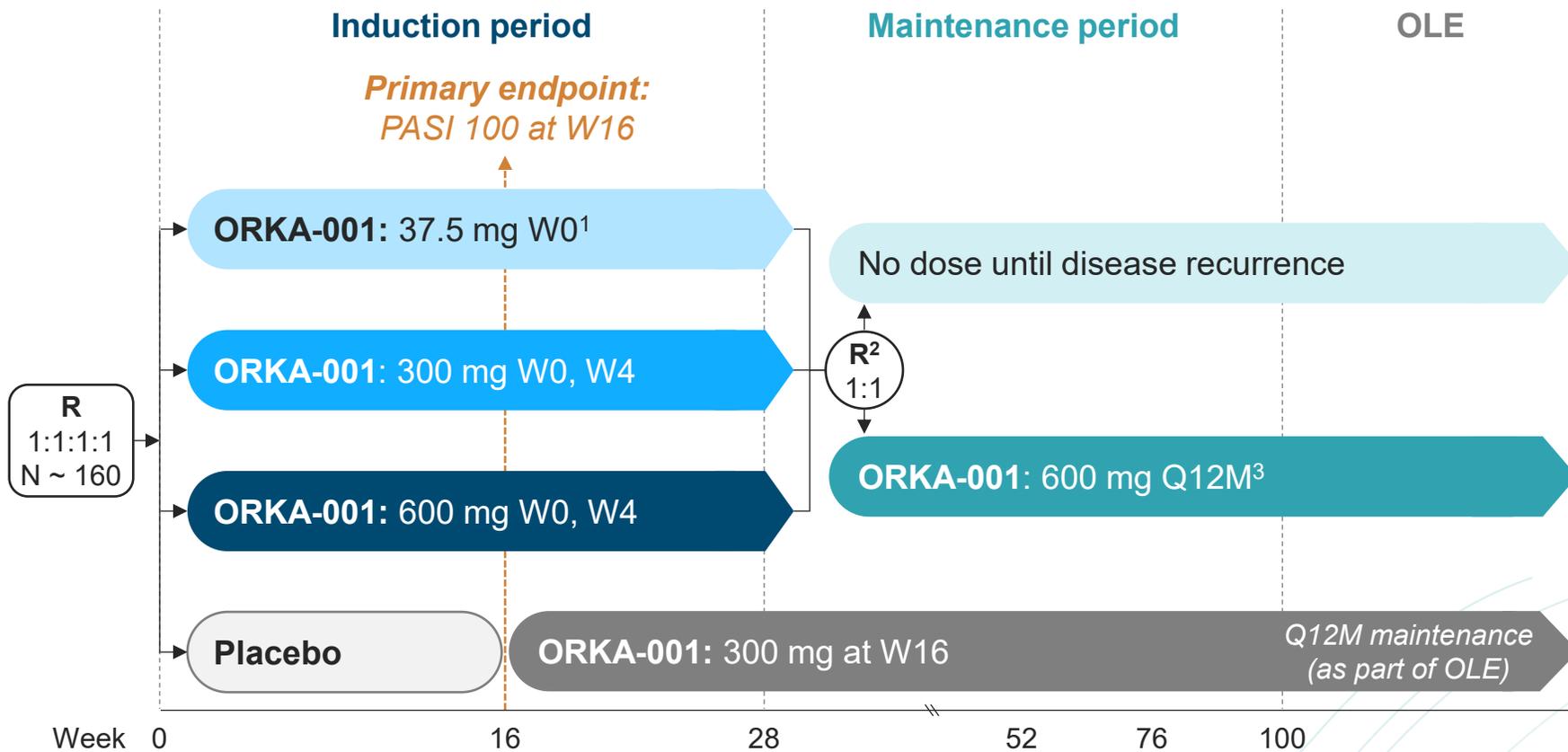
**Initial data in 2H 2026 has potential to deliver on all “upside” scenarios:**

- **Definitive test of higher efficacy at higher exposures:** PASI 100 at W16, W28, and beyond
- **Evidence for annual dosing and off-treatment remissions** from durability in “no dose” cohort

# EVERLAST-B Phase 2b – initiated in December 2025



## EVERLAST-B Phase 2b dose-ranging trial in moderate-to-severe psoriasis (NCT07290569)

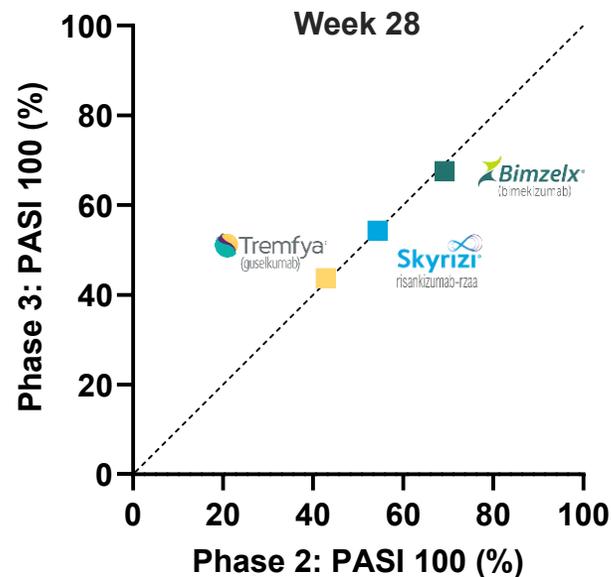
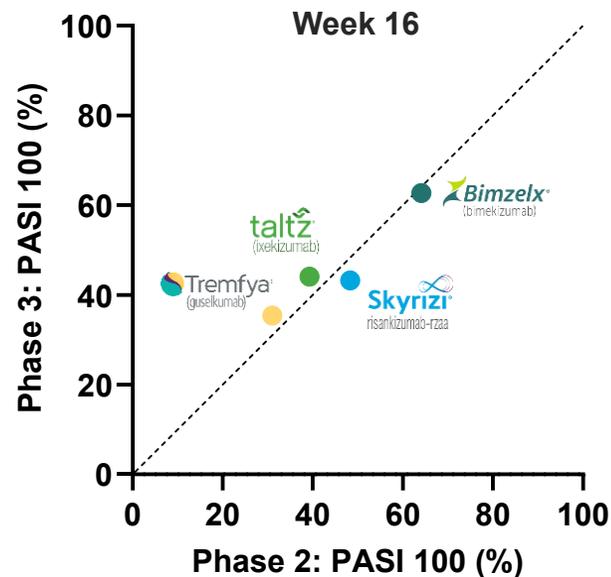


- Dose-ranging trial to enable Phase 3
- Rapid enrollment facilitated by rolling some EVERLAST-A sites to EVERLAST-B
- Data expected in 2027

# Phase 2 psoriasis data is robust and predictive of Phase 3

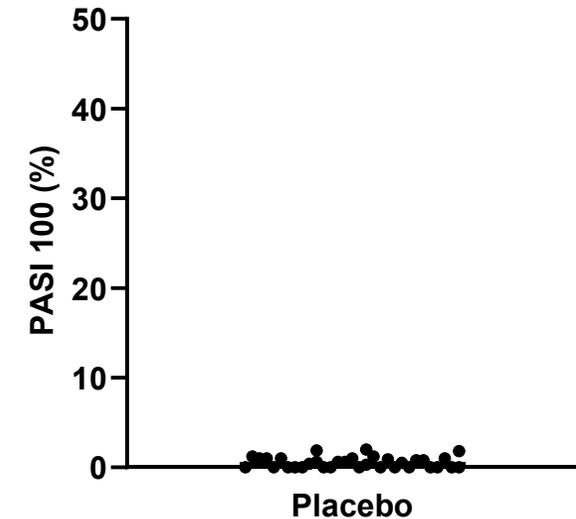
## Consistent Phase 2 to 3 translation

Phase 2 PASI 100 rates strongly correlate with Phase 3 at both Week 16 and 28



## Low placebo rates

0-2% PASI 100 placebo rate



**Facilitates rapid FIH to BLA/NDA timeline** (e.g., 6 years for Skyrizi and 6.1 years for Sotyktu)

# EVERLAST-A provides multiple “ways to win”



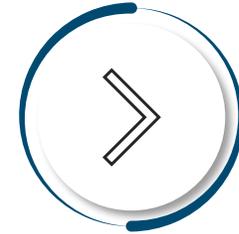
**Provide definitive test of higher efficacy at higher exposures**

