



Oruka Therapeutics Announces Preclinical Data for ORKA-002 at the 2025 American Academy of Dermatology Annual Meeting

March 7, 2025

Half-life in non-human primates (NHP) of more than 30 days, over three times longer than bimekizumab and expected to support a dose interval of two to three times per year

Equivalent potency to bimekizumab with similar binding affinity and epitope demonstrated in several preclinical assays

First subject dosed with ORKA-002 expected in Q3 2025

MENLO PARK, Calif., March 07, 2025 (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, today announced new preclinical data on ORKA-002, a novel extended half-life monoclonal antibody targeting IL-17A/F, from its presentation at the 2025 American Academy of Dermatology (AAD) Annual Meeting.

- **ORKA-002 has an NHP half-life of more than 30 days following subcutaneous and intravenous administration, over three times longer than bimekizumab.** Projections of ORKA-002 pharmacokinetics (PK) in humans indicate that a human half-life of approximately 50 days could enable dosing once every four months, while a human half-life of approximately 75 days could enable twice-yearly dosing. The NHP half-life observed for ORKA-002 supports the potential to achieve these extended dosing intervals given that other YTE-modified antibodies have had an approximately two to four times longer half-life in humans than in NHPs.
- **ORKA-002 binds to a similar epitope with similar affinity to bimekizumab and shows equivalent potency across a variety of *in vitro* assays.** ORKA-002 binds IL-17A and IL-17F with a comparable picomolar affinity as bimekizumab. Based on cryo-EM structural analysis, ORKA-002 binds to a nearly identical epitope to bimekizumab on both IL-17A and IL-17F. When assessed across multiple different assays in cell lines and primary cells, ORKA-002 also had comparable functional potency for IL-17A and IL-17F antagonism. These findings further derisk the development path for ORKA-002.

"We are highly encouraged by the exceptional properties of ORKA-002, including a half-life in NHPs that is, for the second time in two programs, one of the longest seen to date for any antibody," said Lawrence Klein, Oruka's Chief Executive Officer.

"Bimekizumab has had a remarkable launch, showing the excitement around IL-17A/F inhibition. We believe ORKA-002 could offer an even better product profile to people with psoriasis, psoriatic arthritis, and additional indications."

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 a 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-002, including timelines to clinical and data release milestones, the potential half-life and potency of ORKA-002, its potential dosing interval and its potential product profile. 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 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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