You are cordially invited to attend a program entitled

PEMAZYRE® (pemigatinib): The First FDA-Approved Treatment for Previously Treated, Unresectable Locally Advanced or Metastatic Cholangiocarcinoma (CCA) with FGFR2 Fusion or Rearrangement

Wednesday, December 8, 2021 at 6:00 PM

The program will begin at 6:00 PM. Please plan to arrive 15 minutes early to sign in.

Featured Speaker:
Gazala Khan, MD
Henry Ford Health System
Detroit, MI

Location:
Ruth’s Chris Steakhouse
314 S. Fourth Ave
Ann Arbor, MI 48104

REGISTRATION
Register by December 1, 2021

http://sphase.info/inc8305

To register manually, please contact your Incyte representative Joe Goerge at (517) 881-4462 or jgoerge@incyte.com with the following information: name, title/degree, state(s) and state license #(s), affiliation, address, phone, and e-mail

Prior to registering, please review the program title and speaker to ensure you have not attended this program within the past year.

INDICATIONS AND USAGE

PEMAZYRE is indicated for the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test.

This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Please see Important Safety Information for PEMAZYRE® on back cover and accompanying Full Prescribing Information.

Please note this program is intended for healthcare professionals (HCPs) only. This program is sponsored by Incyte Corporation and is not eligible for CE credits.

Consistent with PhRMA guidelines, spouses and other guests of an HCP are not permitted to attend. The cost of meals associated with this event may be disclosed consistent with applicable federal and state law disclosure requirements. State and federal laws and regulations may restrict state or federal employees from receiving meals. By attending this event, you confirm that you have obtained any necessary approvals from your employer. HCPs may be subject to state law restrictions regarding attendance. HCPs licensed in Vermont or employees/agents of Vermont HCPs may not attend this event. Minnesota law restricts Incyte from offering meals or other refreshments to certain HCPs who are licensed in Minnesota and have the ability to prescribe prescription drugs (e.g., physicians, physician assistants, nurse practitioners, advanced nurses). If you are licensed to prescribe in Minnesota, please identify yourself when you register and inform an Incyte representative prior to the start of the program.
**IMPORTANT SAFETY INFORMATION**

**Ocular Toxicity**

Retinal Pigment Epithelial Detachment (RPED): PEMAZYRE can cause RPED, which may cause symptoms such as blurred vision, visual floaters, or photopsia. Clinical trials of PEMAZYRE did not conduct routine monitoring including optical coherence tomography (OCT) to detect asymptomatic RPED; therefore, the incidence of asymptomatic RPED with PEMAZYRE is unknown.

Among 466 patients who received PEMAZYRE across clinical trials, RPED occurred in 6% of patients, including Grade 3-4 RPED in 0.8%. The median time to first onset of RPED was 82 days. RPED led to dose interruption of PEMAZYRE in 1.7% of patients, and dose reduction and permanent discontinuation in 0.4% and in 0.4% of patients, respectively. RPED resolved or improved to Grade 1 levels in 87.5% of patients who required dosage modification of PEMAZYRE for RPED.

Perform a comprehensive ophthalmological examination including OCT prior to initiation of PEMAZYRE and every 2 months for the first 6 months and every 3 months thereafter during treatment. For onset of visual symptoms, refer patients for ophthalmological evaluation urgently, with follow-up every 3 weeks until resolution or discontinuation of PEMAZYRE. Modify the dose or permanently discontinue PEMAZYRE as recommended in the prescribing information for PEMAZYRE.

**Dry Eye:** Among 466 patients who received PEMAZYRE across clinical trials, dry eye occurred in 27% of patients, including Grade 3-4 in 0.6% of patients. Treat patients with ocular demulcents as needed.

**Hyperphosphatemia and Soft Tissue Mineralization**

PEMAZYRE can cause hyperphosphatemia leading to soft tissue mineralization, cutaneous calcification, calcinosis, and non-uremic calciphylaxis. Increases in phosphate levels are a pharmacodynamic effect of PEMAZYRE. Among 466 patients who received PEMAZYRE across clinical trials, hyperphosphatemia was reported in 93% of patients based on laboratory values above the upper limit of normal. The median time to onset of hyperphosphatemia was 8 days (range 1-189). Phosphate lowering therapy was required in 26% of patients receiving PEMAZYRE.

