You are invited to attend a Presentation and Dinner

Rubraca (rucaparib) tablets Prescribing Overview

Rubraca™ (rucaparib) tablets

Presented by: John Chan, MD

Date: March 15, 2017

Time: 6:30 PM PT

Location: LB Steak
334 Santana Row Suite 1000
San Jose, CA
(408) 244-1180

RSVP: **CLICK HERE**

Or go to www.rubracaspeakers.com and enter EVENT CODE: 0215

Or contact your Clovis Territory Manager:
Renel Gologhlan
(323) 363-2124
rgologhlan@clovisoncology.com

Registration questions? Call or e-mail Kristi Cowling (kcowling@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

John Chan, MD

Dr. Chan is regional cancer center director of gynecologic oncology at California Pacific-Palo Alto Medical Foundation Research Institute. He serves as principal investigator lead of Sutter Cancer Research Consortium and holds the Denise & Prentis Cobb Hale Endowed Chair at the California Pacific Medical Center. He is adjunct clinical professor in the Department of Obstetrics, Gynecology, and Reproductive Sciences at the University of California – San Francisco, Stanford University, and Dartmouth School of Medicine. Dr. Chan's research focuses on developing new therapies for gynecologic cancers and he is currently serving as principal investigator of a prospective randomized trial sponsored by the Gynecologic Oncology Group and National Cancer Institute. Dr. Chan has authored or co-authored numerous manuscripts and textbooks in the field of gynecologic oncology.

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

Introducing Rubraca

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

There are no contraindications with Rubraca.

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.

Rubraca can cause fetal harm when administered to pregnant women based on its mechanism of action and findings from animal studies. 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.

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