

# ORIC Pharmaceuticals Provides Corporate Update and Highlights Key 2021 Milestones

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Lead program ORIC-101 continues patient enrollment investigating two therapeutic mechanisms of action and on track for two initial data readouts in 2021

Three IND/CTA filings for ORIC-533, -944, and -114 expected in 2021

SOUTH SAN FRANCISCO, Calif. and SAN DIEGO, Jan. 11, 2021 (GLOBE NEWSWIRE) -- ORIC Pharmaceuticals, Inc. (Nasdaq: ORIC), a clinical stage oncology company focused on developing treatments that address mechanisms of therapeutic resistance, today provided program updates and announced key milestones for 2021, which are expected to substantially expand and advance the company's clinical pipeline.

"2020 was a transformational year for ORIC during which we significantly broadened the pipeline via internal discovery and business development efforts, expanded the team, and strengthened the balance sheet with the completion of an IPO and follow-on financing," said Jacob Chacko, M.D., president and chief executive officer. "These efforts have positioned us for a dynamic 2021, with our first data from two ongoing trials of our lead program ORIC-101 and three INDs/CTAs for our other product candidates, which represents a tremendous amount of development activity for a company at our stage."

## **Program Updates and 2021 Milestones**

### ORIC-101: Glucocorticoid Receptor (GR) Antagonist

ORIC-101 is a potent and selective GR antagonist, with two distinct mechanisms of action being evaluated in two Phase 1b trials in combination with: (1) Xtandi (enzalutamide) in metastatic prostate cancer and (2) Abraxane (nab-paclitaxel) in advanced or metastatic solid tumors.

- The company announced today the completion of the Part I dose escalation portion of the Phase 1b trial of ORIC-101 in combination with enzalutamide in metastatic prostate cancer, by identifying the provisional recommended Phase 2 dose (RP2D) that will be used in the Part II expansion portion of the trial. The selection of the provisional 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. In the Part I dose escalation portion of the trial, patients were enrolled to evaluate daily dosing of ORIC-101 with doses ranging from 80 to 240 mg, in combination with daily dosing of 160 mg of enzalutamide. In the Part II dose expansion portion of the trial, up to 48 patients are expected to be enrolled and treated at the RP2D of 240 mg of ORIC-101 and 160 mg of enzalutamide on a continuous daily dosing schedule. Patients will be enrolled independent of GR status, with retrospective analysis of GR expression and other potentially predictive biomarkers. The company expects to report interim safety, efficacy, and translational data from this trial in the second half of 2021.
- The Phase 1b trial of ORIC-101 in combination with nab-paclitaxel is now enrolling patients in the Part II dose expansion portion. In December 2020, the company announced the completion of the Part I dose escalation portion of ORIC-101 in combination with nab-paclitaxel in solid tumors, the selection of the RP2D, and the initiation of the dose expansion portion of the trial. For the Part II dose expansion portion of the trial, 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 Part II of the trial will be treated at the RP2D of 160 mg of ORIC-101 continuous once daily dosing and 75 mg/m² of nab-paclitaxel on days 1, 8, and 15 of a 28-day cycle, without requirement for prophylactic granulocyte colony-stimulating factor. Eligible patients must have previously progressed on a taxane-containing regimen and will be enrolled independent of baseline GR status, with retrospective analysis of GR expression and other potentially predictive biomarkers. The company expects to report interim safety, efficacy, and translational data from this trial in the first half of 2021.

#### ORIC-533: CD73 Inhibitor

ORIC-533 was designed to be a highly potent, orally bioavailable CD73 inhibitor and has demonstrated more potent adenosine inhibition in preclinical studies compared to an antibody approach and other small molecule CD73 inhibitors. ORIC-533 continues to progress in Investigational New Drug (IND) enabling studies and the company expects to file an IND with the Food and Drug Administration (FDA) in the first half of 2021. Having conducted a preclinical collaboration with an academic key opinion leader that generated compelling single agent activity in patient derived model systems in an undisclosed tumor type, the company plans to pursue a single agent clinical development path in this indication.

### ORIC-944: PRC2 Inhibitor

ORIC-944, in-licensed in August 2020, is a potent and selective allosteric inhibitor of polycomb repressive complex 2 (PRC2), that targets its regulatory embryonic ectoderm development (EED) subunit and has demonstrated single agent efficacy in multiple enzalutamide-resistant prostate cancer models in preclinical studies. The company plans to conduct IND enabling studies and then file an IND with the FDA in the second half of 2021, with initial clinical development as a single agent in treatment-resistant prostate cancer.

ORIC-114, in-licensed in October 2020, 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 greater brain exposure in preclinical studies compared to other compounds being developed against exon 20 mutations and has shown strong antitumor activity in an EGFR-driven intracranial lung cancer model. The company plans to conduct IND enabling studies and then file a Clinical Trial Application (CTA) in South Korea in the second half of 2021.

#### Discovery Pipeline

In addition to the four product candidates, the company is leveraging its resistance platform in pursuit of multiple discovery research programs that focus on its expertise in precision oncology, hormone-dependent cancers, and key tumor dependencies. These programs highlight the company's medicinal chemistry and structure-based drug design proficiency to target drivers of resistance in solid tumors like prostate, breast, and lung cancer that relapse with innate, acquired or bypass mechanisms of resistance. The company recently advanced one of these programs into lead optimization.

### **Anticipated 2021 Milestones**

ORIC anticipates the following milestones in 2021:

- ORIC-101: Report interim safety, efficacy, and translational data from ongoing combination trial with nab-paclitaxel in the first half of 2021
- ORIC-101: Report interim safety, efficacy, and translational data from ongoing combination trial with enzalutamide in the second half of 2021
- ORIC-533: File an IND in the first half of 2021
- ORIC-944: File an IND in the second half of 2021
- ORIC-114: File a CTA in the second half of 2021
- Present additional preclinical and translational research data on ORIC-101, ORIC-533, ORIC-944, and ORIC-114 at scientific conferences in 2021

#### **Financial Guidance**

Cash, cash equivalents and marketable securities totaled \$293.6 million as of December 31, 2020, which included gross proceeds of \$133.3 million from the follow-on financing completed in November 2020. The company expects its cash, cash equivalents and marketable securities will be sufficient to fund its current operating plan into the second half of 2023.

#### **Presentation and Webcast**

Jacob Chacko, M.D., president and chief executive officer, will present a corporate overview at the 39th J.P. Morgan Healthcare Conference beginning at 12:40 p.m. PT on Tuesday, January 12, 2021. A live webcast will be available through the investor section of the company's website at <a href="https://investors.oricpharma.com/">https://investors.oricpharma.com/</a>. A replay of the webcast will be available for 90 days following the event.

# About ORIC Pharmaceuticals, Inc.

ORIC Pharmaceuticals is a clinical stage biopharmaceutical company dedicated to improving patients' lives by <u>Overcoming Resistance In Cancer.</u> 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, statements regarding ORIC's development plans and timelines; the potential advantages of ORIC's product candidates and programs; plans underlying ORIC-101 clinical trials and development; the expected timing of reporting interim data from the ORIC-101 clinical trials; plans underlying ORIC-533, ORIC-944, ORIC-114 or any other programs; the planned IND filings for ORIC-533 and ORIC-944 and CTA filing for ORIC-114; ORIC's anticipated 2021 milestones; the period over which ORIC estimates its existing cash, cash equivalents and marketable securities 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-944, ORIC-114 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; the risk of the occurrence of any event, change or other circumstance that could give rise to the termination of the Mirati license agreement or the Voronoi license agreement; 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 5, 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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