



NEWS RELEASE

FDA Approves FoundationOne® Liquid CDx to Serve as Rubraca® (rucaparib) Companion Diagnostic to Identify Eligible Patients with BRCA1/2-Mutant, Metastatic Castration-Resistant Prostate Cancer (mCRPC)

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FDA-approved plasma-based companion diagnostic provides advantages for patients and practices

BOULDER, Colo.--(BUSINESS WIRE)-- Clovis Oncology, Inc. (NASDAQ: CLVS) announced today that the U.S. Food and Drug Administration (FDA) approved the FoundationOne® Liquid CDx, Foundation Medicine's comprehensive liquid biopsy test for all solid tumors with multiple companion diagnostic indications, including for Rubraca® (rucaparib) tablets, recently approved for the treatment of adult patients with a deleterious BRCA mutation (germline and/or somatic)-associated metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor-directed therapy and a taxane-based chemotherapy.i,ii FoundationOne Liquid CDx is intended for use by health care professionals to help inform cancer treatment decisions in accordance with FDA-approved labeling and professional guidelines for patients with solid tumors.

FoundationOne Liquid CDx is intended to be used as a companion diagnostic to identify patients who may benefit from treatment with specific FDA-approved targeted therapies, including Rubraca, the first PARP inhibitor approved for the treatment of BRCA1/2-mutant mCRPC.

"Tumors with BRCA mutations are by far the most responsive to PARP inhibitors in metastatic castration-resistant prostate cancer, and when we started development of Rubraca for mCRPC, we knew it was important to develop a plasma-based companion diagnostic for physician and patient ease of use," said Patrick J. Mahaffy, President and CEO of Clovis Oncology. "What we could not have foreseen was how important a plasma-based test would be in this COVID-19 environment, in which even important procedures, such as tissue-based biopsies, can be difficult to schedule for patients. We are pleased that the FDA has approved a plasma-based companion diagnostic to identify mCRPC patients who may benefit from treatment with Rubraca."

The objective response rate in BRCA positive patients as determined by FoundationOne Liquid CDx was 46% (95% CI, 31-63), comparable to 44% (95% CI, 31-57) as determined by clinical trial assays for patients enrolled in TRITON2, highlighting the utility and consistency of using a liquid biopsy test for patient selection.i,iii

“Now that we have drugs that specifically benefit patients with BRCA mutations, the ability to identify who has these mutations is paramount,” said Professor Celestia S. Higano, MD FACP, University of Washington School of Medicine. “In contrast to tissue biopsy, a liquid biopsy is a blood-plasma test that is less invasive than a tissue biopsy for assessing germline or somatic BRCA mutations. The FDA’s approval of liquid biopsy tests represents a significant advancement for clinicians and patients to make timely decisions about treatment options.”

Foundation Medicine expects the FoundationOne Liquid CDx to be commercially available on Friday, August 28, 2020.

About Prostate Cancer

The American Cancer Society estimates that nearly 192,000 men in the United States will be diagnosed with prostate cancer in 2020iv, and the GLOBOCAN Cancer Fact Sheets estimated that approximately 450,000 men in Europe were diagnosed with prostate cancer in 2018.v Castration-resistant prostate cancer has a high likelihood of developing metastases. Metastatic castration-resistant prostate cancer, or mCRPC, is an incurable disease, usually associated with poor prognosis. Approximately 43,000 men in the U.S. are expected to be diagnosed with mCRPC in 2020.vi According to the American Cancer Society, the five-year survival rate for mCRPC is approximately 30 percent.vii Approximately 12 percent of patients with mCRPC harbor a deleterious germline and/or somatic mutation in the genes BRCA1 and BRCA2. These molecular markers may be used to select patients for treatment with a PARP inhibitor.viii

Rubraca U.S. FDA Approved Indication

Rubraca is indicated for the treatment of adult patients with a deleterious BRCA mutation (germline and/or somatic)-associated metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor-directed therapy and a taxane-based chemotherapy.

