# Oruka Therapeutics Announces Positive Interim Phase 1 Data for ORKA-002 and Initiation of EVERLAST-B Trial of ORKA-001

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*ORKA-002 interim Phase 1 data demonstrates a half-life of 75-80 days supporting potential for twice-per-year dosing in psoriasis and quarterly dosing in hidradenitis suppurativa*

*Phase 2 studies for ORKA-002 expected to begin in 1H 2026 for psoriasis and 2H 2026 for hidradenitis suppurativa*

*First patients dosed in EVERLAST-B Phase 2b trial of ORKA-001 in December 2025 with data expected in 2027*

MENLO PARK, Calif., Jan. 12, 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 including plaque psoriasis (PsO), today announced positive interim data from its Phase 1 trial of ORKA-002 and updates from the ongoing trials of ORKA-001.

“We’re thrilled with the rapid progress we are making with both ORKA-001 and ORKA-002 and their emerging potentially best-in-class product profiles,” said Lawrence Klein, PhD, CEO. “We continue to build conviction that each of these assets could play a very important role in the future treatment of psoriatic disease and beyond. This Phase 1 data for ORKA-002 increases our confidence in its potential differentiation in both psoriasis and hidradenitis suppurativa (HS), and we’re highly encouraged by how quickly our EVERLAST trials are progressing and the enthusiasm we are seeing for ORKA-001’s paradigm-changing potential.”

***ORKA-002: Key Phase 1 Interim Findings***

The Phase 1 trial is a first-in-human, randomized, double-blind, placebo-controlled trial designed to evaluate the safety and pharmacokinetics (PK) of ORKA-002 in healthy volunteers. The study enrolled 24 healthy adult participants into three single-ascending subcutaneous dose cohorts of 160 mg, 320 mg and 640 mg. Interim results from the trial as of the January 2026 data cutoff are as follows, and additional data will be presented at an upcoming medical meeting.

- **PK:** ORKA-002 showed a half-life of 75-80 days, greater than three times that of bimekizumab, and a comparable $C_{max}$ to bimekizumab at equivalent doses based on previously reported bimekizumab data. Pharmacokinetic modeling based on these results supports achieving twice-yearly maintenance dosing in PsO and quarterly maintenance dosing in HS.
- **Pharmacodynamics (PD):** In an *ex vivo* IL-17 stimulation assay, ORKA-002 was shown to potently inhibit IL-17 signaling at all dose levels through last follow-up (up to 24 weeks), further supporting the potential for twice-yearly dosing.
- **Safety:** ORKA-002 was well tolerated at all dose levels, with a favorable safety profile consistent with the anti-IL-17 class. There were no severe treatment-emergent adverse events (TEAEs) or serious adverse events, and no discontinuations. The only TEAEs to occur in more than two subjects were contusion, headache, skin abrasion and upper respiratory tract infection. The study remains blinded, and all subjects remain on study.

***ORKA-002: Phase 2 Trials in Plaque Psoriasis and Hidradenitis Suppurativa***

- ORCA-SURGE, a randomized, double-blind, placebo-controlled, dose-ranging Phase 2 trial designed to evaluate the safety and efficacy of ORKA-002 in moderate-to-severe PsO patients, is expected to commence in the first half of 2026. ORCA-SURGE is designed to enroll approximately 160 patients randomized 1:1:1:1 to receive 40 mg, 160 mg or 320 mg of ORKA-002 at Weeks 0 and 4, or matching placebo. The primary endpoint will be PASI 100 at Week 16. Maintenance dosing will evaluate the potential for twice-yearly dosing with ORKA-002. Data from ORCA-SURGE is anticipated in 2027.
- In addition, the Company expects to initiate a Phase 2 trial of ORKA-002 in HS patients in the second half of 2026.

***ORKA-001 Updates***

- The first patients were dosed in EVERLAST-B in December 2025, and enrollment is ongoing. EVERLAST-B is evaluating three induction dose levels of ORKA-001: 37.5 mg at Week 0, 300 mg at Weeks 0 and 4, and 600 mg at Weeks 0 and 4, versus placebo. The primary endpoint is PASI 100 at Week 16. At Week 28, patients receiving ORKA-001 will be re-randomized 1:1 if they have achieved PASI 100 to either a 600 mg dose once-yearly or placebo. Patients who have not achieved PASI 100 will receive a 300 mg dose every six months. Building on EVERLAST-A, this design will further test the potential for ORKA-001 to achieve yearly dosing, higher efficacy and extended off-treatment remissions. Data from

EVERLAST-B is anticipated in 2027.

- The EVERLAST-A study is ongoing, and the Company continues to expect to share PASI 100 data at Week 16 for all patients, as well as response duration data out to approximately one year for some patients, in 2H 2026.

**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, and the details of its planned clinical studies, as well as the potential dosing intervals of ORKA-001 and ORKA-002. 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 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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