Monitor for hyperphosphatemia and initiate a low phosphate diet when serum phosphate level is >5.5 mg/dL. For serum phosphate levels >7 mg/dL, initiate phosphate lowering therapy and withhold, reduce the dose, or permanently discontinue PEMAZYRE based on duration and severity of hyperphosphatemia as recommended in the prescribing information.

**Embryo-Fetal Toxicity**

Based on findings in an animal study and its mechanism of action, PEMAZYRE can cause fetal harm when administered to a pregnant woman. Oral administration of pemigatinib to pregnant rats during the period of organogenesis caused fetal malformations, fetal growth retardation, and embryo-fetal death at maternal exposures lower than the human exposure based on area under the curve (AUC) at the clinical dose of 13.5 mg.

Advise pregnant women of the potential risk to the fetus. Advise female patients of reproductive potential to use effective contraception during treatment with PEMAZYRE and for 1 week after the final dose.”

**Adverse Reactions**

Serious adverse reactions occurred in 46% of patients receiving PEMAZYRE. Serious adverse reactions in ≥2% of patients who received PEMAZYRE included abdominal pain, pyrexia, cholangitis, pleural effusion, acute kidney injury, cholangitis infective, failure to thrive, hypercalcemia, hyponatremia, small intestinal obstruction, and urinary tract infection. Fatal adverse reactions occurred in 4.1% of patients, including failure to thrive, biliary obstruction, cholangitis, sepsis, and pleural effusion.

Permanent discontinuation due to an adverse reaction occurred in 9% of patients who received PEMAZYRE. Adverse reactions requiring permanent discontinuation in ≥1% of patients included intestinal obstruction and acute kidney injury.

Dose interruptions due to an adverse reaction occurred in 43% of patients who received PEMAZYRE. Adverse reactions requiring dosage interruption in ≥1% of patients included stomatitis, palmar-plantar erythrodysesthesia syndrome, arthralgia, fatigue, abdominal pain, AST increased, anemia, pyrexia, ALT increased, cholangitis, small intestinal obstruction, alkaline phosphatase increased, diarrhea, hyperbilirubinemia, electrocardiogram QT prolonged, decreased appetite, dehydration, hypercalcemia, hyperphosphatemia, hypophosphatemia, back pain, pain in extremity, syncope, acute kidney injury, encephalopathy, and hypotension.

Dose reductions due to an adverse reaction occurred in 14% of patients who received PEMAZYRE. Adverse reactions requiring dosage reductions in ≥1% of patients who received PEMAZYRE included stomatitis, arthralgia, palmar-plantar erythrodysesthesia syndrome, anemia, and encephalopathy.

Clinically relevant adverse reactions occurring in ≥10% of patients included fractures (2.1%). In all patients treated with pemigatinib, 1.3% experienced pathologic fractures (which included patients with and without cholangiocarcinoma [N = 468]). Soft tissue mineralization, including cutaneous calcification, calcinosis, and non-uremic calciphylaxis associated with hyperphosphatemia were observed with PEMAZYRE treatment.

Within the first 21-day cycle of PEMAZYRE dosing, serum creatinine increased (mean increase of 0.2 mg/dL) and reached steady state by Day 8, and then decreased during the 7 days off therapy. Consider alternative markers of renal function if persistent elevations in serum creatinine are observed.

The most common adverse reactions (incidence ≥20%) were hyperphosphatemia (60%), alopecia (40%), diarrhea (47%), nail toxicity (43%), fatigue (42%), dysgeusia (40%), nausea (40%), constipation (35%), stomatitis (25%), dry eye (35%), dry mouth (34%), decreased appetite (33%), vomiting (27%), arthralgia (25%), abdominal pain (23%), hypophosphatemia (23%), back pain (20%), and dry skin (20%).

**Drug Interactions**

Avoid concomitant use of strong and moderate CYP3A inhibitors with PEMAZYRE. Reduce the dose of PEMAZYRE if concomitant use with a strong or moderate CYP3A inhibitor cannot be avoided. Avoid concomitant use of strong and moderate CYP3A inducers with PEMAZYRE.

**Special Populations**

Advise lactating women not to breastfeed during treatment with PEMAZYRE and for 1 week after the final dose.

Reduce the recommended dose of PEMAZYRE for patients with severe renal impairment as described in the prescribing information.

Reduce the recommended dose of PEMAZYRE for patients with severe hepatic impairment as described in the prescribing information.

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Please see Full Prescribing Information for PEMAZYRE.

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