

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 OR 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): April 27, 2026

Oruka Therapeutics, Inc.  
(Exact name of Registrant as Specified in its Charter)

Delaware  
(State or other jurisdiction  
of incorporation)

000-22873  
(Commission File Number)

36-3855489  
(IRS Employer  
Identification No.)

855 Oak Grove Avenue  
Suite 100  
Menlo Park, California  
(Address of principal executive offices)

94025  
(Zip Code)

Registrant's telephone number, including area code: (650) 606-7910

N/A  
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.001 par value	ORKA	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

## Item 7.01 Regulation FD Disclosure.

On April 27, 2026, Oruka Therapeutics, Inc. (“Oruka” or the “Company”) issued a press release, and made publicly available a data presentation, announcing results from its Phase 2a EVERLAST-A clinical trial of ORKA-001, its potentially best-in-class anti-IL-23 antibody, in patients with moderate-to-severe psoriasis (“PsO”). Oruka will host a conference call and webcast today, Monday, April 27, 2026, at 8:00 a.m., Eastern Time, to discuss the data results.

The information in Item 7.01 of this Current Report on Form 8-K, including the information in the press release and presentation attached as Exhibits 99.1 and 99.2 to this Current Report on Form 8-K, is furnished pursuant to Item 7.01 of Form 8-K and shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section. Furthermore, the information in Item 7.01 of this Current Report on Form 8-K, including the information in the press release attached as Exhibit 99.1 and the presentation attached as Exhibit 99.2 to this Current Report on Form 8-K, shall not be deemed to be incorporated by reference in the filings of the Company under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such filing.

## Item 8.01 Other Events.

On April 27, 2026, Oruka announced results from its Phase 2a EVERLAST-A clinical trial of ORKA-001 in patients with moderate-to-severe PsO.

### EVERLAST-A Phase 2a Key 16-Week Results

The Phase 2a EVERLAST-A clinical trial is a randomized, double-blind, placebo-controlled study evaluating ORKA-001 in patients with moderate-to-severe PsO. EVERLAST-A enrolled 84 patients randomized 3:1 to receive 600 mg of ORKA-001 at Weeks 0 and 4 or matching placebo. The primary endpoint is PASI 100, a 100% reduction from baseline in Psoriasis Area and Severity Index (“PASI”), at Week 16. At Week 28, patients who achieve PASI 100 are randomized 2:1 to an arm where either (1) they do not receive another dose until disease recurrence (to evaluate the possibility of both yearly dosing and extended off-treatment remission) or (2) they receive 300 mg ORKA-001 every six months. Patients who do not achieve PASI 100 receive a 300 mg dose every six months.

Initial 16-week findings from EVERLAST-A include efficacy results, which compare favorably versus standard of care across endpoints based on cross-trial comparisons, as well as a favorable safety profile consistent with the IL-23p19 inhibitor class:

- Primary endpoint achieved: ORKA-001 met the primary endpoint of PASI 100 at Week 16, with 63.5% (40/63) of treated patients achieving complete skin clearance compared to 4.8% (1/21) for placebo ( $p < 0.0001$ ).
- Key secondary endpoints were also met, including:
  - IGA 0: 63.5% vs. 4.8% for placebo ( $p < 0.0001$ )
  - PASI 90: 82.5% vs. 4.8% for placebo
  - IGA 0/1: 84.1% vs. 4.8% for placebo
- Safety profile: ORKA-001 was generally well tolerated, with a safety profile consistent with the IL-23p19 inhibitor class:
  - Treatment-emergent adverse events (TEAEs) were reported in 50.8% of ORKA-001-treated patients compared to 57.1% in placebo
  - No serious TEAEs were reported in the ORKA-001 treatment arm
  - No discontinuations due to adverse events were observed
  - The most common TEAE ( $\geq 5\%$  in either group) was upper respiratory tract infection (19.0% in the treatment arm vs. 14.3% for placebo)
  - No injection site reactions were reported

The trial is ongoing, and longer-term data, including durability of response and additional safety follow-up, are expected in the second half of 2026.

#### **ORKA-001 Phase 1 Trial**

Oruka also reported updated pharmacokinetic (PK) and pharmacodynamic (PD) data from its Phase 1 trial of ORKA-001. Following a single 600 mg dose, ORKA-001 concentrations in the patient population (n=6) remained well above effective trough levels through 52 weeks, with sustained inhibition of IL-23 pathway signaling observed throughout that period. These data support the potential for annual dosing. No impact of anti-drug antibodies on PK was observed in the Phase 1 trial or in the EVERLAST-A trial.

#### **EVERLAST-B Phase 2b Trial**

EVERLAST-B is a dose-ranging Phase 2b trial of ORKA-001 in patients with moderate-to-severe PsO. It is designed to enroll approximately 160 patients and will evaluate three dose levels of ORKA-001: 37.5 mg at Week 0, 300 mg at Weeks 0 and 4, and 600 mg at Weeks 0 and 4, versus placebo. The primary endpoint is PASI 100 at Week 16. At Week 28, patients who have achieved PASI 100 will be re-randomized 1:1 to either a 600 mg dose once-yearly or matching placebo. Patients who have not achieved PASI 100 at Week 28 will receive a 300 mg dose every six months. Building on EVERLAST-A, the EVERLAST-B trial is designed to evaluate the potential for ORKA-001 to achieve yearly dosing, higher efficacy and extended off-treatment remissions. EVERLAST-B continues to enroll participants with data expected in 2027.