PASI 100 data at Week 16, Week 28, and beyond



**Establish evidence for annual dosing and lock in Q6M**

Open-ended cohort will validate annual dosing; Q6M dosing arm to show response maintenance



**Show compelling signs of off-treatment remissions<sup>1</sup>**

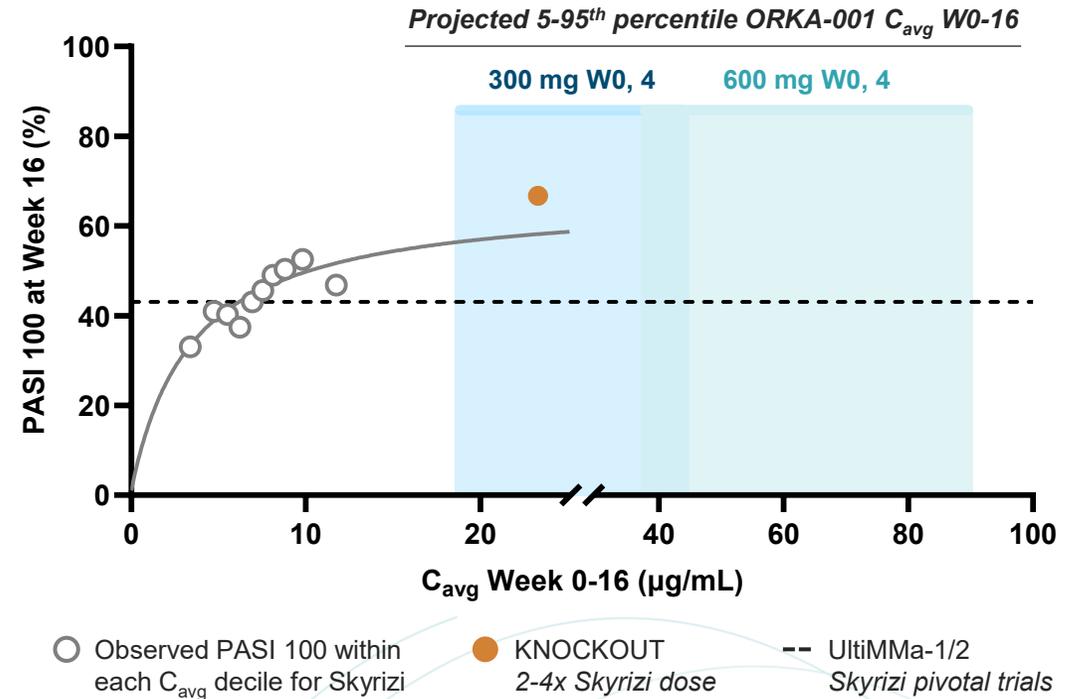
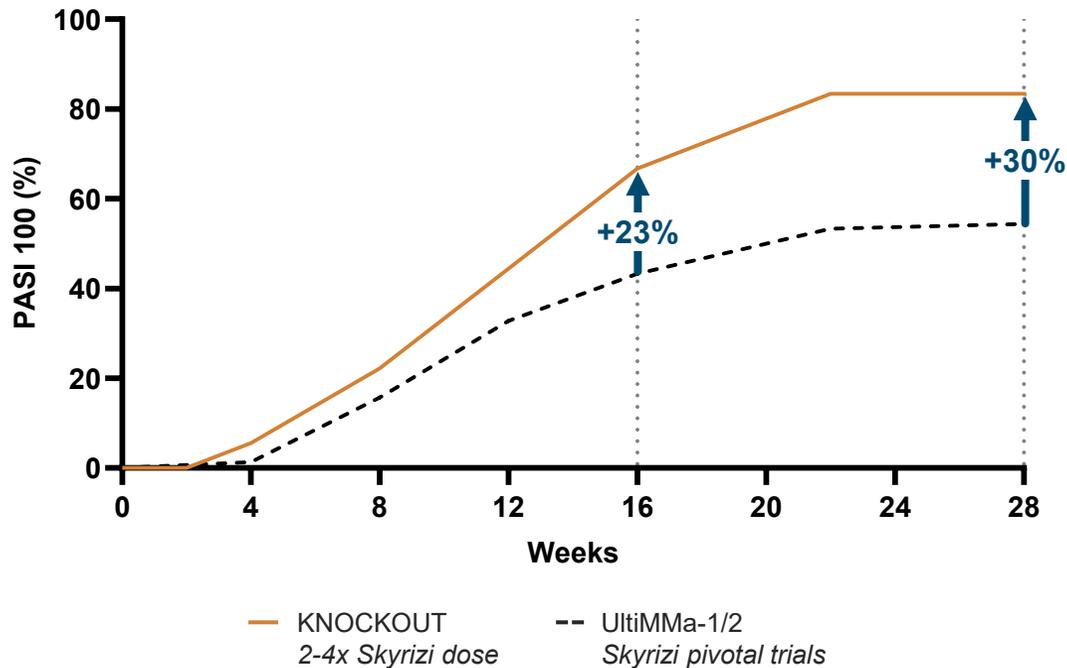
Kaplan-Meier curve of PASI 100 durability after induction, with some patients out to ~1 year

