



ORIC Pharmaceuticals Announces First Patient Dosed in Phase 1b Clinical Trial of ORIC-101 in Combination with XTANDI® for the Treatment of Prostate Cancer in Collaboration with Astellas

January 27, 2020

Study based on preclinical evidence suggesting ORIC-101, a novel glucocorticoid receptor antagonist, may inhibit a potential mechanism of resistance to XTANDI® in patients with metastatic prostate cancer

SOUTH SAN FRANCISCO, CA – January 27, 2020 – ORIC Pharmaceuticals, a privately held, clinical-stage oncology company focused on developing treatments that address mechanisms of therapeutic resistance, today announced dosing of the first patient in a Phase 1b clinical trial being conducted under a collaboration with Astellas Pharma Inc., to evaluate the combination of ORIC-101, ORIC's investigational glucocorticoid receptor (GR) antagonist, with XTANDI® (enzalutamide) as a treatment for patients with metastatic prostate cancer that is progressing on enzalutamide.

Research conducted by ORIC's co-founder Charles Sawyers, MD, published in *Cell*, has elucidated that increased expression of GR in prostate cancer is associated with resistance to enzalutamide therapy. Furthermore, preclinical data generated by ORIC demonstrated that inhibition of GR signaling by ORIC-101 can re-sensitize treatment-resistant prostate cancer models to enzalutamide.

"Enrollment of the first patient in this Phase 1b clinical trial of [ORIC-101](#) marks the second clinical trial for this program and another major milestone for ORIC," said Jacob M. Chacko, MD, Chief Executive Officer. "Just as the glucocorticoid receptor has been linked to treatment resistance for multiple classes of chemotherapeutics across a variety of solid tumors, there are also strong scientific rationale and preclinical evidence supporting its linkage to prostate cancer resistance. We are delighted to collaborate with Astellas on this important study assessing the potential of ORIC-101 to benefit patients with metastatic prostate cancer that has progressed on enzalutamide, for which there are limited treatment options today."

The Phase 1b trial is a multi-center, open label, dose finding study designed to evaluate the safety, pharmacokinetics, pharmacodynamics and preliminary antitumor activity of ORIC-101 combined with enzalutamide when administered to patients with metastatic prostate cancer that has progressed on enzalutamide. Once the recommended Phase 2 dose of ORIC-101 in combination with enzalutamide has been identified, the study will enroll patients into expansion cohorts based upon GR expression using ORIC's proprietary immunohistochemistry assay.

"Despite the introduction of novel antiandrogen therapies for the treatment of prostate cancer, such as enzalutamide, the majority of responsive patients will ultimately become treatment resistant, resulting in poor prognoses for men diagnosed with this devastating condition," said Pratik S. Multani, MD, Chief Medical Officer. "We are excited to evaluate the therapeutic potential of ORIC-101 to overcome what we believe may be a key mechanism of resistance to antiandrogen therapy."

Under the terms of the clinical trial collaboration and supply agreement with Astellas, ORIC is sponsoring and conducting the Phase 1b study of ORIC-101 in combination with enzalutamide. Astellas, which commercializes XTANDI® in the United States with Pfizer Inc, is providing enzalutamide for the study. ORIC maintains global development and commercial rights to ORIC-101 and rights to develop the program in combination with other agents.

Further details about the clinical study are available at ClinicalTrials.gov ([NCT04033328](#)).

About Metastatic Prostate Cancer

In the United States, prostate cancer is the second most prevalent cancer in men and the second leading cause of cancer death in men. The American Cancer Society estimates there are approximately 175,000 new cases of prostate cancer and over 30,000 deaths from the disease in the U.S. annually.

In men with prostate cancer, the disease is considered metastatic once the cancer has spread outside of the prostate gland to other parts of the body, such as the bones, lymph nodes, bladder and rectum. Men are considered hormone (or castration) sensitive if their disease still responds to medical or surgical treatment to lower testosterone levels. Men are considered castration-resistant if their disease progresses despite androgen deprivation therapy and is often correlated with rising levels of prostate-specific antigen. Over 50,000 men are estimated to develop metastatic prostate cancer in the U.S. annually.

About ORIC Pharmaceuticals

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's second product candidate, ORIC-533, is 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. Beyond these two product candidates, ORIC is also developing multiple precision medicines targeting other hallmark cancer resistance mechanisms. ORIC's scientific founders, Charles Sawyers, MD, and Scott Lowe, PhD, have long records of discovering novel targets in cancer that have led to innovative treatments. The company has assembled strong leadership and scientific teams and a board with extensive experience in drug development and financing. ORIC is headquartered in South San Francisco, California. For more information, please go to <http://oricpharma.com/>.

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