#### *Forward-looking Statements*

This Current Report on Form 8-K contains certain statements that may constitute “forward-looking statements” within the meaning of the federal securities laws, including for purposes of the safe harbor provisions under the United States Private Securities Litigation Reform Act of 1995, concerning Oruka and other matters. These forward-looking statements include, but are not limited to: Oruka’s plans for its product candidates and development programs; the expected timing, progress and results of its clinical trials, including anticipated data readouts from EVERLAST-A and EVERLAST-B; its clinical trial designs and development strategy; its plans for future clinical trials and potential regulatory pathways; the potential clinical profile of ORKA-001, including its safety, efficacy, half-life, pharmacokinetics, dosing regimen and durability; and its business strategy and objectives, as well as other statements that are not historical fact. The words “believe,” “may,” “will,” “potentially,” “estimate,” “continue,” “anticipate,” “predict,” “target,” “intend,” “could,” “would,” “should,” “project,” “plan,” “expect,” and similar expressions that convey uncertainty of future events or outcomes are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements are based on current expectations and beliefs concerning future developments and their potential effects. There can be no assurance that future developments affecting Oruka will be those that have been anticipated. These forward-looking statements involve a number of risks and uncertainties (some of which are beyond Oruka’s control), including the risks and uncertainties included under the section titled “Risk Factors” contained in our most recent Annual Report on Form 10-K and other periodic or current reports subsequently filed with the Securities and Exchange Commission, or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. Accordingly, undue reliance should not be placed on these forward-looking statements. All forward-looking statements are based on information currently available to Oruka, and Oruka does not assume any obligation to update any statement to reflect changes in circumstances or its expectations, except as required by law.

#### **Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

<b>Exhibit No.</b>	<b>Description</b>
99.1	<a href="#">Press Release, dated April 27, 2026</a>
99.2	<a href="#">Presentation, dated April 27, 2026</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**Oruka Therapeutics, Inc.**  
(Registrant)

Date: April 27, 2026

By: /s/ Paul Quinlan  
Name: Paul Quinlan  
Title: General Counsel

**Oruka Therapeutics Announces Positive Week 16 Data for ORKA-001 from the Ongoing  
EVERLAST-A Phase 2a Trial in Moderate-to-Severe Plaque Psoriasis**

*ORKA-001 achieved 63.5% (40/63) PASI 100 at Week 16*

*Favorable safety profile consistent with the IL-23p19 class*

*Updated Phase 1 PK/PD data continue to support the potential for once-yearly dosing, with longer-term EVERLAST-A data expected in 2H 2026*

*Management to host a conference call today at 8:00 a.m. ET*

MENLO PARK, Calif., April 27, 2026 (GLOBE NEWSWIRE) -- Oruka Therapeutics, Inc. ("Oruka") (Nasdaq: ORKA), a clinical-stage biotechnology company developing novel biologics designed to set a new standard for the treatment of chronic skin diseases, today announced positive interim results from its EVERLAST-A Phase 2a trial of ORKA-001, a novel half-life extended IL-23p19 monoclonal antibody, in moderate-to-severe plaque psoriasis.

"These data reached the top end of what we could have expected from ORKA-001 across efficacy, tolerability, and potential for long-lasting response," said Joana Goncalves, MBChB, Chief Medical Officer of Oruka. "We're thrilled with the profile that is emerging for this program and are excited to see how the data mature with longer-term follow-up. I want to thank the Oruka team, the EVERLAST-A investigators, and the trial participants for getting this study off to a tremendous start."

"These data with ORKA-001 are highly compelling," said Dr. Bruce Strober, MD, PhD, Clinical Professor of Dermatology at Yale University School of Medicine and lead investigator for EVERLAST-A. "If this type of efficacy and safety profile could be available with dosing once to twice per year, it would represent a major step forward for the field. I could envision this being the preferred product for any patient with moderate-to-severe psoriasis."

EVERLAST-A is a randomized, double-blind, placebo-controlled Phase 2a trial evaluating the safety, efficacy, and pharmacokinetics of ORKA-001 in participants with moderate-to-severe plaque psoriasis. The study is being conducted across 26 sites in the United States and Canada, and enrolled 84 patients randomized 3:1 to receive 600 mg of ORKA-001 at Week 0 and 4 or matching placebo. Baseline characteristics were comparable to recent studies in moderate-to-severe psoriasis.

### ***Efficacy***

40 of 63 participants (63.5%) treated with ORKA-001 achieved the primary endpoint of PASI 100 at Week 16, representing complete skin clearance. Identical results were observed for IGA 0. Other key secondary endpoints included PASI 90 at Week 16, achieved by 83% of participants, and IGA 0/1 at Week 16, achieved by 84% of participants. One of 21 participants receiving placebo reached PASI 100, IGA 0, PASI 90, and IGA 0/1 at Week 16, in line with historical psoriasis trials. All response rates were calculated using non-responder imputation. Based on a cross-trial comparison, these data with ORKA-001 demonstrate numerically higher rates of skin clearance than all other IL-23p19 inhibitors and are comparable to the highest reported in plaque psoriasis for any mechanism of action.

