Oruka Therapeutics Announces First Participants Dosed in Phase 1 Trial of ORKA-001, its Novel Half-life Extended Anti-IL-23p19 Antibody

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Pharmacokinetic and safety data from healthy volunteers anticipated in the second half of 2025

On track to initiate a proof-of-concept study in psoriasis in the second half of 2025, with initial efficacy data expected in the second half of 2026

Preclinical data with ORKA-001 demonstrate the potential for once- or twice-yearly dosing, a significant improvement over standard of care

MENLO PARK, Calif., Dec. 19, 2024 (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 it has initiated dosing of healthy volunteers in its first clinical trial of ORKA-001, the Company's novel, subcutaneously administered, half-life extended monoclonal antibody targeting IL-23p19.

"The initiation of this Phase 1 study of ORKA-001 marks an important milestone for Oruka, which our team has delivered ahead of schedule," said Lawrence Klein, PhD, Chief Executive Officer of Oruka. "We look forward to sharing initial data for ORKA-001 in the second half of 2025, which could validate ORKA-001's half-life and safety profile, supporting extended dosing intervals and best-in-class potential."

The ORKA-001 Phase 1 trial is a double-blind, placebo-controlled, single ascending dose study evaluating the safety, tolerability, and pharmacokinetics (PK) of ORKA-001 in healthy volunteers. The study is expected to enroll approximately 24 healthy volunteers across three subcutaneous dose cohorts. Oruka expects to share interim data from this study in the second half of 2025.

Pending data from the Phase 1 trial, Oruka plans to initiate a proof-of-concept study of ORKA-001 in moderate-to-severe psoriasis in the second half of 2025. This study is anticipated to evaluate the safety and efficacy of a single dose level of ORKA-001 versus placebo in approximately 80 subjects, followed by randomization to one of two maintenance dosing arms. In one maintenance arm, subjects will receive ORKA-001 every six months. In the other, subjects will receive only induction dosing to assess the length of time patients maintain clear skin, which could support once-yearly dosing or even longer-term durability in some patients. Subjects then can continue to an open-label extension study. The company expects to share initial data from the proof-of concept study in the second half of 2026.

"We believe that ORKA-001 has the potential to set a new standard in the treatment of plaque psoriasis in terms of both depth and duration of response," said Joana Goncalves, MBChB, Chief Medical Officer of Oruka. "We hear consistently that people with psoriasis want to achieve freedom from their disease, and that is what we hope to offer with this program. The initiation of this Phase 1 study brings us one step closer to that goal."

Additionally, the Company announced that it has entered into a license agreement with Paragon Therapeutics granting it worldwide exclusive rights to ORKA-001 in all indications other than inflammatory bowel disease.

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.

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 proof of concept study and the potential half-life of ORKA-001 and its potential dosing interval. 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 registration statement on Form S-1 and its 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.

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