Oruka Therapeutics Announces First Participants Dosed in Phase 1 Trial of ORKA-002, its Novel Half-life Extended Anti-IL-17A/F Antibody

May 20, 2025

Pharmacokinetic and safety data from healthy volunteers anticipated around YE 2025

On track to initiate a Phase 2 study in 1H 2026

ORKA-002 preclinical data demonstrate the potential for dosing two to three times per year in psoriasis, a significant improvement over standard of care

MENLO PARK, Calif., May 20, 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 it has initiated dosing of healthy volunteers in its first clinical trial of ORKA-002, the Company’s novel, subcutaneously administered, half-life extended monoclonal antibody targeting IL-17A and IL-17F (IL-17A/F).

“With both ORKA-001 and ORKA-002 now in human trials, we are moving quickly to demonstrate the clinical differentiation of both assets,” said Lawrence Klein, PhD, Chief Executive Officer of Oruka. “Bimekizumab is launching extremely well as IL-17A/F has emerged as superior to IL-17A inhibition in several important indications. Uniquely, we could have the best targeting approaches for both IL-23p19 and IL-17A/F, potentially allowing us to offer the ideal regimen to patients through our ORKA-001 and -002 monotherapies and our ORKA-021 sequential combination.”

The ORKA-002 Phase 1 trial is a double-blind, placebo-controlled, single ascending dose study evaluating the safety, tolerability and pharmacokinetics (PK) of ORKA-002 in approximately 24 healthy volunteers across three subcutaneous dose cohorts. Oruka expects to share interim data from this study around year end 2025.

Pending data from the Phase 1 trial, Oruka plans to initiate a Phase 2 study of ORKA-002 in moderate-to-severe psoriasis in the first half of 2026. The planned study design will evaluate the safety and efficacy of multiple dose levels and regimens of ORKA-002, with a primary endpoint of PASI 100 at week 16.

“ORKA-002 has the opportunity to become the best antibody in the IL-17 class, which is preferred when treating psoriasis with joint involvement or recalcitrant skin disease, as well as psoriatic arthritis, hidradenitis suppurativa, and beyond,” said Joana Goncalves, MBChB, Chief Medical Officer of Oruka. “With this program now in the clinic, we are one step closer to our goal of offering the most possible freedom from disease to patients with psoriasis and other conditions.”

About ORKA-002

ORKA-002 is a novel, subcutaneously administered, half-life extended monoclonal antibody targeting IL-17A/F. Dual inhibition of both IL-17A and IL-17F has shown superior efficacy compared to IL-17A inhibition alone in psoriasis (PsO) and other indications, as shown by the performance of Bimzelx (bimekizumab) compared to Cosentyx (secukinumab) and Taltz (ixekizumab) in Phase 3 trials. These therapies all utilize monthly maintenance dosing in PsO and psoriatic arthritis (PsA), except Bimzelx in PsO patients weighing <120 kg, where Q8W maintenance dosing is recommended. In contrast, ORKA-002 has the potential to be dosed just two to three times per year in PsO and PsA, which we believe could allow ORKA-002 to become the leading therapy in the IL-17 class. Data from studies in non-human primates and other preclinical assays show that ORKA-002 binds to a similar epitope with similar affinity as bimekizumab and has a significantly extended half-life over three times longer than bimekizumab.

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 and ORKA-002, including timelines to clinical and data release milestones, the details of its clinical studies and the potential half-life of ORKA-001 and ORKA-002 and their potential dosing intervals. 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 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.

Investor Contact:
Alan Lada
(650)-606-7911
alan.lada@orukatx.com