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## ***Safety***

ORKA-001 was well tolerated with a safety profile similar to placebo and consistent with prior IL-23p19 inhibitors. There were no serious treatment-emergent adverse events (“TEAEs”) and one severe TEAE, which occurred in the placebo group. Most TEAEs were mild in severity. The overall rate of TEAEs was comparable across groups, with 51% of participants treated with ORKA-001 and 57% of participants receiving placebo experiencing at least one TEAE. The only TEAE that occurred in 5% or more of subjects in either group was upper respiratory tract infection (19% for ORKA-001 and 14% for placebo). There were no injection site reactions.

## ***Pharmacokinetics (“PK”) and Pharmacodynamics (“PD”)***

Updated PK and PD data from the Phase 1 trial of ORKA-001 continue to support the potential for annual dosing. Following a single 600 mg dose, ORKA-001 concentrations remained well above effective trough levels for an entire year, with sustained inhibition of IL-23 pathway signaling observed throughout that time period. No impact of anti-drug antibodies on PK has been seen in either the Phase 1 or EVERLAST-A trials.

## ***Upcoming Milestones for ORKA-001***

Oruka plans to share longer-term data from EVERLAST-A, including efficacy at Week 28 for all patients and 52-week follow-up for a subset of the cohort, in the second half of 2026. The Company also continues to advance the Phase 2b EVERLAST-B trial, with data expected in 2027.

## ***Webcast Details***

Oruka Therapeutics’ live webcast of the EVERLAST-A results will begin today at 8:00 a.m. ET. The live webcast can be accessed via this link, or through the Investors section on the company’s website at <https://ir.orukatx.com/news-events/events-presentations>. A replay of the webcast will be available following the call.

## ***About Oruka Therapeutics***

Oruka Therapeutics is developing novel biologics designed to set a new standard for the treatment of chronic skin diseases. Oruka’s mission is to offer patients suffering from chronic skin diseases like plaque psoriasis the greatest possible freedom from their condition by achieving high rates of complete disease clearance with dosing as infrequently as once or twice a year. Oruka is advancing a proprietary portfolio of potentially best-in-class antibodies that were engineered by Paragon Therapeutics and target the core mechanisms underlying plaque psoriasis and other dermatologic and inflammatory diseases. For more information, visit [www.orukatx.com](http://www.orukatx.com) and follow Oruka on LinkedIn.

## **Forward Looking Statements**

Certain statements in this press release, other than purely historical information, may constitute “forward-looking statements” within the meaning of the federal securities laws, including for purposes of the safe harbor provisions under the United States Private Securities Litigation Reform Act of 1995. These forward-looking statements include, but are not limited to, express or implied statements relating to Oruka’s expectations, hopes, beliefs, intentions or strategies regarding the future of its pipeline and business including, without limitation, Oruka’s ability to achieve the expected benefits or opportunities with respect to ORKA-001, including timelines to clinical and data release milestones, the details of its planned clinical trials and the potential dosing interval of ORKA-001. These forward-looking statements are based on current expectations and beliefs concerning future developments and their potential effects. There can be no assurance that future developments affecting Oruka will be those that have been anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond Oruka’s control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to, those uncertainties and factors described under the heading “Risk Factors” and “Cautionary Note Regarding Forward-Looking Statements” in Oruka’s most recent filings with the Securities and Exchange Commission (SEC), including its most recent Annual Report on Form 10-K. Should one or more of these risks or uncertainties materialize, or should any of Oruka’s assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. Nothing in this press release should be regarded as a representation by any person that the forward-looking statements set forth therein will be achieved or that any of the contemplated results of such forward-looking statements will be achieved. You should not place undue reliance on forward-looking statements in this press release, which speak only as of the date they are made and are qualified in their entirety by reference to the cautionary statements herein and in Oruka’s SEC filings. Oruka does not undertake or accept any duty to make any updates or revisions to any forward-looking statements.

### **Investor Contact:**

Alan Lada  
(650)-606-7911  
alan.lada@orukatx.com



# EVERLAST-A Interim Data

ORKA-001 Phase 2a trial in psoriasis

April 27, 2026

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# Disclaimers

The information contained in this presentation has been prepared by Oruka Therapeutics, Inc. (the "Company") and contains information pertaining to the business and operations of the Company. The information contained in this presentation: (a) is provided as at the date hereof, is subject to change without notice, and is based on publicly available information, internally developed data as well as third party information from other sources; (b) does not purport to contain all the information that may be necessary or desirable to fully and accurately evaluate an investment in the Company; (c) is not to be considered as a recommendation by the Company that any person make an investment in the Company; (d) is for information purposes only and shall not constitute an offer to buy, sell, issue or subscribe for, or the solicitation of an offer to buy, sell or issue, or subscribe for any securities of the Company in any jurisdiction in which such offer, solicitation or sale would be unlawful. Where any opinion or belief is expressed in this presentation, it is based on certain assumptions and limitations and is an expression of present opinion or belief only. This presentation should not be construed as legal, financial or tax advice to any individual, as each individual's circumstances are different. This document is for informational purposes only and should not be considered a solicitation or recommendation to purchase, sell or hold a security.