**Durability data will mature in open label portion creating opportunities for future data releases**

# ORKA-001 PK profile could enable higher efficacy in PsO

**KNOCKOUT study testing 2-4x the approved Skyrizi dose showed the highest anti-IL-23 efficacy to date**

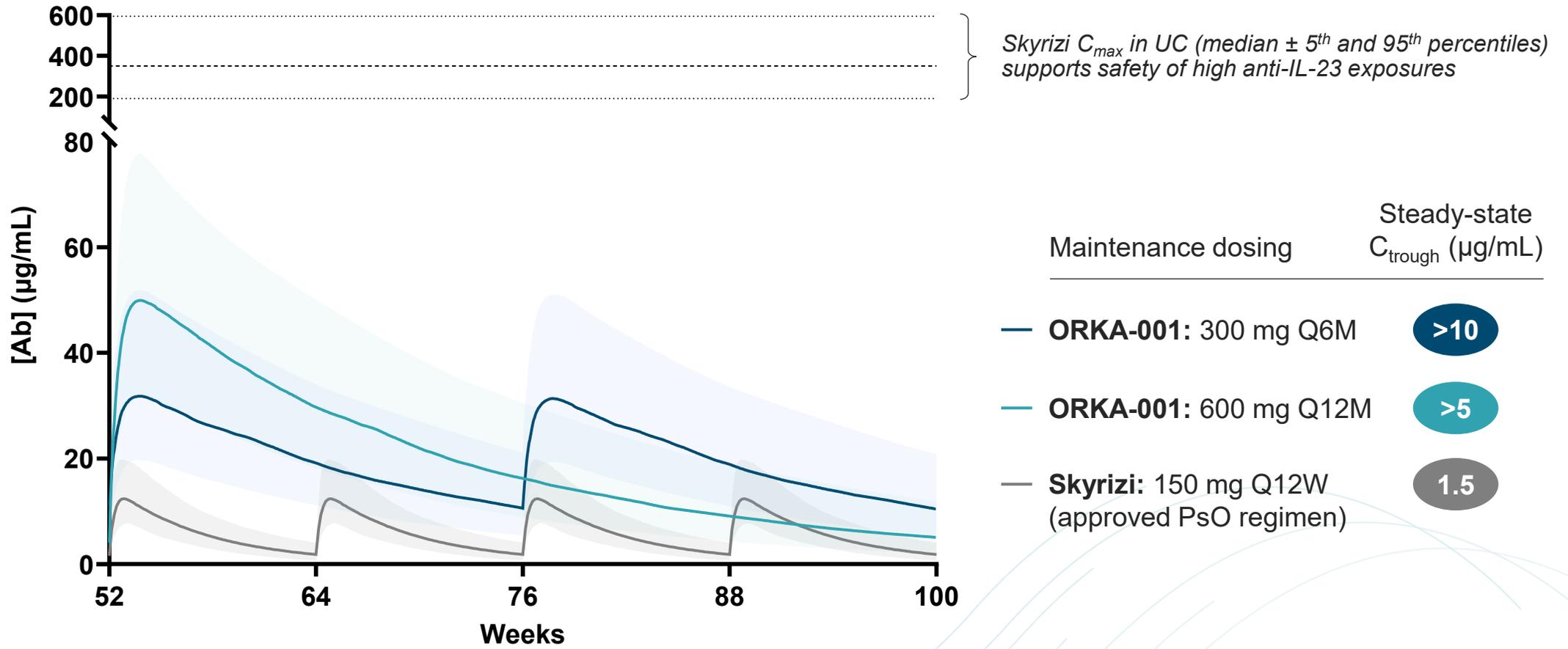
**Skyrizi exposure-response model indicates potential to increase efficacy with higher exposure**



**Higher efficacy observed with higher anti-IL-23 exposure, with separation increasing from W16 to W28 as efficacy reaches peak**

# 100-day half-life brings once annual dosing within reach

ORKA-001 projected steady-state exposures significantly exceed Skyrizi and make annual dosing likely



Notes & Sources: Oruka modeling based on internal data and published population pharmacokinetic model for Skyrizi; error bars reflect 5<sup>th</sup> and 95<sup>th</sup> percentiles. Skyrizi exposures in ulcerative colitis from 2024 Thrake (Clin Pharmacol Ther). Steady-state C<sub>trough</sub> reflects projected values from PK model for ORKA-001 and observed value from Phase 3 trials for Skyrizi in BLA MDR



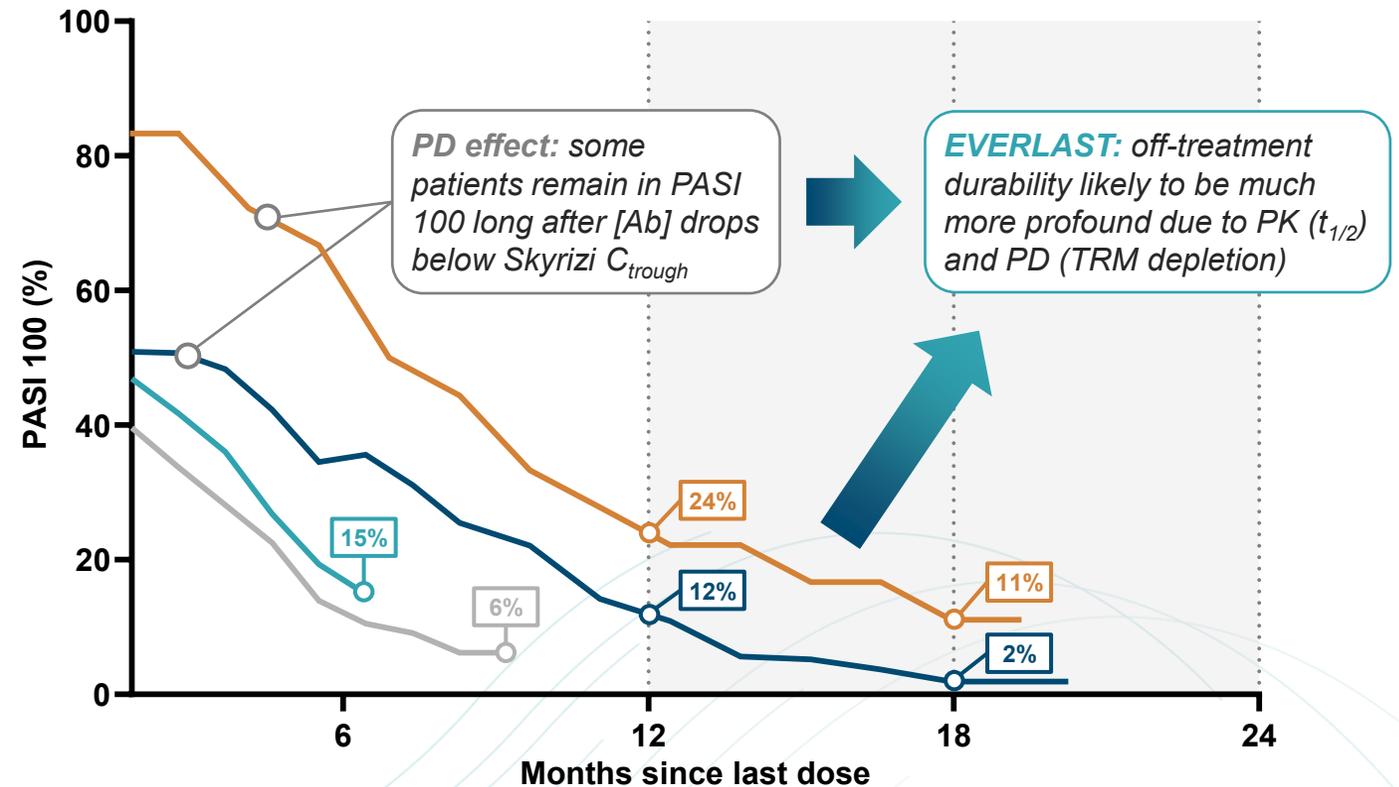
# EVERLAST could enable compelling rates of “off-treatment remission” for the first time in psoriasis

ORKA-001 could affect the disease biology in a unique way due to optimized exposure and PK...

...potentially resulting in longer-term responses that exceed those seen with prior IL-23 inhibitors

	Dose	Half-life
	600 mg	~100d
 KNOCKOUT	300-600 mg	28d
 Risankizumab	150 mg	28d
 Guselkumab	100 mg	17d
 Mirikizumab	250 mg	9d

Maintenance of PASI 100 in randomized withdrawal trials



# Looking forward to a potential label – illustrating the paradigm-changing potential of ORKA-001

## Induction

Induction with ORKA-001 at a dose level selected based on EVERLAST studies



## Maintenance

Evaluate at 6 and 12 months after induction dosing to inform whether to give ORKA-001 on one of the following regimens:

- Every 6 months
- Every 12 months
- For patients in remission, i.e., clear skin beyond 12 months, initiate maintenance dosing only if disease recurs



