You are cordially invited to attend a program

Evolving Treatment Approaches in MDS & CMML

Featured Speaker:

BART SCOTT, MD
Fred Hutchinson Cancer Research Center
Seattle, WA

Date:

TUESDAY, JUNE 7, 2022

Time:

6:00PM - 8:00PM PACIFIC

Location:

FLEMING'S PRIME STEAKHOUSE & WINE BAR
180 El Camino Real
Palo Alto, CA 94304

TO RSVP, PLEASE GO TO: http://sphase.info/tai01515

If you have any questions about this program, please contact Monica Ferrone with Taiho Oncology at mferrone@taihooncology.com and (530) 796-1058 or Gabriel Barrett with S Phase at gbarrett@sphase.com or (770) 984-5136.

Pursuant to the PhRMA Code on Interactions with Healthcare Professionals, as well as the policies of Taiho Oncology, Inc., attendance at this promotional program is restricted to healthcare professionals (HCPs) within the targeted oncology specialty. Accordingly, spouses and guests are not permitted to attend this program unless they are an HCP within the targeted oncology specialty.

Taiho will report information related to the event, such as your name and the value and purpose of any educational item, meal or other items of value you receive, to the extent required by federal and state laws, as applicable. Please let us know if you are licensed in any state or other jurisdiction, or are an employee or contractor of any organization or government entity that limits or prohibits meals from pharmaceutical companies. HCPs may attend the program and decline a meal. Please note this with your registration and designate this at the venue as you sign-in for the program.

Please see Indication and Important Safety Information on the back and the accompanying full Prescribing Information or at www.inqovi.com/pi

INQOVI®
(decitabine and cedazuridine)
35mg/100mg tablets

Indication

INQOVI is indicated for treatment of adult patients with myelodysplastic syndromes (MDS), including previously treated and untreated, de novo and secondary MDS with the following French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, and chronic myelomonocytic leukemia [CMML]) and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups.

Important Safety Information

WARNINGS AND PRECAUTIONS

Myelosuppression: Fatal and serious myelosuppression can occur with INQOVI. Based on laboratory values, new or worsening thrombocytopenia occurred in 82% of patients, with Grade 3 or 4 occurring in 76%. Neutropenia occurred in 73% of patients, with Grade 3 or 4 occurring in 71%. Anemia occurred in 71% of patients, with Grade 3 or 4 occurring in 55%. Febrile neutropenia occurred in 33% of patients, with Grade 3 or 4 occurring in 32%. Myelosuppression (thrombocytopenia, neutropenia, anemia, and febrile neutropenia) is the most frequent cause of INQOVI dose reduction or interruption, occurring in 36% of patients. Permanent discontinuation due to myelosuppression (febrile neutropenia) occurred in 1% of patients. Myelosuppression and worsening neutropenia may occur more frequently in the first or second treatment cycles and may not necessarily indicate progression of underlying MDS.

Fatal and serious infectious complications can occur with INQOVI. Pneumonia occurred in 21% of patients, with Grade 3 or 4 occurring in 15%. Sepsis occurred in 14% of patients, with Grade 3 or 4 occurring in 11%. Fatal pneumonia occurred in 1% of patients, fatal sepsis in 1%, and fatal septic shock in 1%.

Obtain complete blood cell counts prior to initiation of INQOVI, prior to each cycle, and as clinically indicated to monitor response and toxicity. Administer growth factors and anti-infective therapies for treatment or prophylaxis as appropriate. Delay the next cycle and resume at the same or reduced dose as recommended.

Embryo-Fetal Toxicity: INQOVI can cause fetal harm. Advise pregnant women of the potential risk to a fetus. Advise patients to use effective contraception during treatment and for 6 months (females) or 3 months (males) after last dose.

ADVERSE REACTIONS

Serious adverse reactions in > 5% of patients included febrile neutropenia (30%), pneumonia (14%), and sepsis (13%). Fatal adverse reactions included sepsis (1%), septic shock (1%), pneumonia (1%), respiratory failure (1%), and one case each of cerebral hemorrhage and sudden death.

The most common adverse reactions (≥ 20%) were fatigue (55%), constipation (44%), hemorrhage (43%), myalgia (42%), mucositis (41%), arthralgia (40%), nausea (40%), dyspnea (38%), diarrhea (37%), rash (33%), dizziness (33%), febrile neutropenia (33%), edema (30%), headache (30%), cough (28%), decreased appetite (24%), upper respiratory tract infection (23%), pneumonia (21%), and transaminase increased (21%). The most common Grade 3 or 4 laboratory abnormalities (≥ 50%) were leukocytes decreased (81%), platelet count decreased (76%), neutrophil count decreased (71%), and hemoglobin decreased (55%).

USE IN SPECIFIC POPULATIONS

Lactation: Because of the potential for serious adverse reactions in the breastfed child, advise women not to breastfeed during treatment with INQOVI and for at least 2 weeks after the last dose.

Renal Impairment: No dosage modification of INQOVI is recommended for patients with mild or moderate renal impairment (creatinine clearance [CLcr] of 30 to 89 mL/min based on Cockcroft-Gault). Due to the potential for increased adverse reactions, monitor patients with moderate renal impairment (CLcr 30 to 59 mL/min) frequently for adverse reactions. INQOVI has not been studied in patients with severe renal impairment (CLcr 15 to 29 mL/min) or end-stage renal disease (ESRD: CLcr <15 mL/min).

PLEASE SEE FULL PRESCRIBING INFORMATION.

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