## Forward-Looking Information

Certain information set forth in this presentation contains "forward-looking statements" within the meaning of applicable United States securities legislation. Except for statements of historical fact, certain information contained herein constitutes forward-looking statements, which include but are not limited to statements regarding: expectations regarding the efficacy, durability of effect, dosing interval and safety of our product candidates; expectations regarding our plans for clinical trials and research and development programs, including the timing of clinical trials and data readouts; the time periods over which the Company's capital resources will be sufficient to fund its anticipated operations; the Company's business strategy objectives and goals; and management's assessment of future plans and operations, which are based on current internal expectations, estimates, projections, assumptions and beliefs, which may prove to be incorrect. Forward-looking statements are neither historical facts nor assurances of future performance. Forward-looking statements are based on a number of factors and assumptions made by management and considered reasonable at the time such information is provided, and forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause the actual results, performance or achievements to be materially different from those expressed or implied by the forward-looking statements including those uncertainties and factors described under the heading "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements" in the Company's most recent filings with the SEC, including its Annual Report on Form 10-K, its Quarterly Reports on Form 10-Q and its other filings with the SEC, as well as discussions of potential risks, uncertainties by the Company from time to time, as well as risk factors associated with companies that operate in the biopharma industry, including those associated with the uncertainties of drug development. All of the forward-looking statements made in this presentation are qualified by these cautionary statements and other cautionary statements or other factors contained herein. Although management believes that the expectations conveyed by forward-looking statements herein are reasonable based on information available on the date such forward-looking statements are made, there can be no assurance that forward looking statements will prove to be accurate, as actual results and future events could differ materially from those anticipated in such statements. The Company undertakes no obligation to update forward-looking statements if circumstances or management's estimates or opinions should change except as required by applicable securities laws. The forward-looking statements contained herein are presented for the purposes of assisting readers in understanding the Company's plans, objectives and goals and may not be appropriate for other purposes. The reader is cautioned not to place undue reliance on forward-looking statements.

## Industry Information

This presentation also contains or references certain industry data that is based upon information from independent industry publications, market research, and surveys and other publicly available sources. Although the Company believes these sources to be generally reliable, such information is subject to interpretation and cannot be verified with complete certainty due to limits on the availability and reliability of data, the voluntary nature of the data gathering process and other inherent limitations and uncertainties. The Company has not independently verified any of the data from third party sources referred to in this presentation and accordingly, the Company makes no representation or warranty as to the origin, validity, accuracy, completeness, currency or reliability of the information in this presentation.



# Agenda

- **Introduction**  
Lawrence Klein, PhD  
Chief Executive Officer
- **ORKA-001 EVERLAST-A Phase 2a interim results**  
Joana Goncalves, MBChB  
Chief Medical Officer
- **Understanding ORKA-001's potential**  
Lawrence Klein, PhD  
Chief Executive Officer
- **Analyst Q&A**  
Lawrence Klein, CEO  
Joana Goncalves, CMO

# Introduction

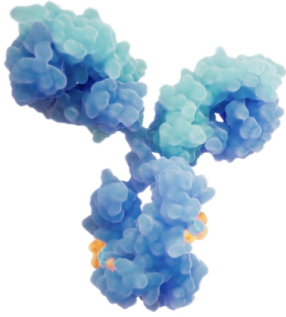
Lawrence Klein  
CEO



# Two programs that could set a new standard in psoriatic disease

## ORKA-001

*Ultra-long-acting IL-23p19 mAb with potential for annual dosing, superior efficacy, and off-treatment remission*



**EVERLAST-A**

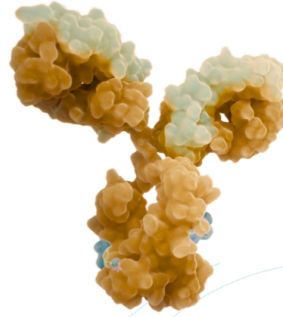
Phase 2a in PsO  
**TODAY:** 16-week data

**EVERLAST-B**

Dose-ranging Phase 2b to support Phase 3 initiation; data expected in 2027

## ORKA-002

*Ultra-long-acting IL-17A/F mAb with potential for Q6M dosing in PsO/PsA and Q3M dosing in HS*



**ORCA SURGE**

Phase 2 in PsO; data expected in 2027

**ORCA SPLASH**

Phase 2 start in HS anticipated in 2H 2026



Abbreviations: HS, hidradenitis suppurativa; PsA, psoriatic arthritis; PsO, psoriasis

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# PsO is a \$30B+ market where better biologics consistently win



**\$31B market today** for biologics and other advanced therapies, expected to grow to **\$39B by 2030<sup>1</sup>**



**Bimzelx launch (~\$1.4B in PsO alone in 2<sup>nd</sup> year)** shows that **better biologics continue to win**, even when launched by a non-incumbent



New orals have **not reached the efficacy of modern biologics**, but will likely expand the market, as Otezla did with the first generation of biologics



**A once- or twice-yearly IL-23p19 antibody with improved efficacy** has the potential to become the **preferred medicine in psoriasis**

