# ORIC Pharmaceuticals Announces Regulatory Clearance of Clinical Trial Application for ORIC-114 in Advanced Solid Tumors with EGFR or HER2 Exon 20 Alterations or HER2 Amplifications

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SOUTH SAN FRANCISCO, Calif. and SAN DIEGO, Jan. 25, 2022 (GLOBE NEWSWIRE) -- ORIC Pharmaceuticals, Inc. (Nasdaq: ORIC), a clinical stage oncology company focused on developing treatments that address mechanisms of therapeutic resistance, today announced clearance of its Clinical Trial Application (CTA) by the regulatory authorities of the Republic of Korea for ORIC-114, a brain penetrant, orally bioavailable, irreversible inhibitor designed to selectively target EGFR and HER2 with high potency against exon 20 insertion mutations.

"This marks our third IND/CTA regulatory clearance in the last eight months and further demonstrates the productivity and commitment of our team as we expand our clinical portfolio to advance our mission on behalf of patients," said Jacob M. Chacko, M.D., president and chief executive officer. "We are encouraged by the brain penetrant properties and selectivity that ORIC-114 has demonstrated in preclinical studies, and we look forward to advancing the program into a Phase 1 study in the coming months. As we enter 2022, we are well positioned with five expected clinical updates across four clinical programs through the first half of 2023, and with cash and investments to fund our operating plan into the first half of 2024."

**About ORIC-114**

ORIC-114 is a brain penetrant, orally bioavailable, irreversible inhibitor designed to selectively target EGFR and HER2 with high potency against exon 20 insertion mutations. ORIC-114 has demonstrated systemic tumor regressions and strong intracranial antitumor activity in various EGFR exon 20 insertion NSCLC and HER2-positive breast cancer models. ORIC-114 also compares favorably in head to head in vivo studies versus multiple approved and clinical stage EGFR exon 20 and HER2 inhibitors. The company plans to initiate a Phase 1b single agent study in patients with advanced solid tumors with EGFR or HER2 exon 20 alterations or HER2 amplification and will allow patients with CNS metastases that are either treated or untreated but asymptomatic. The company expects to report initial data from this trial in the first half of 2023.

**About ORIC Pharmaceuticals, Inc.**

ORIC Pharmaceuticals is a clinical stage biopharmaceutical company dedicated to improving patients' lives by *Overcoming Resistance In Cancer.* ORIC's lead product candidate, ORIC-101, is a potent and selective small molecule antagonist of the glucocorticoid receptor, which has been linked to resistance to multiple classes of cancer therapeutics across a variety of solid tumors. ORIC-101 is currently in two separate Phase 1b trials of ORIC-101 in combination with (1) Xtandi (enzalutamide) in metastatic prostate cancer and (2) Abraxane (nab-paclitaxel) in advanced or metastatic solid tumors. ORIC's other product candidates include (1) ORIC-533, an orally bioavailable small molecule inhibitor of CD73, a key node in the adenosine pathway believed to play a central role in resistance to chemotherapy- and immunotherapy-based treatment regimens, being developed for multiple myeloma, (2) ORIC-114, a brain penetrant inhibitor designed to selectively target EGFR and HER2 with high potency against exon 20 insertion mutations, being developed across multiple genetically defined cancers, and (3) ORIC-944, an allosteric inhibitor of the polycomb repressive complex 2 (PRC2) via the EED subunit, being developed for prostate cancer. Beyond these four 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 Twitter 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 development plans and timelines for ORIC-114; the potential advantages of ORIC-114; plans underlying ORIC's clinical trials and development; the expected timing of clinical updates for the ORIC-101, ORIC-533, ORIC-114 and ORIC-944 clinical trials; the period over which ORIC estimates its existing cash, and investments will be sufficient to fund its current operating plan; and statements by the company's president and 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-101, ORIC-533, ORIC-114, ORIC-944 or any other product candidates to differ from preclinical, initial, interim, preliminary or expected results; negative impacts of the COVID-19 pandemic 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 agreements; 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 entitled "Risk Factors" in ORIC's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (the "SEC") on November 8, 2021, 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.

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