



## Oruka Therapeutics Announces Positive Week 16 Results for ORKA-001 from the Ongoing EVERLAST-B Trial in Moderate-to-Severe Psoriasis

October 26, 2026

*61% PASI 100 and 86% PASI 90 in the ORKA-001 high-dose (600 mg) group, highly similar to EVERLAST-A*

*Continued favorable safety and tolerability profile consistent with the IL-23p19 class*

*ORKA-001 on track to advance into Phase 3 trials in 1H 2027*

*52-week EVERLAST-A results on track for December 2026*

*ORKA-002 16-week results from ORCA-SURGE Phase 2 in psoriasis on track for 1Q 2027*

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

MENLO PARK, Calif., Oct. 26, 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 including plaque psoriasis (PsO) and hidradenitis suppurativa (HS), today announced positive Week 16 results from its EVERLAST-B Phase 2b trial of ORKA-001, a novel half-life extended IL-23p19 monoclonal antibody, in moderate-to-severe PsO.

"We are incredibly pleased with the remarkable profile of ORKA-001 observed to date, with highly consistent results achieved across EVERLAST-B and EVERLAST-A. These results further solidify our confidence that ORKA-001 could become the preferred medicine for psoriasis, with high rates of complete skin clearance, a favorable safety profile, and potential for dosing once to twice per year," said Joana Goncalves, MBChB, Chief Medical Officer of Oruka. "The data shared today support our next step: engaging with regulatory agencies as we advance ORKA-001 towards Phase 3 trials, which we plan to initiate in the first half of next year."

"These results suggest ORKA-001 is likely to be the most effective IL-23-targeting biologic to date," said Joel Gelfand, MD, MSCE, FAAD, James J. Leyden Professor of Dermatology and Epidemiology at the University of Pennsylvania and lead investigator for EVERLAST-B. "Virtually all patients could expect to have a very good response, and the majority could expect to achieve completely clear skin within just 16 weeks. The potential for these effects to be long lasting, with just one or two doses a year, would be a paradigm shift in moderate-to-severe psoriasis management, allowing for the trifecta of clear skin, convenience, and excellent safety that would further elevate the standard of care we can offer our patients."

EVERLAST-B is a randomized, double-blind, placebo-controlled Phase 2b trial evaluating the safety, efficacy, and pharmacokinetics of ORKA-001 in patients with moderate-to-severe PsO. The trial is being conducted across 36 sites in the United States, Canada, and Europe. Less than 30% of these sites participated in EVERLAST-A. EVERLAST-B enrolled 187 patients randomized 1:1:1:1 to receive 37.5 mg ORKA-001 at Week 0 (low dose), 300 mg ORKA-001 at Weeks 0 and 4 (mid dose), 600 mg ORKA-001 at Weeks 0 and 4 (high dose), or placebo. The primary endpoint is PASI 100 at Week 16. At Week 28, patients receiving ORKA-001 who have achieved PASI 100 will be re-randomized 1:1 to either 600 mg ORKA-001 once yearly or placebo. Patients who have not achieved PASI 100 will receive 300 mg ORKA-001 every six months. The study continues through Week 100 to assess durability of response, maintenance dosing, and long-term safety.

### **Efficacy**

Efficacy increased in a dose-dependent manner across ORKA-001 treatment groups, with the high-dose (600 mg) group outperforming both lower dose groups on complete skin clearance. 61% of patients in the high-dose group achieved the primary endpoint of PASI 100 at Week 16, compared to 0% of patients receiving placebo ( $p < 0.0001$ ). The ORKA-001 high-dose group demonstrated high response rates across secondary endpoints, including 86% of patients achieving PASI 90 and IGA 0/1, consistent with the results observed in EVERLAST-A.