## Treatment upon recurrence

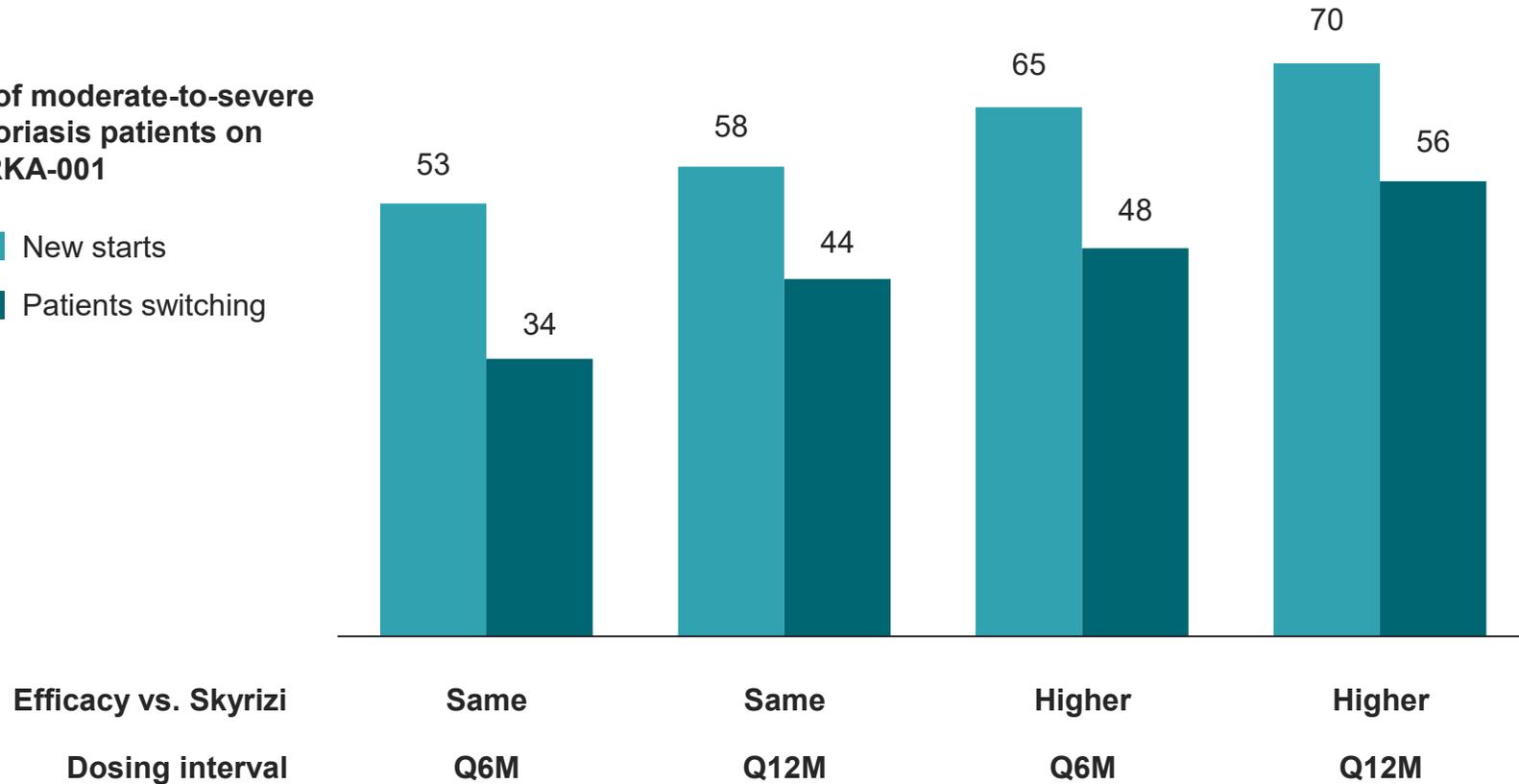
Administer ORKA-001 as a subcutaneous injection on recurrence based on clinical evaluation using a dosing regimen of either every 6 or 12 months

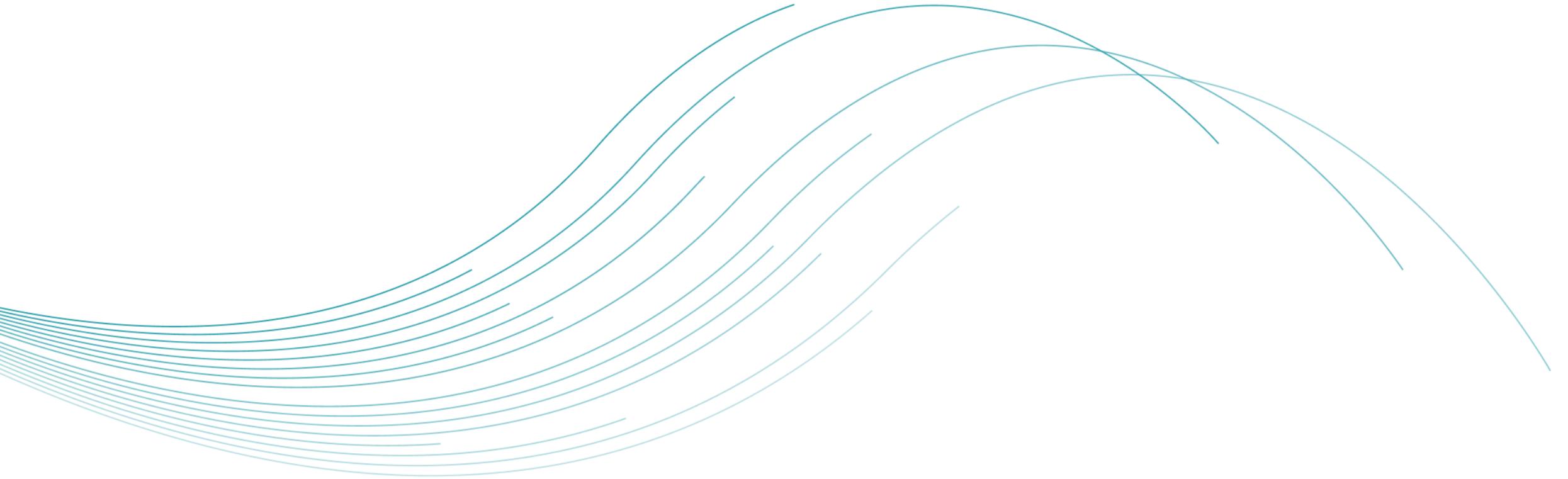
# Dermatologists value both extended dosing and higher efficacy

Dermatologists say that annual dosing and higher efficacy would drive similar 50%+ share for ORKA-001, even when accounting for entry of icotrokinra