# ORKA-001 offers Bimzelx-like efficacy with potential Q12M dosing



Very high rates of complete skin clearance

**63.5% PASI 100 at Week 16**, on par with Bimzelx, and replicating the effect seen in KNOCKOUT

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Potential for annual dosing

**Updated PK data further supports annual dosing**, while durability and off-treatment remission data continue to accrue

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Favorable safety profile

**Adverse event rates comparable to placebo** and consistent with the IL-23p19 class

# EVERLAST-A Interim Data

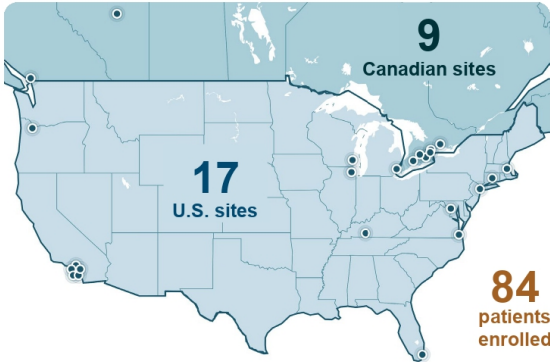
Joana Goncalves  
CMO



# EVERLAST-A is a large, multi-center Phase 2a trial designed as a definitive test of ORKA-001's potential

26 experienced sites that all participated in trials of approved psoriasis biologics

Nearly identical eligibility criteria as prior anti-IL-23 trials

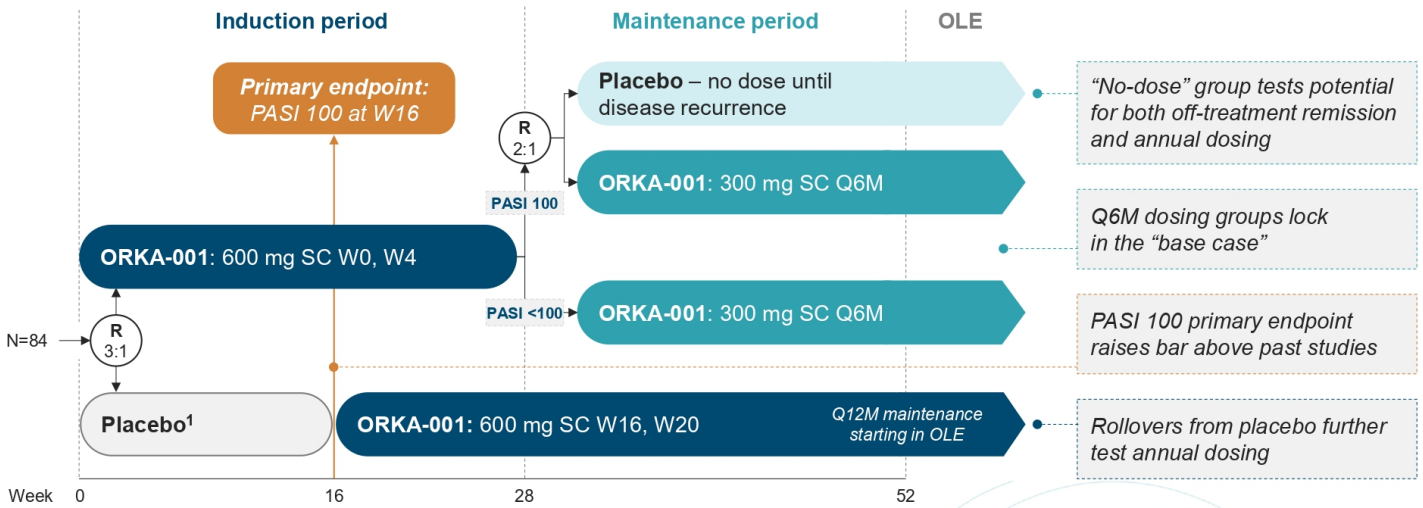


- Participants  $\geq 18$  years of age with moderate-to-severe chronic plaque psoriasis, defined as:
  - BSA  $\geq 10\%$ , and
  - PASI  $\geq 12$ , and
  - IGA score of  $\geq 3$  on a 5-point scale
- Candidate for systemic therapy or phototherapy
- No prior anti-IL-23p19 exposure allowed, as in trials of risankizumab, guselkumab, and icotrokinra

The EVERLAST-A active cohort (n=63) is larger than all active cohorts across recent Phase 2 trials in psoriasis



# EVERLAST-A has an innovative design (NCT07090330)



All patients have reached the Week 16 primary endpoint, with no discontinuations in either arm



Notes: (1) Any placebo patients achieving PASI  $\geq 90$  at Week 16 do not receive ORKA-001  
Abbreviations: OLE, open-label extension; SC, subcutaneous

# Baseline characteristics were comparable to prior trials in PsO

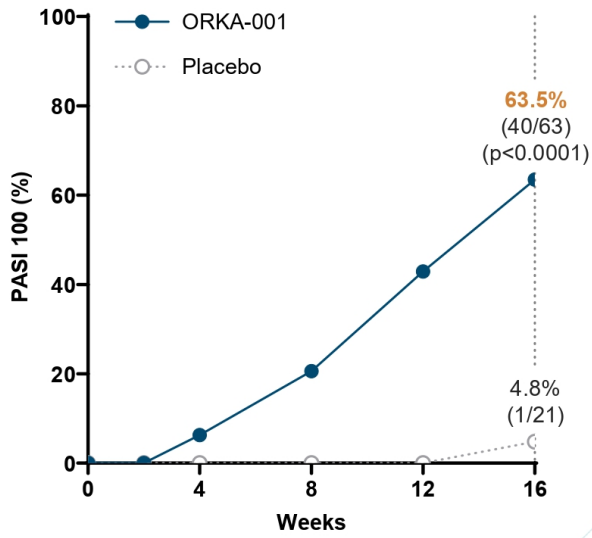
	ORKA-001	Placebo
<b>N</b>	63	21
<b>Age, mean (SD)</b>	45 (15)	39 (11)
<b>Sex (female), %</b>	29%	29%
<b>Race, %</b>		
White	76%	76%
Asian	13%	19%
Other or not reported	11%	5%
<b>Weight (kg), mean (SD)</b>	84 (16)	87 (13)
<b>BMI, mean (SD)</b>	28 (4)	29 (3)
<b>Disease duration (years), mean (SD)</b>	15 (12)	16 (13)
<b>BSA (%), mean (SD)</b>	21 (12)	19 (12)
<b>PASI, mean (SD)</b>	18 (7)	17 (5)
<b>IGA, %</b>		
3	71%	81%
4	29%	19%
<b>Prior biologic use, %</b>	14%	24%
<b>DLQI, mean (SD)</b>	12 (7)	10 (6)