| <b>Week 16</b> | <b>Placebo<br/>(N=47)</b> | <b>Low dose<br/>(N=47)</b> | <b>Mid dose<br/>(N=47)</b> | <b>High dose<br/>(N=46)</b> |
|----------------|---------------------------|----------------------------|----------------------------|-----------------------------|
| PASI 100       | 0%                        | 43%                        | 44%                        | 61%                         |
| PASI 90        | 0%                        | 70%                        | 85%                        | 86%                         |
| IGA 0/1        | 0%                        | 74%                        | 85%                        | 86%                         |

## Safety

ORKA-001 continues to be well tolerated, with a safety profile consistent with the IL-23p19 class. The overall rate of treatment-emergent adverse events (TEAEs) was comparable across groups, with 39% of patients in the high-dose group experiencing at least one TEAE, versus 43% of participants receiving placebo. The only TEAEs occurring in ≥5% of patients treated with ORKA-001 were upper respiratory tract infection and headache, occurring at rates similar to those seen with approved IL-23 inhibitors. No dose-dependent trends in adverse events were observed across ORKA-001 treatment groups, and no injection-site reactions occurred in any patients who received ORKA-001.

| Week 0-16                             | Placebo<br>(N=47) | Low dose<br>(N=47) | Mid dose<br>(N=47) | High dose<br>(N=46) | All<br>ORKA-001<br>(N=140) |
|---------------------------------------|-------------------|--------------------|--------------------|---------------------|----------------------------|
| ≥1 TEAE, n (%)                        | 20 (43%)          | 22 (47%)           | 28 (60%)           | 18 (39%)            | 68 (49%)                   |
| ≥1 serious TEAE, n (%)                | 2 (4%)            | 1 (2%)             | 2 (4%)             | -                   | 3 (2%)                     |
| ≥1 severe TEAE, n (%)                 | 2 (4%)            | 1 (2%)             | 2 (4%)             | -                   | 3 (2%)                     |
| Discontinuation due to<br>TEAE, n (%) | 1 (2%)            | 1 (2%)             | 1 (2%)             | -                   | 2 (1%)                     |
| Most frequent TEAEs, n (%)            |                   |                    |                    |                     |                            |
| Upper respiratory tract<br>infection  | 4 (9%)            | 5 (11%)            | 9 (19%)            | 6 (13%)             | 20 (14%)                   |
| Headache                              | 1 (2%)            | 2 (4%)             | 3 (6%)             | 3 (7%)              | 8 (6%)                     |
| Injection site reactions, n (%)       | 1 (2%)            | -                  | -                  | -                   | -                          |

No serious TEAEs occurred in the high-dose group. Serious TEAEs occurring in the other groups were kidney stones, miscarriage, psoriasis, substance-induced psychotic disorder, and syncope following a blood draw and jaw fracture. None were considered treatment related.

## Upcoming Milestones for ORKA-001

Based on the results from the EVERLAST clinical program, the company intends to discuss Phase 3 plans with regulatory authorities. Pending results from those discussions, Oruka plans to initiate Phase 3 trials of ORKA-001 in moderate-to-severe PsO in the first half of 2027 with the high dose (600 mg). In addition, Oruka expects to share 52-week results from EVERLAST-A in December 2026, as well as 52-week results from EVERLAST-B in the second half of 2027.

## Webcast Details

Oruka Therapeutics' live webcast of the EVERLAST-B 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 inflammatory diseases like plaque psoriasis and hidradenitis suppurativa the greatest possible freedom from their condition by achieving high rates of disease clearance with dosing as infrequently as once or twice a year. 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 statements of historical fact, are "forward-looking statements" within the meaning of the federal securities laws, including the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, but are not limited to, statements regarding: the potential therapeutic benefits, efficacy, safety, tolerability, durability of response and dosing profile of ORKA-001; the potential for ORKA-001 to provide durable disease control with infrequent dosing; the planned conduct, progress, timing and results of the EVERLAST-A and EVERLAST-B trials; and the anticipated timing of clinical data readouts and ORKA-001 Phase 3 trial commencement. These forward-looking statements are based on Oruka's 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 Annual Report on Form 10-K and Quarterly Reports on Form 10-Q. 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 except as required by applicable law.

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