% of moderate-to-severe psoriasis patients on ORKA-001

- New starts
- Patients switching



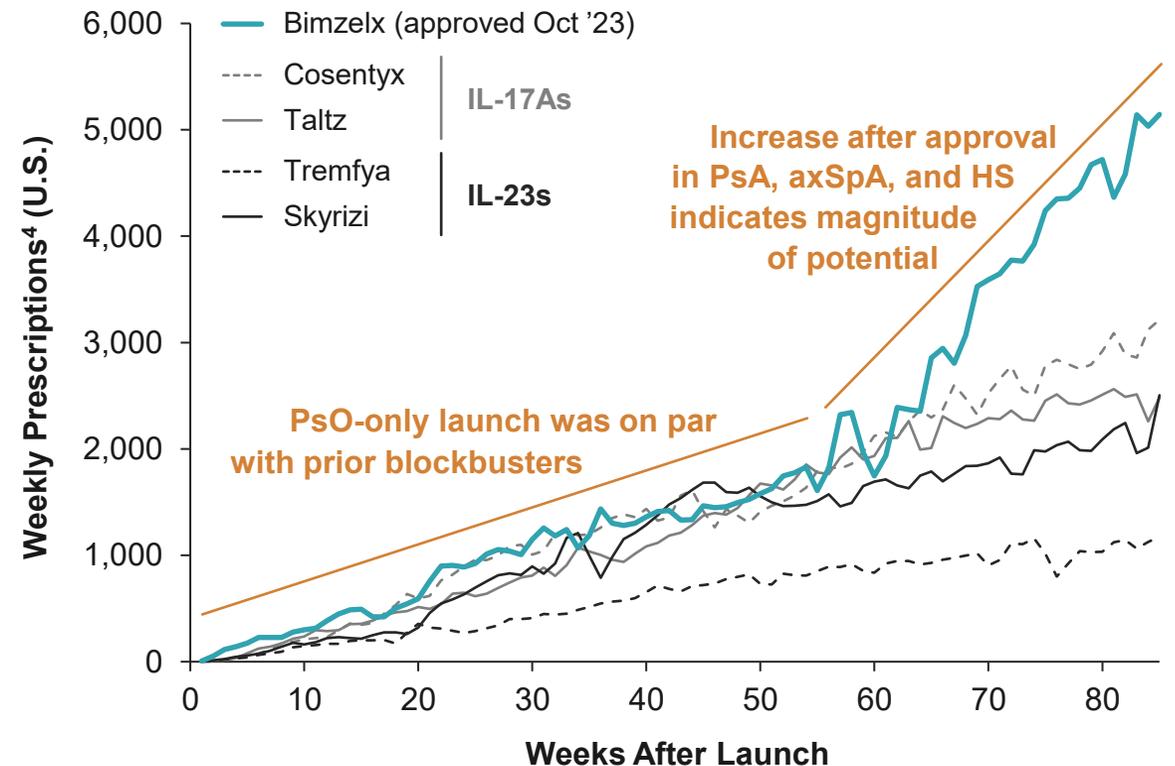


# **ORKA-002: potentially best-in-class anti-IL-17A/F**

# ORKA-002 targets IL-17A/F, a new mega-blockbuster class with an ideal setup for a longer-acting entrant

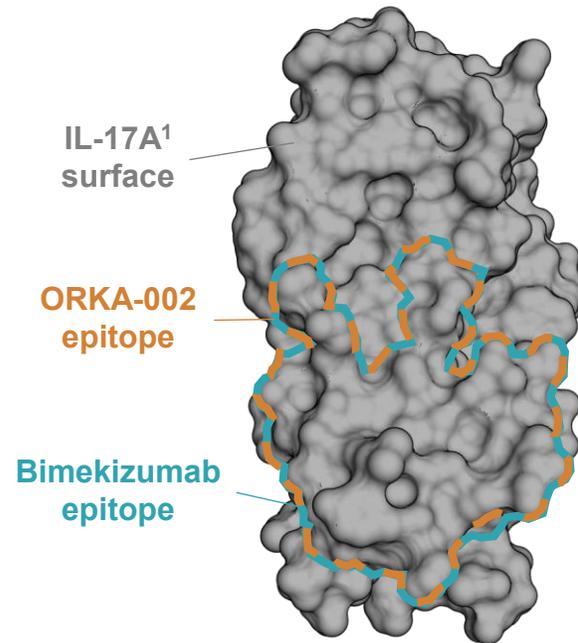
- **Brand new class** – superior efficacy vs. IL-17A<sup>1</sup> across multiple indications and high levels of skin clearance in IL-17A non-responders<sup>2</sup>
- **Long timeline to biosimilars** – Bimzelx recently approved, and only one other IL-17A/F antibody (sonelokimab) in clinical development
- **Very strong launch** – Bimzelx peak sales estimate now exceeds \$5B<sup>3</sup>; strong formulary positioning achieved soon after approval
- **Pipeline-in-a-product expansion potential** – PsA, HS, axSpA, and others

Bimzelx launch validates both the IL-17A/F class and ability to differentiate in PsO

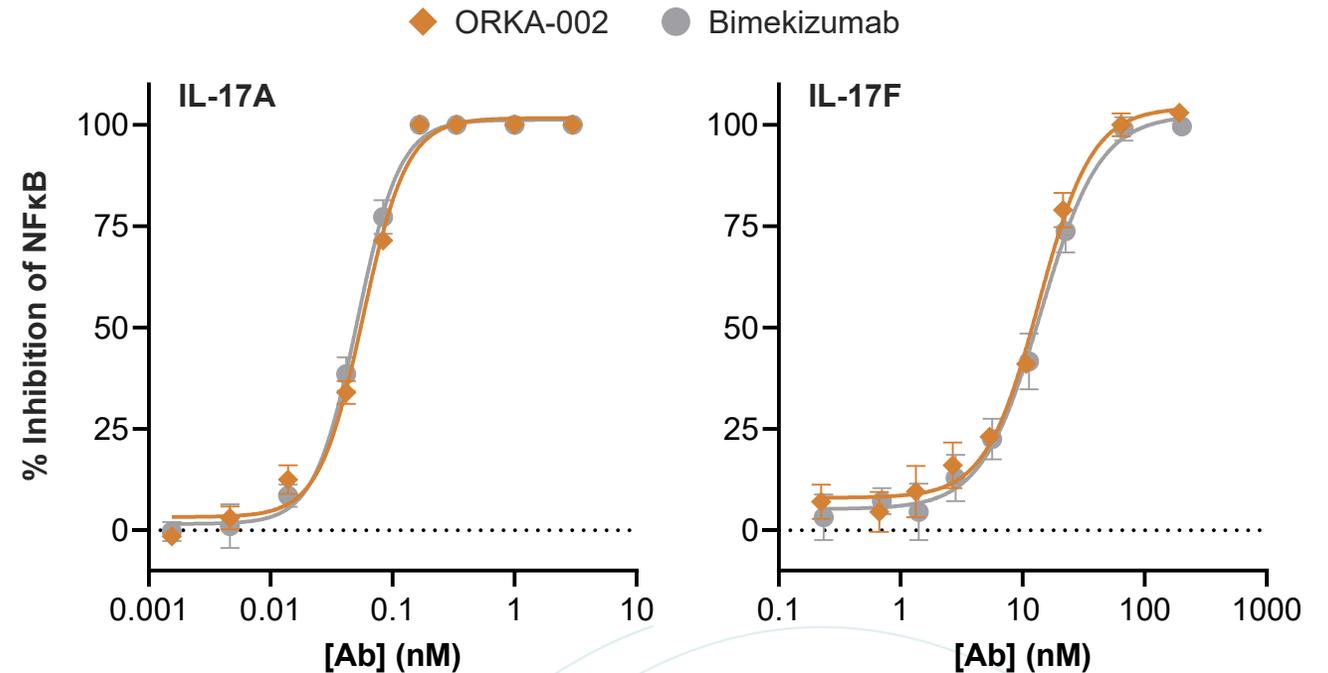


# ORKA-002 matches Bimzelx's IL-17A/F potency with extended PK

ORKA-002 binds a nearly identical epitope to bimekizumab



ORKA-002 has comparable potency to bimekizumab across a variety of assays



ORKA-002 is designed to match the validated biology of Bimzelx (bimekizumab), but with a dramatically extended half-life

# ORKA-002 Phase 1 trial design

Phase 1 trial to evaluate the safety, tolerability, and PK of ORKA-002 in healthy participants (NCT06944379)

## Design

- Double-blind and placebo-controlled
- Single ascending dose

## Population

- Healthy adult volunteers
- N=8 per cohort (6:2 active:placebo)

## Endpoints

- Primary: Safety and tolerability
- Secondary: Pharmacokinetics
- Exploratory: Pharmacodynamic markers