This indication is approved under accelerated approval based on objective response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Select Important Safety Information

Myelodysplastic Syndrome (MDS)/Acute Myeloid Leukemia (AML) has occurred in patients treated with Rubraca, and are potentially fatal adverse reactions. In 1146 treated patients, MDS/AML occurred in 20 patients (1.7%), including those in long term follow-up. Of these, 8 occurred during treatment or during the 28 day safety follow-up (0.7%). The duration of Rubraca treatment prior to the diagnosis of MDS/AML ranged from 1 month to approximately 53 months. The cases were typical of secondary MDS/cancer therapy-related AML; in all cases, patients had received previous platinum-containing regimens and/or other DNA damaging agents. In TRITON2, MDS/AML was not observed in patients with mCRPC (n=209) regardless of homologous recombination deficiency (HRD) mutation.

Do not start Rubraca until patients have recovered from hematological toxicity caused by previous chemotherapy (\leq Grade 1). Monitor complete blood counts for cytopenia at baseline and monthly thereafter for clinically significant changes during treatment. For prolonged hematological toxicities (> 4 weeks), interrupt Rubraca or reduce dose and monitor blood counts weekly until recovery. If the levels have not recovered to Grade 1 or less after 4 weeks or if MDS/AML is suspected, refer the patient to a hematologist for further investigations, including bone marrow analysis and blood sample for cytogenetics. If MDS/AML is confirmed, discontinue Rubraca.

Based on findings in genetic toxicity and animal reproduction studies, advise male patients with female partners of reproductive potential or who are pregnant to use effective methods of contraception during treatment and for 3 months following last dose of Rubraca. Advise male patients not to donate sperm during therapy and for 3 months following the last dose of Rubraca.

Most common adverse reactions in TRITON2 ($\geq 20\%$; Grade 1-4) were fatigue/asthenia (62%), nausea (52%), anemia (43%), AST/ALT elevation (33%), decreased appetite (28%), rash (27%), constipation (27%), thrombocytopenia (25%), vomiting (22%), and diarrhea (20%).

Co-administration of rucaparib can increase the systemic exposure of CYP1A2, CYP3A, CYP2C9, or CYP2C19 substrates, which may increase the risk of toxicities of these drugs. Adjust dosage of CYP1A2, CYP3A, CYP2C9, or CYP2C19 substrates, if clinically indicated. If co-administration with warfarin (a CYP2C9 substrate) cannot be avoided, consider increasing frequency of international normalized ratio (INR) monitoring.

[Click here](#) for full Prescribing Information for Rubraca.

You may also report side effects to Clovis Oncology, Inc. at 1-415-409-7220 (US toll) or 1-844-CLVS-ONC (1-844-258-7662; US toll-free).

About Accessing Rubraca

Rubraca is available in the United States through specialty pharmacies and distributors. Clovis is committed to ensuring Rubraca access for patients and offers eligible patients financial and reimbursement support through Rubraca Connections. More information about Rubraca Connections is available at RubracaConnections.com or by calling 1-844-779-7707 between 8 a.m. and 8 p.m. Eastern Time, Monday through Friday.

About Rubraca (rucaparib)

Rucaparib is an oral, small molecule inhibitor of PARP1, PARP2 and PARP3 being developed in multiple tumor types, including ovarian and metastatic castration-resistant prostate cancers, as monotherapy, and in combination with other anti-cancer agents. Exploratory studies in other tumor types are also underway.

About Clovis Oncology

Clovis Oncology, Inc. is a biopharmaceutical company focused on acquiring, developing and commercializing innovative anti-cancer agents in the U.S., Europe and additional international markets. Clovis Oncology targets development programs at specific subsets of cancer populations, and simultaneously develops, with partners, for those indications that require them, diagnostic tools intended to direct a compound in development to the population that is most likely to benefit from its use. Clovis Oncology is headquartered in Boulder, Colorado, with additional office locations in the U.S. and Europe. Please visit www.clovisoncology.com for more information.

