You are Invited to Attend a Presentation and Dinner

Rubraca Prescribing Overview

Rubraca™ (rucaparib) tablets

Presented by: W. Douglas Bunn Jr, MD

Date: April 19, 2018

Time: 5:30 PM ET

Location: Due Mari
78 Albany Street
new brunswick, NJ
(732) 296-1600

RSVP: **CLICK HERE**

Or go to www.rubracaspeakers.com
and enter EVENT CODE: 0173

Or contact your Clovis Territory Manager:
Steven Soutter
(551) 999-1334
ssoutter@clovisoncology.com

Registration questions? Call or e-mail Sara Anderson (sanderson@rrhealthcare.com) at R&R Healthcare Communications – 813-855-5533.

Consistent with the PhRMA Code on Interactions with Healthcare Professionals, attendance at this educational program is limited to healthcare professionals. Accordingly, attendance by guests or spouses is not appropriate and cannot be accommodated. The value of a meal and other transfers of value, if any are provided, may be disclosed pursuant to state and federal law.

Please Note: This is not a CME event.

FACULTY BIO

W. Douglas Bunn Jr, MD

Dr. Bunn is a practicing gynecologic oncologist and surgeon at GYN Oncology of Central New York and assistant clinical professor, Department of Obstetrics and Gynecology, State University of New York, School of Medicine in Syracuse. He received his medical degree from the University of Southern California, School of Medicine, Los Angeles; served his residency at Los Angeles County/University of Southern California Women's Hospital; and completed fellowship training at Mayo Clinic in Rochester, Minnesota. Dr. Bunn is a governor and fellow of ACS, a fellow of ACOG, and a member of SGO.

Rubraca is indicated as monotherapy for the treatment of patients with deleterious BRCA mutation (germline and/or somatic) associated advanced ovarian cancer who have been treated with two or more chemotherapies. Select patients for therapy based on an FDA-approved companion diagnostic for Rubraca.

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) was reported in 2 of 377 (0.5%) patients with ovarian cancer treated with Rubraca. The duration of Rubraca treatment prior to the diagnosis of MDS/AML was 57 days and 539 days. Both patients received prior treatment with platinum and other DNA damaging agents.

AML was reported in 2 (<1%) patients with ovarian cancer enrolled in a blinded randomized trial evaluating Rubraca versus placebo. One case of AML was fatal. The duration of treatment prior to the diagnosis of AML was 107 days and 427 days. Both patients had received prior treatment with platinum and other DNA damaging agents.

Do not start Rubraca until patients have recovered from hematological toxicity caused by previous chemotherapy (≤ Grade 1).

Monitor complete blood count testing at baseline and monthly thereafter. For prolonged hematological toxicities, interrupt Rubraca and monitor blood counts weekly until recovery. If the levels have not recovered to Grade 1 or less after 4 weeks, 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 its mechanism of action and findings from animal studies, Rubraca can cause fetal harm when administered to a pregnant woman. Apprise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment and for 6 months following the last dose of Rubraca.

Most common adverse reactions (≥20%; Grade 1-4) were nausea (77%), asthenia/fatigue (77%), vomiting (46%), anemia (44%), constipation (40%), dysgeusia (39%), decreased appetite (39%), diarrhea (34%), abdominal pain (32%), dyspnea (21%), and thrombocytopenia (21%).

Most common laboratory abnormalities (≥35%; Grade 1-4) were increase in creatinine (92%), increase in alanine aminotransferase (ALT) (74%), increase in aspartate aminotransferase (AST) (73%), decrease in hemoglobin (67%), decrease in lymphocytes (45%), increase in cholesterol (40%), decrease in platelets (39%), and decrease in absolute neutrophil count (35%).

Because of the potential for serious adverse reactions in breast-fed infants from Rubraca, advise lactating women not to breastfeed during treatment with Rubraca and for 2 weeks after the final dose.

You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Clovis Oncology, Inc. at 1-844-258-7652.

Please see accompanying full Prescribing Information for additional Important Safety Information.

Reference: 1. Rubraca [prescribing information]. Boulder, CO: Clovis Oncology; 2016.

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