## Dose levels and length of follow-up to date



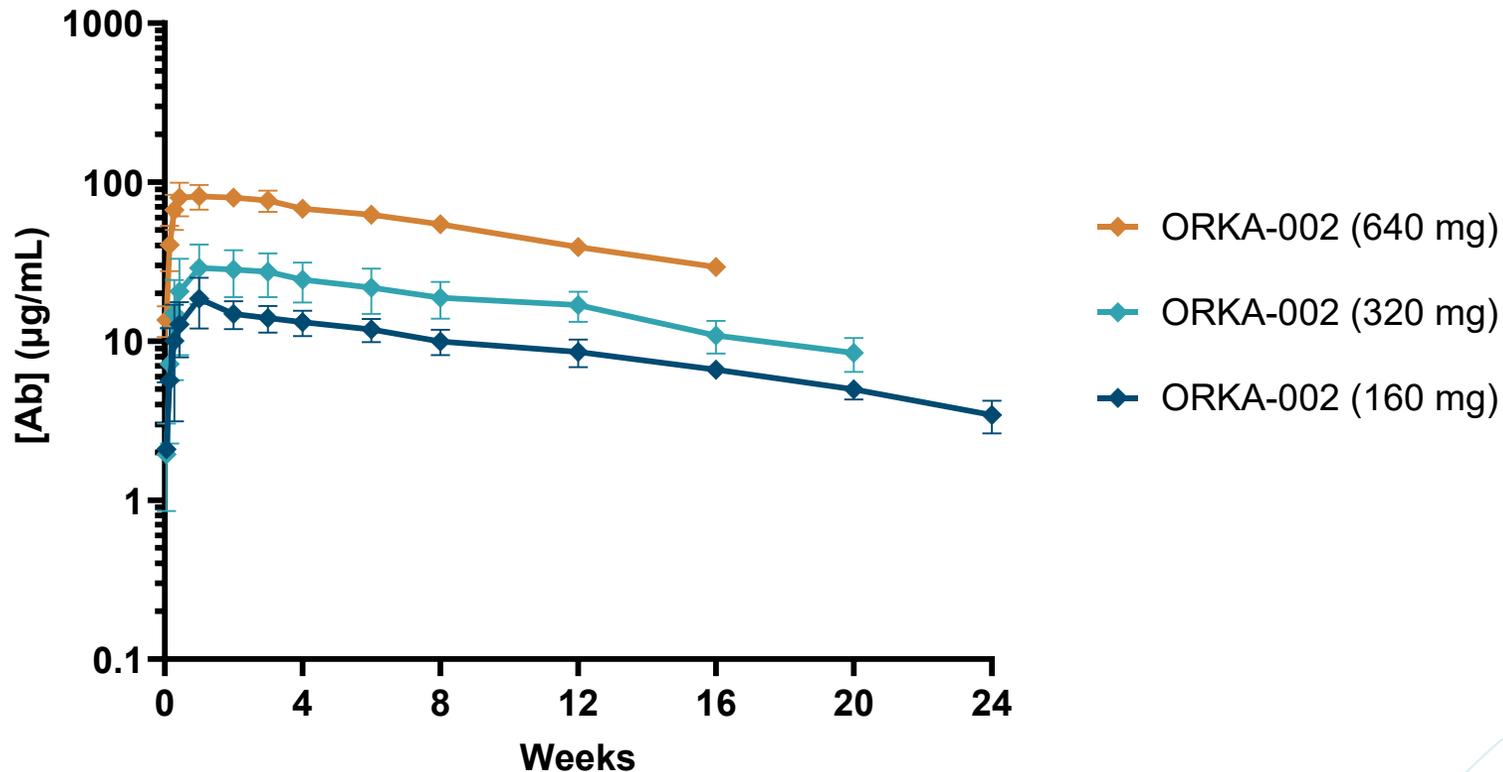
# ORKA-002 safety profile was consistent with the IL-17 class

<i>ORKA-001 and placebo (blinded)</i>	160 mg	320 mg	640 mg	All cohorts
<b>N</b>	8	8	8	24
<b>≥1 TEAE</b>	8 (100%)	8 (100%)	7 (87.5%)	23 (95.8%)
<b>≥1 SAE</b>	0%	0%	0%	0%
<b>≥1 severe TEAE</b>	0%	0%	0%	0%
<b>Discontinued due to TEAE</b>	0%	0%	0%	0%

Only AEs occurring in >2 subjects were contusion<sup>1</sup>, headache, skin abrasion<sup>1</sup>, and upper respiratory tract infection

# Half-life of 75-80 days enables potential for twice-yearly dosing

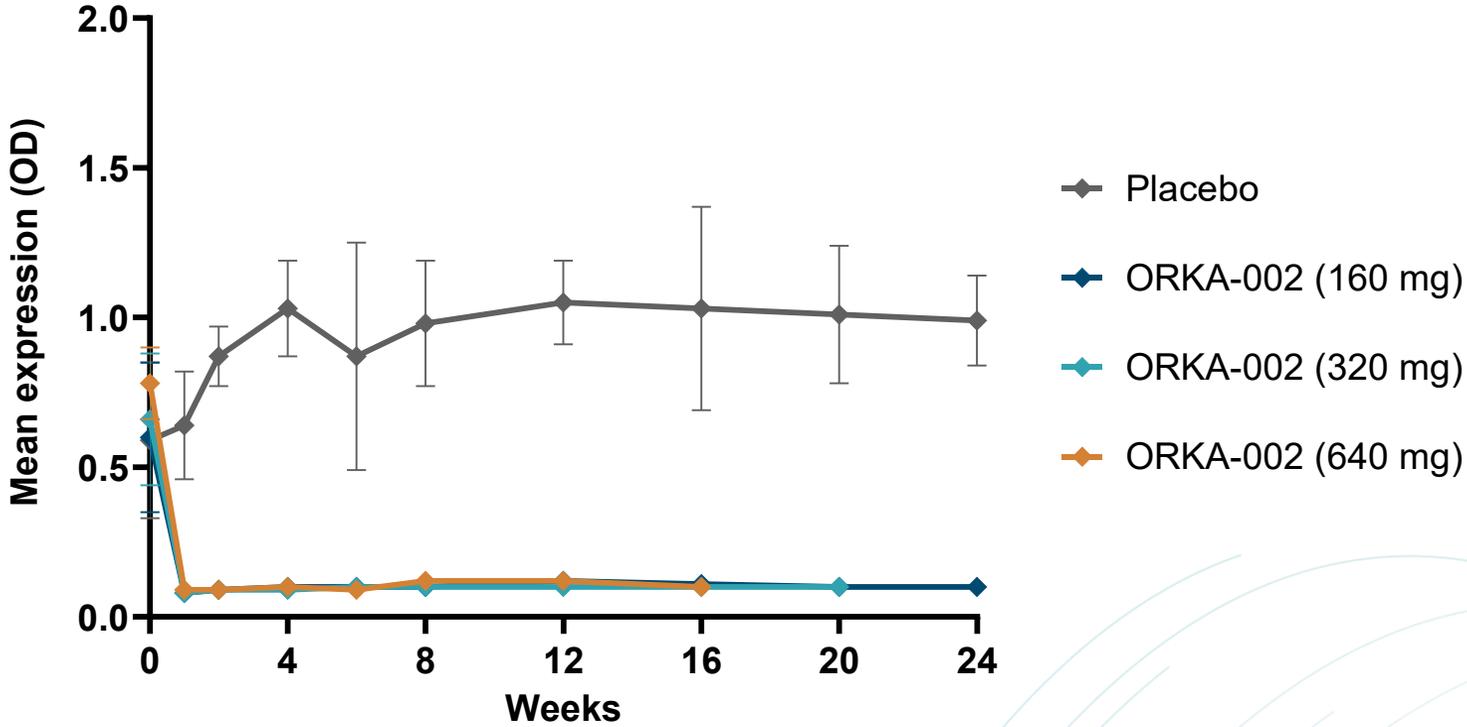
## Pharmacokinetic profile of a single subcutaneous dose of ORKA-002