Notes: Data cut as of April 9, 2026

# 63.5% of patients achieved completely clear skin at Week 16

PASI 100



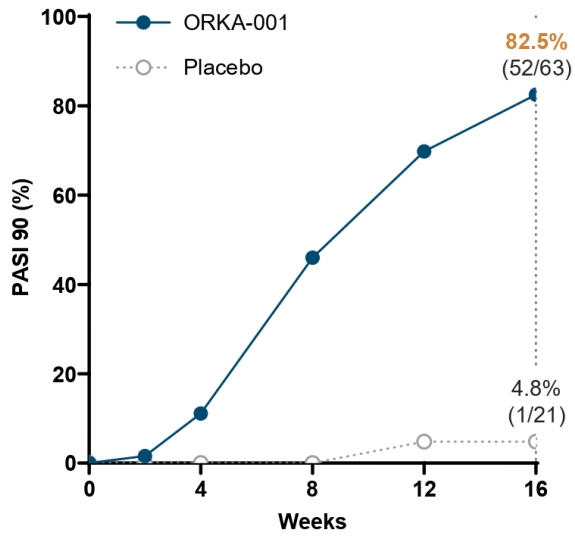
Identical IGA 0 results



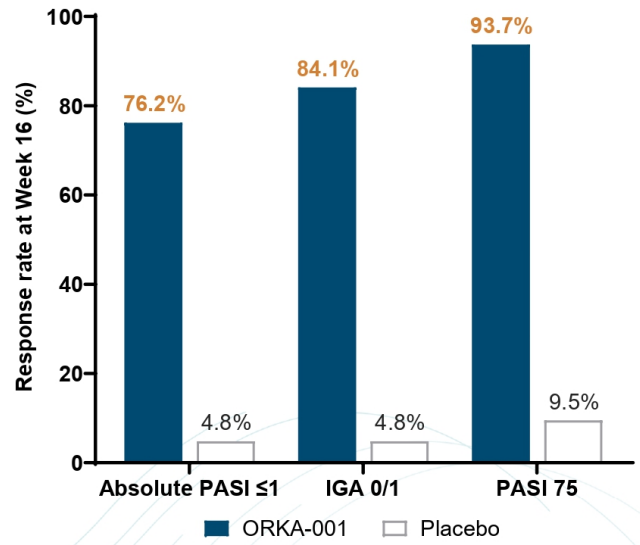
Notes: Data cut as of April 9, 2026. Data based on non-responder imputation (NRI)

# High response rates achieved on other efficacy measures

PASI 90



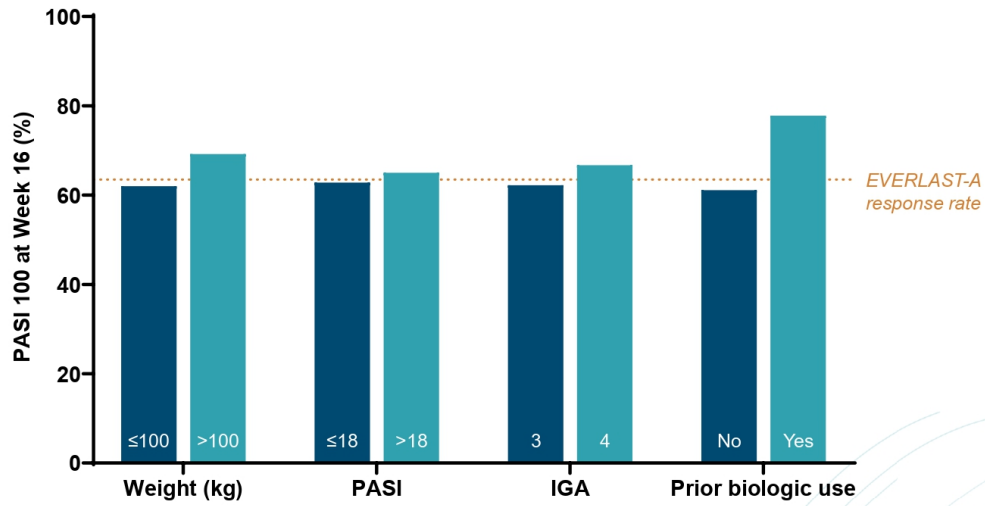
Additional PASI and IGA scores



Notes: Data cut as of April 9, 2026. Data based on non-responder imputation (NRI)

# Baseline characteristics had no apparent impact on efficacy

PASI 100 by baseline characteristic subgroup



No significant correlation observed for any baseline characteristic



Notes: Data cut as of April 9, 2026. Data based on non-responder imputation (NRI). Post hoc analysis conducted to mirror analysis of risankizumab in UH1MMa-1/2 in BLA Multi-discipline Review, EPAR, and 2020 Strober (J Eur Acad Dermatol Venerol.)

