



Oruka Therapeutics Announces IND Clearance for EVERLAST-A Phase 2a Trial of ORKA-001 in Psoriasis with Phase 1 Data to be Presented at EADV in September

July 21, 2025

IND cleared for the EVERLAST-A Phase 2a trial of ORKA-001 in moderate-to-severe psoriasis, with initial data expected 2H 2026

Interim Phase 1 data and further details on EVERLAST-A study design to be shared in an oral presentation at EADV in September

MENLO PARK, Calif., July 21, 2025 (GLOBE NEWSWIRE) -- Oruka Therapeutics, Inc. ("Oruka") (Nasdaq: ORKA), a biotechnology company developing novel biologics designed to set a new standard for the treatment of chronic skin diseases including plaque psoriasis, today announced that the U.S. FDA cleared its investigational new drug (IND) application for its Phase 2a trial of ORKA-001 (the Company's long-acting anti-IL-23p19 antibody) in moderate-to-severe psoriasis, called EVERLAST-A.

"We're thrilled by this rapid progress into Phase 2 development, and very excited to start our first psoriasis study," said Lawrence Klein, PhD, CEO of Oruka. "We think that ORKA-001 can redefine the standard of care in this important disease with potential for once per year dosing, off-treatment remissions and higher rates of disease clearance."

The U.S. FDA cleared the Company's IND submission to initiate EVERLAST-A. EVERLAST-A is a randomized, double-blind, placebo-controlled Phase 2a trial designed to evaluate the safety and efficacy of a single dose level of ORKA-001 in moderate-to-severe psoriasis patients. EVERLAST-A will enroll approximately 80 patients, randomized 3:1 to receive ORKA-001 or matching placebo. The primary endpoint is PASI 100 at Week 16. ORKA-001 exposures are expected to match or exceed exposures in the KNOCKOUT study, providing a definitive test of whether higher exposures of an anti-IL-23p19 antibody can lead to greater efficacy. At Week 28, patients who have achieved PASI 100, or completely clear skin, will be randomized 2:1 to either (1) an arm where they do not receive another dose until disease recurs or (2) ORKA-001 every six months. This "no-dose" arm will provide evidence for both yearly dosing and the potential for extended off-treatment remissions. Patients who have not yet achieved PASI 100 at Week 28 will receive ORKA-001 every six months. Additional details on the EVERLAST-A design, as well as interim data from the ORKA-001 Phase 1 study, will be presented at the European Academy of Dermatology and Venereology (EADV) Congress in September. The Company expects to share efficacy and response duration data from EVERLAST-A in 2H 2026.

"We have made great strides in our ability to treat psoriatic disease, but many patients are still seeking improved treatment options. I'm excited about EVERLAST-A and the potential that ORKA-001 could enable long dosing intervals and greater efficacy than current IL-23 inhibiting medications. There is evidence now that these improvements could be within reach, and they would be a significant step forward for both patients and the field," commented Bruce Strober, MD, PhD, the lead Principal Investigator on the EVERLAST-A study on behalf of Oruka's Scientific Advisory Board. Oruka's Scientific Advisory Board played a key role in designing the EVERLAST clinical program. Other SAB members include Drs. Andy Blauvelt, Joel Gelfand, Johann Gudjonsson, Mark Lebwohl, James Kreuger, and Joe Merola, all leading physicians whose work has underpinned advances in the psoriasis treatment landscape over the last 25 years.

About ORKA-001

ORKA-001 is a novel, subcutaneously administered, half-life extended monoclonal antibody targeting IL-23p19. Inhibitors of IL-23p19 have become the preferred first-line therapy for patients with moderate-to-severe PsO given their strong efficacy and safety profile. Currently approved therapies are dosed four to six times per year and deliver PASI 100, or fully clear skin, for less than half of patients after four months. ORKA-001 has the potential to be dosed just once or twice a year and is designed to achieve higher exposures than currently marketed IL-23p19 antibodies, which could lead to higher rates of disease clearance. Data from studies in non-human primates and other preclinical assays show that ORKA-001 binds to a similar epitope with similar affinity as risankizumab and has a significantly extended half-life over three times longer than risankizumab.

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.

Financial Disclosures

Oruka's SAB members receive compensation as scientific advisors.

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 clinical studies, the potential half-life and exposures of ORKA-001 and its potential dosing interval as well as the potential of ORKA-001 treatment to lead to off-treatment remissions and/or higher rates of disease clearance than other treatments. 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, its Quarterly Reports on Form 10-Q and its registration statement on Form S-1. 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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