ORIC Pharmaceuticals Announces Initiation of Expansion Cohorts in Phase 1b Study of ORIC-101

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Initiated Part II expansion of the Phase 1b study of ORIC-101 in combination with Abraxane (nab-paclitaxel) using recommended Phase 2 dose selected from Part I of the study

Expansion cohorts will enroll patients with pancreatic ductal adenocarcinoma, ovarian cancer, triple negative breast cancer and other advanced solid tumors

SOUTH SAN FRANCISCO, Calif. and SAN DIEGO, Dec. 21, 2020 (GLOBE NEWSWIRE) -- ORIC Pharmaceuticals, Inc. (Nasdaq: ORIC), a clinical stage oncology company focused on developing treatments that address mechanisms of therapeutic resistance, today announced the initiation of the Part II dose expansion portion of the Phase 1b study of ORIC-101, a potent and selective glucocorticoid receptor (GR) antagonist, in combination with Abraxane (nab-paclitaxel) for the treatment of advanced solid tumors.

"We are pleased to announce continued progress of our GR program with the selection of the recommended Phase 2 dose of ORIC-101 in combination with Abraxane triggering the initiation of multiple expansion cohorts in cancers with high unmet medical need," said Jacob Chacko, M.D., president and chief executive officer of ORIC. "I am grateful to the patients and their families, investigators, and our employees who have helped us reach this important milestone."

The Phase 1b clinical study of ORIC-101 in combination with nab-paclitaxel is a non-randomized, multicenter, open-label study conducted in two parts, intended to establish the recommended Phase 2 dose (RP2D), safety, pharmacokinetics, pharmacodynamics, and preliminary antitumor activity when administered to patients with advanced or metastatic solid tumors.

In the Part I dose escalation portion of the study, five cohorts of patients across multiple solid tumors were enrolled to evaluate ORIC-101 doses ranging from 80 to 240 mg administered orally in both intermittent and continuous once daily dosing regimens, in combination with either 75 or 100 mg/m^2 nab-paclitaxel. Following the completion of the dose escalation portion of the study, the RP2D was determined to be 160 mg of ORIC-101 continuous once daily dosing and 75 mg/m^2 of nab-paclitaxel on days 1, 8, and 15 of a 28-day cycle, without requirement for prophylactic granulocyte-colony stimulating factor. The selection of RP2D was based upon the totality of safety, pharmacokinetic and pharmacodynamic data demonstrating a well-tolerated regimen that achieved ORIC-101 exposures leading to demonstrable target engagement and GR inhibition.

For the Part II dose expansion portion of the study, up to 132 patients are expected to be enrolled across four cohorts, including pancreatic ductal adenocarcinoma, ovarian cancer, triple negative breast cancer, and other advanced solid tumors. Patients in the dose expansion portion of the study will be required to have previously progressed on a taxane-containing regimen, with retrospective analysis of GR expression and other potentially predictive biomarkers.

The company also announced dose escalation remains ongoing with ORIC-101 in combination with Xtandi (enzalutamide) with no dose-limiting toxicities observed to date. The Phase 1b clinical study of ORIC-101 in combination with enzalutamide is a non-randomized, multicenter, open-label study to establish the RP2D, safety, pharmacokinetics, pharmacodynamics, and preliminary antitumor activity when administered to patients with metastatic prostate cancer. Dose exploration has been conducted in three cohorts to date, with 240 mg of ORIC-101 and 160 mg of enzalutamide both administered continuously once daily currently ongoing.

About ORIC-101

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. Preclinical in vitro and in vivo data suggest ORIC-101 is able to address key resistance mechanisms of multiple classes of cancer treatments, including taxanes and androgen receptor modulators. Based on preclinical and clinical studies, ORIC-101 is expected to have reduced drug-drug interaction liabilities than other glucocorticoid receptor antagonists. Currently, there are no glucocorticoid receptor antagonists approved by the FDA for the treatment of cancer. Following the successful completion of two Phase 1a trials in over 50 healthy volunteers, ORIC initiated 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.

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, (2) ORIC-944, an allosteric inhibitor of the polycomb repressive complex 2 (PRC2) via the EED subunit, being developed for prostate cancer, and (3) 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. 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.

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, progress related to ORIC's Phase 1b clinical study of ORIC-101 with Abraxane (nab-paclitaxel), including expectations related to initiation of expansion cohorts and patient enrollment. 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 ORIC-101 or any other product candidates; the potential for clinical trials of ORIC-101 or any other product candidates to differ from preclinical, preliminary or expected results; negative impacts of the COVID-19 pandemic on ORIC's operations, including clinical trials; ORIC's ability to enroll patients in its ongoing and future clinical trials; operating results and business generally; 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, 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 final prospectus filed with the Securities and Exchange Commission (the "SEC") on November 13, 2020, 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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