ORIC Pharmaceuticals Announces Clinical Supply Agreement to Evaluate ORIC-114 in Combination with Amivantamab for the First-Line Treatment of NSCLC with EGFR Exon 20 Insertion Mutations

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Phase 1b combination trial of ORIC-114 and subcutaneous amivantamab in patients with 1L NSCLC with EGFR exon 20 insertion mutations expected to initiate in Q1 2025, with initial data in mid-2026

SOUTH SAN FRANCISCO, Calif. and SAN DIEGO, Jan. 13, 2025 (GLOBE NEWSWIRE) -- ORIC Pharmaceuticals, Inc. (Nasdaq: ORIC), a clinical stage oncology company focused on developing treatments that address mechanisms of therapeutic resistance, today announced that the company has entered into a supply agreement with Janssen Research & Development, LLC, a Johnson & Johnson company, to evaluate ORIC-114, a brain penetrant, orally bioavailable, irreversible EGFR/HER2 inhibitor, in combination with subcutaneous (SC) amivantamab, Johnson & Johnson's fully-human EGFR-MET bispecific antibody, for the first-line treatment of patients with advanced non-small cell lung cancer (NSCLC) with EGFR exon 20 insertion mutations.

Under the terms of the agreement, ORIC® will conduct and sponsor the trial and Johnson & Johnson will provide SC amivantamab. ORIC maintains development and commercial rights to ORIC-114 and is free to expand the program in combination with other agents.

"ORIC-114 has already demonstrated encouraging systemic and intracranial activity in heavily pre-treated patients with EGFR/HER2 mutated NSCLC," said Jacob M. Chacko, MD, chief executive officer. "Given the prevalence of brain metastases across all lines of EGFR exon 20 NSCLC, we aim to further explore ORIC-114's emerging profile in the first-line setting both as a monotherapy and in combination with SC amivantamab."

ORIC expects to initiate the combination Phase 1b trial to evaluate the safety and tolerability of ORIC-114 in combination with SC amivantamab for the first-line treatment of patients with advanced NSCLC with EGFR exon 20 insertion mutations in the first quarter of 2025. The primary objectives are to determine the provisional recommended Phase 2 dose (RP2D) for the combination, and additional objectives include assessment of efficacy and further characterization of the safety profile of ORIC-114 in combination with SC amivantamab. The company expects to report initial data from the trial in mid-2026.

In 2024, the company announced the completion of the monotherapy dose escalation portion of the Phase 1b trial of ORIC-114 in patients with advanced solid tumors with EGFR and HER2 exon 20 alterations or HER2 amplifications. Based upon these data, ORIC selected the two provisional RP2D levels of ORIC-114 at 80 mg and 120 mg QD, which are being further evaluated in three dose expansion cohorts for dose optimization and final RP2D selection in patients with NSCLC with EGFR exon 20 (EGFR exon 20 inhibitor naïve), HER2 exon 20, or EGFR atypical mutations as well as an extension cohort for the treatment of patients with first-line, treatment-naïve EGFR exon 20 mutated NSCLC.

About ORIC-114

ORIC-114 is a highly selective, brain penetrant, orally bioavailable, irreversible inhibitor that selectively targets EGFR exon 20, HER2 exon 20 and EGFR atypical mutations, making it a promising therapeutic candidate to address the unmet medical need of having both meaningful systemic as well as CNS antitumor activity.

About ORIC Pharmaceuticals, Inc.

ORIC Pharmaceuticals is a clinical stage biopharmaceutical company dedicated to improving patients' lives by *Overcoming Resistance In Cancer.* ORIC's clinical stage product candidates include (1) ORIC-114, a brain penetrant inhibitor that selectively targets EGFR exon 20, HER2 exon 20 and EGFR atypical mutations, being developed across multiple genetically defined cancers, and (2) ORIC-944, an allosteric inhibitor of the polycomb repressive complex 2 (PRC2) via the EED subunit, being developed for prostate cancer. Beyond these two product candidates, ORIC® is also developing multiple precision medicines targeting other hallmark cancer resistance mechanisms. ORIC has offices in South San Francisco and San Diego, California. For more information, please go to www.oricpharma.com, and follow us on X or LinkedIn.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements as that term is defined in Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Statements in this press release that are not purely historical are forward-looking statements. Such forward-looking statements include, among other things, statements regarding the continued clinical development of ORIC-114, including in combination with SC amivantamab; ORIC-114 clinical outcomes, which may materially change as patient enrollment continues or more patient data become available; the development plans and timelines for ORIC-114 and ORIC's other product candidates; the potential advantages of ORIC-114 and ORIC's other product candidates and programs; plans underlying ORIC's clinical trials and development; anticipated program milestones, including timing of program and data updates and the initiation of a Phase 1b trial evaluating ORIC-114 in combination with SC amivantamab; and statements by the company's chief executive officer. Words such as "believes," "anticipates," "plans," "expects," "intends," "will," "goal," "potential" and similar expressions are intended to identify forward-looking statements. The forward-looking statements contained herein are based upon ORIC's current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results could differ materially from those projected in any forward-looking statements due to numerous risks and uncertainties, including but not limited to: risks associated with the process of discovering, developing and commercializing drugs that are safe and effective for use as human therapeutics and operating as an early clinical stage company; ORIC's ability to develop, initiate or complete preclinical studies and clinical trials for, obtain approvals for and commercialize any of its product candidates; changes in ORIC's plans to develop and commercialize its product candidates; the potential for clinical trials of ORIC's product candidates to differ from preclinical, initial, interim, preliminary or expected results; negative impacts of health emergencies, economic instability or international conflicts on ORIC's operations, including clinical trials; the risk of the occurrence of any event, change or other circumstance that could give rise to the termination of ORIC's license and collaboration agreements or its clinical trial collaboration and supply agreements; the potential market for ORIC's product

candidates, and the progress and success of competing therapeutics currently available or in development; ORIC's ability to raise any additional funding it will need to continue to pursue its business and product development plans; regulatory developments in the United States and foreign countries; ORIC's reliance on third parties, including contract manufacturers and contract research organizations; ORIC's ability to obtain and maintain intellectual property protection for its product candidates; the loss of key scientific or management personnel; competition in the industry in which ORIC operates; general economic and market conditions; and other risks. Information regarding the foregoing and additional risks may be found in the section titled "Risk Factors" in ORIC's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (the "SEC") on November 12, 2024, and ORIC's future reports to be filed with the SEC. These forward-looking statements are made as of the date of this press release, and ORIC assumes no obligation to update the forward-looking statements, or to update the reasons why actual results could differ from those projected in the forward-looking statements, except as required by law.

Contact:
Dominic Piscitelli, Chief Financial Officer
dominic.piscitelli@oricpharma.com
info@oricpharma.com