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

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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.

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 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.

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