- **$t_{1/2}$  of 75-80 days** in humans, >3x longer than bimekizumab
- **$C_{max}$  comparable to bimekizumab** at an equivalent dose
- Less than dose-proportional exposure in 320 mg group due to higher body weight
- Individual PK profiles **show no indication of ADAs**

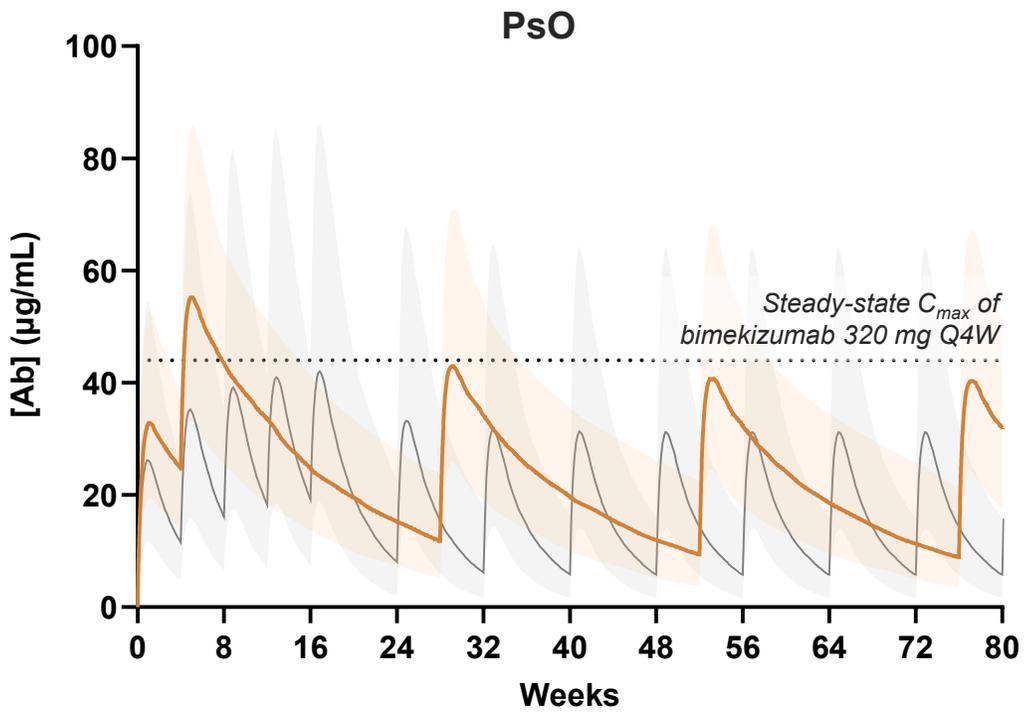
# ORKA-002 demonstrated deep and sustained inhibition of IL-17 signaling in an *ex vivo* IL-17 stimulation assay through 24 weeks

ORKA-002 from serum inhibits IL-17 signaling following *ex vivo* IL-17 stimulation

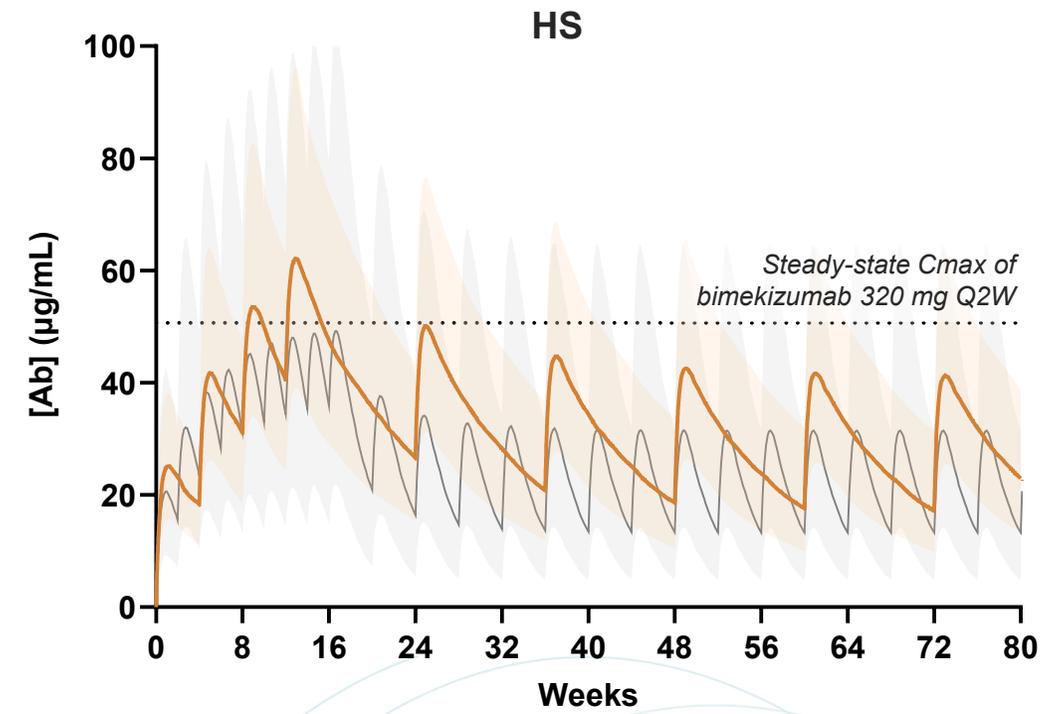


# Potential for Q6M dosing in PsO and Q3M dosing in HS

Projected  $C_{trough}$  of ORKA-002 exceeds approved bimekizumab regimens in PsO and HS



- **ORKA-002:** 320 mg W0, 4 then Q6M
- **Bimekizumab:** 320 mg W0, 4, 8, 12, 16 then Q8W



- **ORKA-002<sup>(1)</sup>:** 320 mg W0, 4, 8, 12 then Q3M
- **Bimekizumab:** 320 mg W0, 2, 4, 6, 8, 10, 12, 14, 16 then Q4W