## Favorable safety profile consistent with the IL-23p19 class

Week 0-16	ORKA-001	Placebo
<b>N</b>	63	21
<b>Treatment-emergent adverse events (TEAEs), N (%)</b>	32 (50.8%)	12 (57.1%)
<b>Serious TEAEs, N (%)</b>	-	-
<b>Severe TEAEs, N (%)</b>	-	1 (4.8%) <sup>1</sup>
<b>TEAE leading to discontinuation, N (%)</b>	-	-
<b>Most frequent TEAEs (≥5.0% in either cohort), N (%)</b>		
Upper respiratory tract infection	12 (19.0%)	3 (14.3%)

**No injection site reactions (0%) and no impact of anti-drug antibodies on safety, efficacy, or PK**



Notes: Data cut as of April 9, 2026. (1) Humerus fracture and joint dislocation

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# Upcoming EVERLAST data to further elucidate ORKA-001's profile

EVERLAST-A

Longer-term durability data



2H 2026

- **Efficacy and durability**
  - **Week 28 efficacy** (PASI 100, PASI 90, etc.)
  - **52-week follow-up** for a subset of patients to support annual dosing and off-treatment remission
- **Updated safety data**

EVERLAST-B

Primary endpoint readout



2027

- **Efficacy across dose levels**
  - **Week 16 efficacy (primary endpoint)** (PASI 100, PASI 90, etc.)
- **Safety data up to Week 16**

EVERLAST-B 16-week data is intended to support Phase 3 initiation

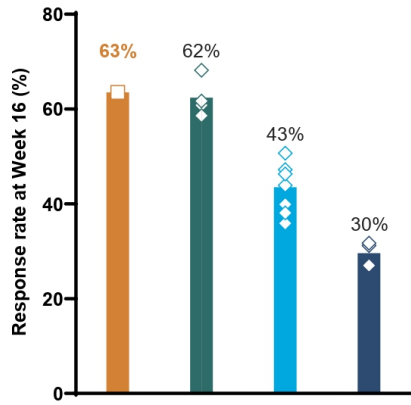
# Understanding ORKA-001's potential

Lawrence Klein  
CEO



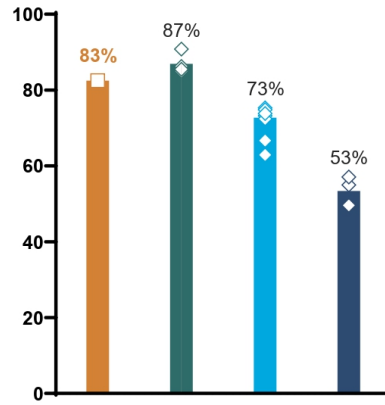
# Leading efficacy potential in an ultra-long-acting IL-23 inhibitor

PASI 100 (Week 16)



**ORKA-001**  
IL-23 | Q6M/Q12M

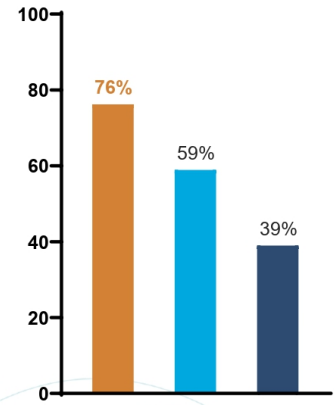
PASI 90 (Week 16)



**Bimzelx**  
IL-17A/F | Q4W/Q8W

**Skyrizi**  
IL-23 | Q12W

Absolute PASI ≤1 (Week 16)



**Icotyde**  
IL-23R | QD

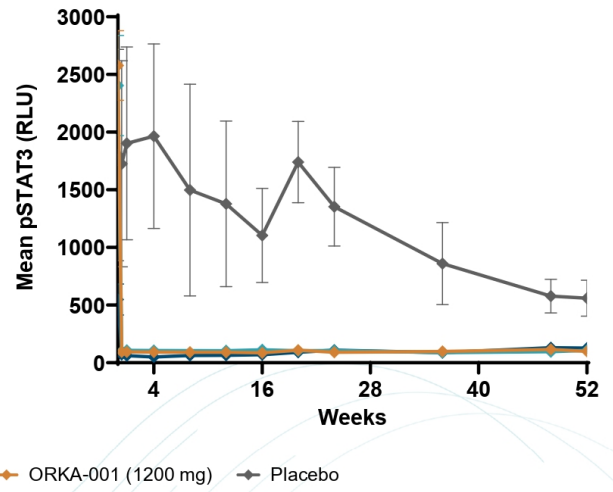
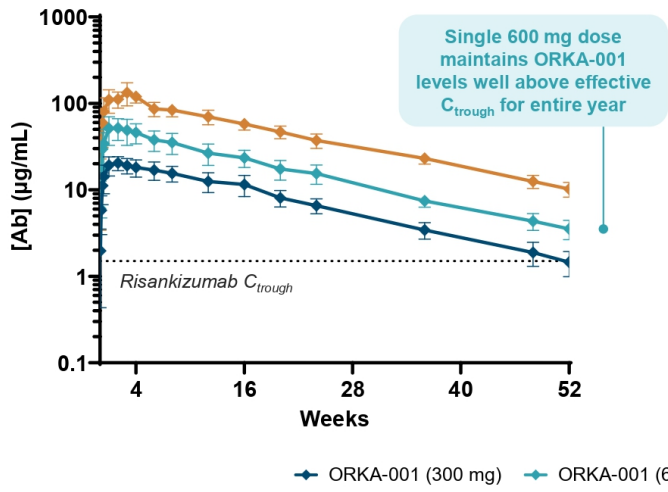


