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## SCEMBLIX® (asciminib) tablets now approved for a new indication

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Dear CHOP Member:

**Novartis is pleased to announce FDA approval of SCEMBLIX for adults with newly diagnosed Philadelphia chromosome–positive chronic myeloid leukemia in chronic phase (Ph+ CML-CP).** FDA approval was based on results from ASC4FIRST, a multicenter, randomized, active-controlled, open-label study that evaluated SCEMBLIX vs investigator-selected tyrosine kinase inhibitors (IS-TKIs) (bosutinib, dasatinib, imatinib, nilotinib) in adult patients with newly diagnosed Ph+ CML-CP. Please distribute this information to relevant stakeholders at your organization.

Should you have questions or wish to discuss further, please provide your availability for a scheduled meeting.

### INDICATION

SCEMBLIX® (asciminib) tablets is indicated for the treatment of adult patients with:

- Newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP)
  - This indication is approved under accelerated approval based on major molecular response rate. Continued approval for this indication may be contingent upon verification of clinical benefit in a confirmatory trial(s)

### IMPORTANT SAFETY INFORMATION for SCEMBLIX

#### Myelosuppression

- Thrombocytopenia, neutropenia, and anemia, including grade 3/4 reactions, have occurred in patients receiving SCEMBLIX
- Perform complete blood counts every 2 weeks for the first 3 months of treatment and monthly thereafter or as clinically indicated. Monitor patients for signs and symptoms of myelosuppression
- Based on the severity of thrombocytopenia and/or neutropenia, reduce dose, temporarily withhold, or permanently discontinue SCEMBLIX as described in the prescribing information

#### Pancreatic Toxicity

- Pancreatitis (including grade 3 reactions) and elevation in serum lipase and amylase (including grade 3/4 elevations), have occurred in patients receiving SCEMBLIX
- Assess serum lipase and amylase levels monthly during treatment with SCEMBLIX, or as clinically indicated. Monitor patients for signs and symptoms of pancreatic toxicity. Perform more frequent monitoring in patients with a history of pancreatitis
- If lipase and amylase elevation are accompanied by abdominal symptoms, temporarily withhold SCEMBLIX and consider appropriate diagnostic tests to exclude pancreatitis
- Based on the severity of lipase and amylase elevation, reduce dose, temporarily withhold, or permanently discontinue SCEMBLIX as described in the prescribing information

#### Hypertension

- Hypertension, including grade 3/4 reactions, have occurred in patients receiving SCEMBLIX

- Monitor and manage hypertension using standard antihypertensive therapy during treatment with SCEMBLIX as clinically indicated
- For grade 3 or higher reactions, temporarily withhold, reduce dose, or permanently discontinue SCEMBLIX as described in the prescribing information depending on persistence of hypertension

### **Hypersensitivity**

- Hypersensitivity, including grade 3/4 reactions, have occurred in patients receiving SCEMBLIX. Reactions included rash, edema, and bronchospasm
- Monitor patients for signs and symptoms and initiate appropriate treatment as clinically indicated
- For grade 3 or higher reactions, temporarily withhold, reduce dose, or permanently discontinue SCEMBLIX as described in the prescribing information depending on persistence of hypersensitivity

### **Cardiovascular Toxicity**

- Cardiovascular toxicity (including ischemic cardiac and central nervous system conditions; and arterial thrombotic and embolic conditions) and cardiac failure have occurred in patients receiving SCEMBLIX. Some toxicities were grade 3/4 and 5 fatalities were reported
- Arrhythmia, including QTc prolongation, have occurred in patients receiving SCEMBLIX. Some of these arrhythmias were grade 3/4
- Monitor patients with a history of cardiovascular risk factors for cardiovascular signs and symptoms. Initiate appropriate treatment as clinically indicated
- For grade 3 or higher cardiovascular toxicity, temporarily withhold, reduce dose, or permanently discontinue SCEMBLIX as described in the prescribing information depending on persistence of cardiovascular toxicity

### **Embryo-Fetal Toxicity**

- SCEMBLIX can cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus if SCEMBLIX is used during pregnancy or if the patient becomes pregnant while taking SCEMBLIX
- Verify the pregnancy status of females of reproductive potential prior to starting treatment with SCEMBLIX. Advise females to use effective contraception during treatment and for at least 1 week after the last SCEMBLIX dose

### **ADVERSE REACTIONS**

- Most common adverse reactions ( $\geq 20\%$ ) were musculoskeletal pain, rash, fatigue, upper respiratory tract infection, headache, abdominal pain, and diarrhea
- Most common select laboratory abnormalities ( $\geq 20\%$ ) were lymphocyte count decreased, leukocyte count decreased, platelet count decreased, neutrophil count decreased, calcium corrected decreased, lipase increased, cholesterol increased, uric acid increased, alanine aminotransferase increased, alkaline phosphatase increased, hemoglobin decreased, triglycerides increased, creatine kinase increased, amylase increased, and aspartate aminotransferase increased

### **DRUG INTERACTIONS**

- Asciminib is an inhibitor of CYP3A4, CYP2C9, P-gp, OATP1B, and BCRP. Asciminib is a CYP3A4 substrate
- Closely monitor for adverse reactions during concomitant use of strong CYP3A4 inhibitors and SCEMBLIX at 200 mg twice daily
- Avoid concomitant use of itraconazole oral solution containing hydroxypropyl- $\beta$ -cyclodextrin and SCEMBLIX at all recommended doses
- Closely monitor for adverse reactions during concomitant use of certain CYP3A4 substrates and SCEMBLIX at 80 mg total daily dose. Avoid use of SCEMBLIX at 200 mg twice daily
- Avoid concomitant use of CYP2C9 substrates and SCEMBLIX at all recommended doses. If coadministration with 80 mg total daily dose is unavoidable, reduce the CYP2C9 substrate dosage as recommended in its prescribing information. If coadministration with 200 mg twice daily is unavoidable, consider alternative therapy with a non-CYP2C9 substrate
- Closely monitor for adverse reactions during concomitant use of certain P-gp substrates and SCEMBLIX at all recommended doses
- Avoid concomitant use of rosuvastatin or atorvastatin and SCEMBLIX at all recommended doses. Closely monitor for adverse reactions during concomitant use of other OATP1B or BCRP

substrates and SCEMBLIX at all recommended doses

Please see full [Prescribing Information](#).

**Jeff Osmundson**

Regional Markets, US Market Access  
Novartis Pharmaceuticals  
[Jeffrey.osmundson@novartis.com](mailto:Jeffrey.osmundson@novartis.com)  
913-484-5444 ( Mobile )

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**Novartis Pharmaceuticals Corporation**  
One Health Plaza  
East Hanover, New Jersey 07936-1080  
431634

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