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Rubraca™ (rucaparib) tablets

Rubraca (rucaparib) Prescribing Overview

January 12, 2017

Panelists:
Michael J. Birrer, MD, PhD
Harvard Medical School
Massachusetts General Hospital

Tina Atkinson, RN
Massachusetts General Hospital

Program Start Time: 6:00 PM

Location:
Fleming's Prime Steakhouse and Wine Bar
180 El Camino Real
Palo Alto, CA 94304
(650) 329-8457

RSVP: **CLICK HERE**

Or go to www.rubracaspeakers.com and enter EVENT CODE: 2017

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

Registration questions? Call or e-mail Joyce Creamer (jcreamer@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.

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 1-844-258-7662.

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

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EXPERT PANELIST BRIEF BIOGRAPHIES

Michael J. Birrer, MD, PhD

Dr. Birrer is professor of medicine, Harvard Medical School, director of Gynecologic Medical Oncology at Massachusetts General Hospital, and director of the gynecologic oncology research program at MGH Cancer Center.

Dr. Birrer is recognized nationally and internationally as an expert in gynecologic oncology. He has published over 235 peer-reviewed manuscripts and another 27 book chapters and review articles. He has served in leadership positions within the greater gynecologic oncology community. He has been the chair and chair emeritus of the DOD Ovarian Cancer Research Program, chair of the Committee for Experimental Medicine of the Gynecologic Oncology Group, a member of the Gynecologic Cancer Steering Committee and chair of the Translational Science Working Group of the Gynecologic Cancer Intergroup. Dr. Birrer has been a member of the Society of Gynecologic Oncology (SGO), American Society of Clinical Oncologists (ASCO), American Association of Cancer Research (AACR), and the International Gynecologic Cancer Society (IGCS). He has been on the program committees of ASCO, SGO, and IGCS.

Tina Atkinson, RN

Ms. Atkinson is a research nurse at Massachusetts General Hospital. She is a member of the Association for Clinical Research Professionals (ACRP) and The Society of Clinical Research Associates (SOCRA). During her time at the Dana Farber Cancer Institute from 2000 to 2013, she was the recipient of the Department of Medical Oncology Staff Recognition award (2004, 2005 and 2006) and the Partners in Excellence Award (2005). Ms. Atkinson has numerous published articles in peer-reviewed journals in the field of gynecologic oncology.

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