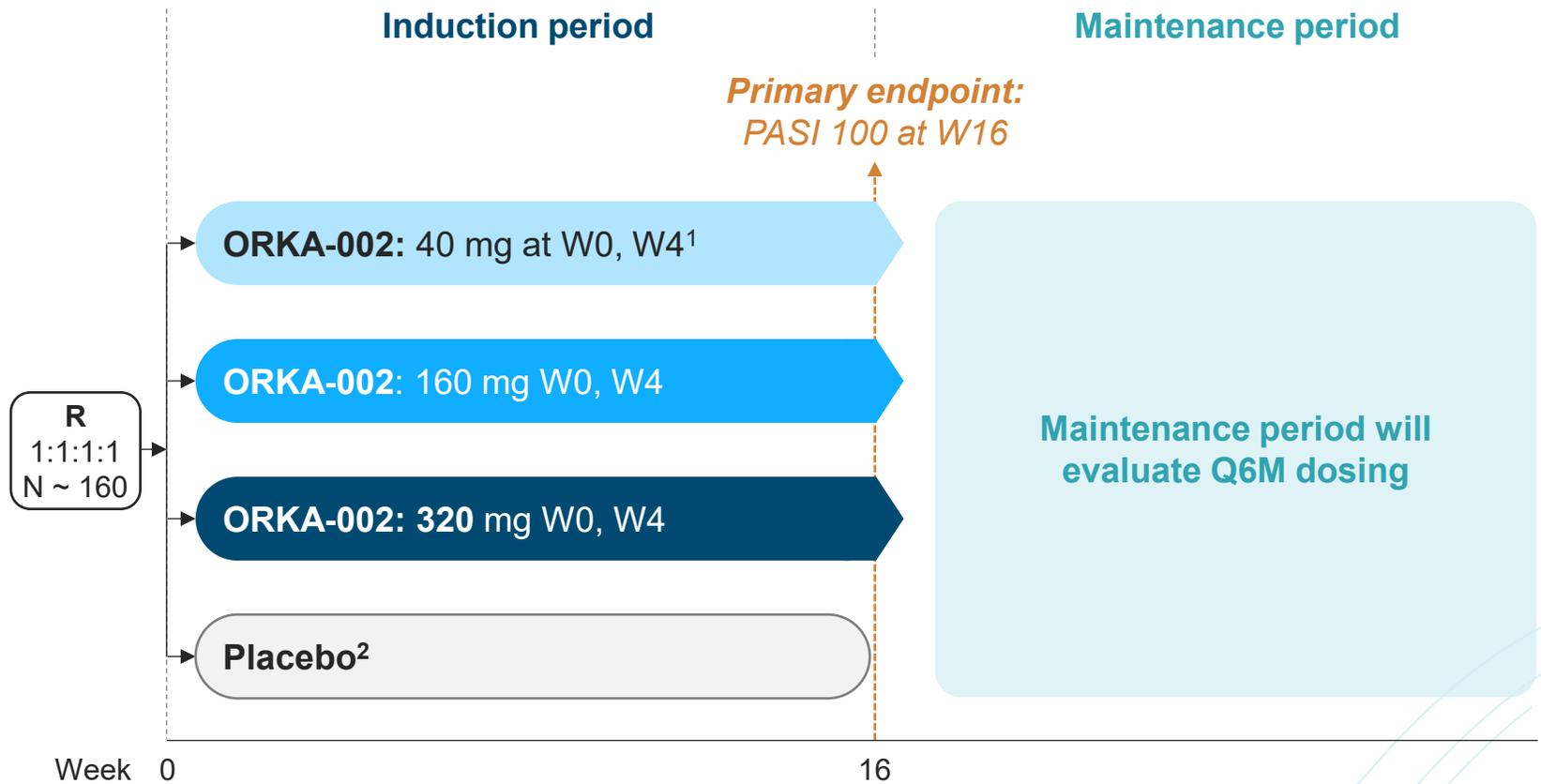


Notes & Sources: Oruka modeling based on internal data and published population pharmacokinetic model and PK parameters for bimekizumab; error bars reflect 5<sup>th</sup> and 95<sup>th</sup> percentiles; (1) Assumes similar increase in clearance and volume of distribution in HS as observed with bimekizumab

# ORCA-SURGE – initiation expected 1H 2026



## ORCA-SURGE Phase 2 dose-ranging trial of ORKA-002 in moderate-to-severe psoriasis



- **ORCA-SURGE data expected in 2027**
- **Phase 2 trial in hidradenitis suppurativa (HS) to start in 2H 2026**

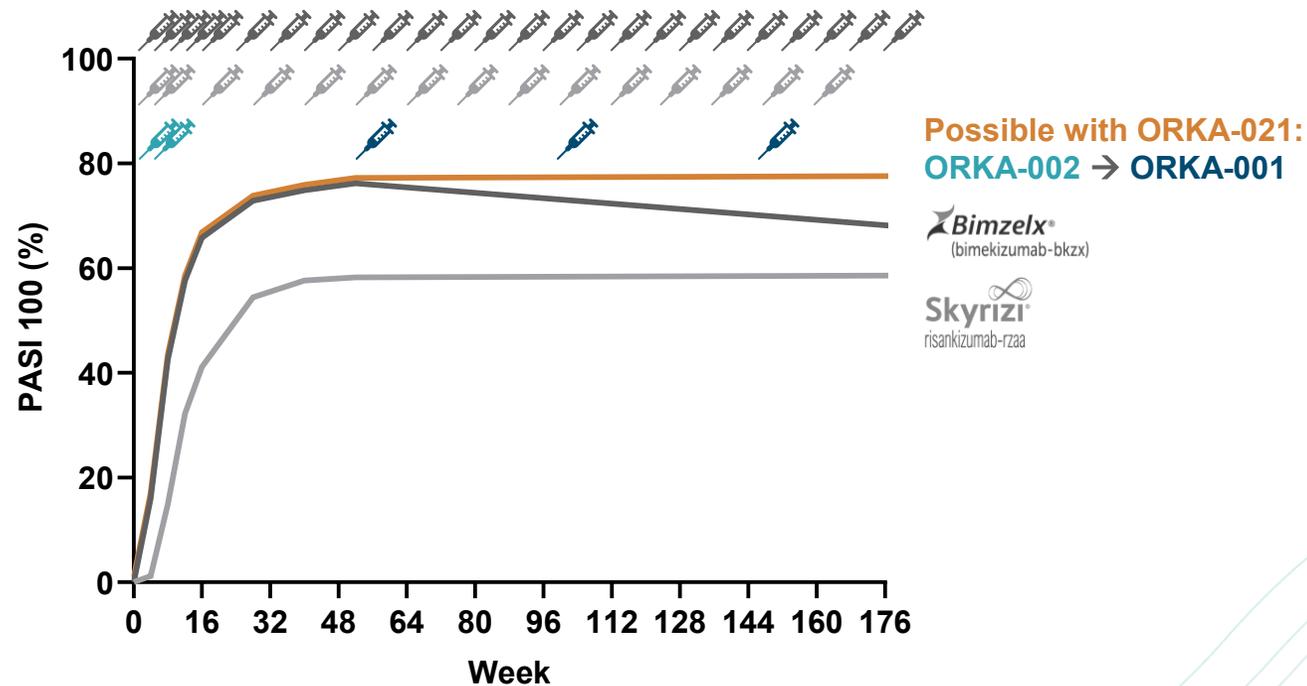
# ORKA-021: Potential to combine the best of IL-17s and IL-23s

IL-17s: fastest onset and highest peak response



IL-23s: less frequent dosing and best durability and safety

Combining the two mechanisms sequentially could provide the “best of both worlds”



Feedback from U.S. dermatologists:

*“It really sounds like a great option”*

*“Conceptually beautiful”*

*“The only reason this hasn’t been done is that no company has both”*

# Four ways to deliver a best-in-class regimen for psoriatic disease

- **Once yearly dosing** and **off-treatment remissions** go beyond convenience to **change the treatment paradigm**



- Clinical precedent supports potential for **best efficacy** in the IL-23 class



- Only long-acting IL-17A/F in a **brand-new, mega-blockbuster class** with a **long timeline to biosimilars** and **indication expansion potential**



- Straightforward path to a potential H2H win – **faster and deeper responses** vs. Skyrizi and **superior maintenance profile** vs. Bimzelx



# Multiple Phase 2 readouts coming over the next two years

ORKA-001



Phase 2a (PsO)

**2H 2026:** PASI 100 rates and response duration



Phase 2b (PsO)

**2027:** Week 16 and durability

ORKA-002



Phase 2 (PsO)

**1H 2026:** Initiation  
**2027:** Week 16 and durability

Phase 2 (HS)

**2H 2026:** Initiation

**Strong cash position provides runway >1 year beyond three major readouts: EVERLAST-A, EVERLAST-B, and ORCA-SURGE**



**ORUKA**  
THERAPEUTICS

# Shares outstanding

As of September 30, 2025

Number of shares<sup>1</sup>

<b>Common stock</b>	<ul style="list-style-type: none"><li>• Shares outstanding</li></ul>	48.4M
<b>Common stock equivalents</b>	<ul style="list-style-type: none"><li>• Preferred stock (as-converted to common stock)</li></ul>	11.4M
	<ul style="list-style-type: none"><li>• Pre-funded warrants</li></ul>	7.3M
<b>Common stock and common stock equivalents</b>	<ul style="list-style-type: none"><li>• <b>Total outstanding<sup>2</sup></b></li></ul>	<b>67.1M</b>