About FoundationOne Liquid CDx

FoundationOne Liquid CDx is a qualitative next generation sequencing based in vitro diagnostic test for prescription use only that uses targeted high throughput hybridization-based capture technology to analyze 324 genes utilizing circulating cell-free DNA (cfDNA) isolated from plasma derived from anti-coagulated peripheral whole blood of advanced cancer patients. The test is FDA-approved to report short variants in 311 genes, including rearrangements and copy number losses in BRCA1 and BRCA2, and is a companion diagnostic to identify patients who may benefit from treatment with specific targeted therapies (listed in Table 1 of the Intended Use) in accordance with the approved therapeutic product labeling. Additional genomic findings may be reported and are not prescriptive or conclusive for labeled use of any specific therapeutic product. Use of the test does not guarantee a patient will be matched to a treatment. A negative result does not rule out the presence of an alteration. Patients who are negative for companion diagnostic mutations should be reflexed to tumor tissue testing and mutation status confirmed using an FDA-approved tumor tissue test, if available. For the complete label, including companion diagnostic indications and complete risk information, please visit www.F1LCDxLabel.com.

This press release contains forward-looking statements (as defined under the Private Securities Litigation Reform Act of 1995) about the potential of Rubraca® (rucaparib) for the treatment of adult patients with deleterious BRCA

mutation (germline and/or somatic)-associated metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor-directed therapy and a taxane-based chemotherapy, and reflects Clovis Oncology's current beliefs. As with any pharmaceutical product, there are substantial risks and uncertainties in the process of development and commercialization that could cause actual results to differ materially from those expressed or implied by the forward-looking statements. In particular, there are no guarantees that future study results and patient experience will be consistent with the study findings to date, that Rubraca will receive regulatory approval for any future indications, or that it will prove to be commercially successful. A further description of risks and uncertainties can be found in Clovis Oncology's filings with the Securities and Exchange Commission, including its Annual Report on Form 10-K and its reports on Form 10-Q and Form 8-K. All forward-looking statements are based on information currently available to the company, and Clovis Oncology does not undertake to update or revise any forward-looking statements.

Rubraca® is a registered trademark of Clovis Oncology, Inc.

Foundation Medicine® and FoundationOne® are registered trademarks of Foundation Medicine, Inc.

i Rubraca [package insert]. Boulder, CO; Clovis Oncology. 2020.

ii Foundation Medicine Inc. news release dated August 26, 2020. FDA Approves Foundation Medicine's FoundationOne® Liquid CDx, a Comprehensive Pan-Tumor Liquid Biopsy Test with Multiple Companion Diagnostic Indications for Patients with Advanced Cancer.

iii Data on file. Clovis Oncology; Boulder, CO.

iv American Cancer Society. Key Statistics for Prostate Cancer. <https://www.cancer.org/cancer/prostate-cancer/about/key-statistics.html>. Accessed January 30, 2020.

v GLOBOCAN Cancer Fact Sheets: prostate cancer. Prostate Cancer Estimated Incidence, Mortality and Prevalence Worldwide in 2018. <https://gco.iarc.fr/today/data/factsheets/cancers/27-Prostate-fact-sheet.pdf>. Accessed February 4, 2020.

vi Cameron A. Wade and Natasha Kyprianou. Profiling Prostate Cancer Therapeutic Resistance. International Journal of Molecular Sciences. 2018, 19, 204. <https://www.mdpi.com/1422-0067/19/3/904/pdf>.

vii American Cancer Society. Survival rates for prostate cancer. <https://www.cancer.org/cancer/prostate-cancer/detection-diagnosis-staging/survival-rates.html>. Accessed February 4, 2020.

viii Abida W, Armenia J, Gopalan A, et al. Prospective Genomic Profiling of Prostate Cancer Across Disease States Reveals Germline and Somatic Alterations That May Affect Clinical Decision Making. JCO Precis Oncol 2017: 1-16.

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