Oruka Therapeutics Announces Positive Week 28 Data for ORKA-001 from the Ongoing EVERLAST-A Trial Showing Deepening of Responses Without Additional Dosing

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PASI 100 increased to 71.4% and PASI 90 increased to 87.3%, despite no dosing after Week 4

Placebo crossover patients reached PASI 100 and PASI 90 rates similar to those initially dosed with ORKA-001

ORKA-001 maintained a favorable safety and tolerability profile through Week 28

52-week EVERLAST-A data for all patients expected in December 2026

16-week EVERLAST-B data expected in 4Q 2026

MENLO PARK, Calif., Sept. 23, 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 28 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 Week 28 results, with responses continuing to deepen months after the last dose, point to the incredible potential of ORKA-001,” said Joana Goncalves, MBChB, Chief Medical Officer of Oruka. “With over 70% of patients achieving completely clear skin after just two induction doses and a safety profile consistent with the IL-23 class, ORKA-001 has the potential to redefine the standard of care for psoriasis. We look forward to sharing the full 52-week data later this year.”

“The depth of clearance seen at Week 28, achieved without any dosing beyond Week 4, is remarkable,” said Bruce Strober, MD, PhD, Clinical Professor of Dermatology at Yale University School of Medicine and lead investigator for EVERLAST-A. “To see PASI 100 rates continue to climb over time speaks to the potential of this molecule. The emerging profile of ORKA-001 could offer patients substantial disease control along with very infrequent dosing.”

EVERLAST-A is a randomized, double-blind, placebo-controlled Phase 2a trial evaluating the safety, efficacy, and pharmacokinetics of ORKA-001 in patients 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. Patients who initially received placebo received 600 mg of ORKA-001 at Week 16 and 20. The study continues through Week 52 to assess durability of response, maintenance dosing, and long-term safety.

Efficacy

As previously reported, 63.5% of patients (40 of 63) treated with ORKA-001 achieved the primary endpoint of PASI 100 at Week 16. Clinical responses continued to deepen through Week 28, six months after the last dose of ORKA-001. PASI 100 response rates increased to 71.4% (45 of 63) and PASI 90 response rates increased to 87.3% (55 of 63) at Week 28. IGA 0/1 response rates were maintained at 84.1% (53 of 63).

Patients who initially received placebo and crossed over blinded to ORKA-001 at Week 16 demonstrated a similar pattern of clinical response to those initially receiving ORKA-001. In this dosing arm, 40.0% (8 of 20) achieved PASI 100 at Week 28 (12 weeks after dosing) compared to 42.9% (27 of 63) of patients in the active arm at the equivalent timepoint.

Safety

ORKA-001 continues to be well tolerated, with a safety profile consistent with the IL-23p19 class. Between Weeks 16-28, the only treatment-emergent adverse event in ≥5% of patients receiving ORKA-001 was upper respiratory tract infection, occurring in 8% (7 of 83) of patients. Two patients experienced serious adverse events, neither deemed drug related: one tibial fracture and one case of prostate adenocarcinoma in a patient with elevated prostate-specific antigen (PSA) at baseline. There continue to be no injection site reactions. No impact of anti-drug antibodies on safety, efficacy, or PK has been observed.

Upcoming Milestones for ORKA-001

Oruka plans to share longer-term data from EVERLAST-A, including efficacy at Week 52 for all patients, in December 2026. The Company also continues to advance the EVERLAST-B Phase 2b trial of ORKA-001, with data expected during the fourth quarter

of 2026.

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 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. 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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