Notes: Icons represent individual trials and bars show weighted average. Cross-trial comparison shown for illustrative purposes only (not a head-to-head trial). Actual results may differ.  
 Source: All company-sponsored trials in moderate-to-severe psoriasis with U.S. sites using the approved dosing for each drug: BE VIVID (N=321), BE SURE (N=319), BE READY (N=349), BE RADIANT (N=373), UliiMa-1/2 (N=304 and 294), IMInance (N=407), IMMerge (N=301), IMMerge (N=164), NCT03875482 (N=105), NCT03875506 (N=108), ICONIC-LEAD (N=458), ICONIC-ADVANCE-1/2 (N=311 and 322). Absolute PASI data from UliiMa-1/2 (2022 Gooderham) and ICONIC-LEAD (2025 Gonzalez Cantero)

# Updated ORKA-001 Phase 1 PK/PD supports annual dosing

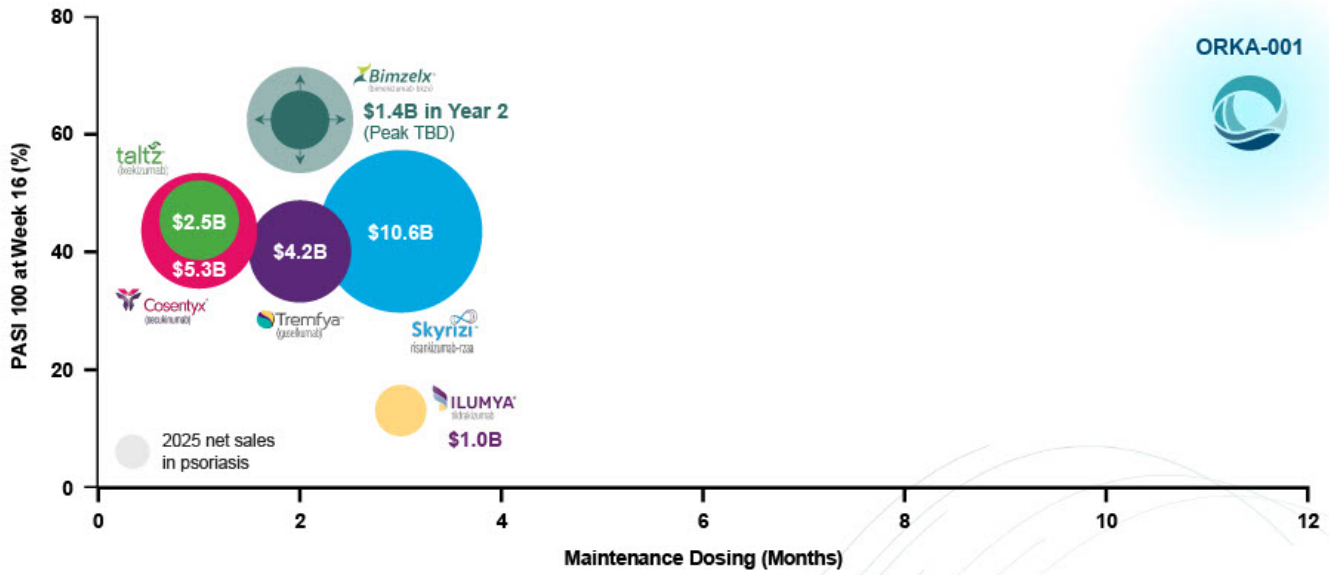
PK: ORKA-001 continues to show ~100-day half-life and no evidence of ADAs

PD: Sustained STAT3 inhibition for a year after a single dose of ORKA-001



Notes: Mean  $\pm$  SD (N=6 per group). (right) Inhibition of STAT3 phosphorylation by ORKA-001 from serum following ex vivo IL-23 stimulation

# ORKA-001 stands apart in a space that has created multiple \$5-10B+ products



Sources: Evaluate Pharma global net sales estimates, excluding psoriatic arthritis. Weighted average PASI 100 from company-sponsored trials in moderate-to-severe psoriasis with U.S. sites using approved dosing for bimekizumab (N=4), risankizumab (N=7), guselkumab (N=5), secukinumab (N=7), ixekizumab (N=4), and tildrakizumab (N=2, Week 12 data shown as Week 16 PASI 100 not reported) (sources on file)

# Well-funded through multiple impactful upcoming milestones

ORKA-001	 Phase 2a (PsO)   2H 2026: Week 28 and durability
	 Phase 2b (PsO)   2027: Week 16 and durability
ORKA-002	 Phase 2 (PsO)   2027: Week 16 and durability
	 Phase 2 (HS)   2H 2026: Initiation

We aim to beat the fastest BLA timeline in psoriasis – 6 years from FIH to BLA for Skyrizi

Strong cash position provides runway into Phase 3 for ORKA-001, and >1 year beyond readouts across EVERLAST-A, EVERLAST-B, and ORCA-SURGE

