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Abu-Alpha GK, Yarnagin W, Dika IE, et al. Cancer of the liver and bile ducts. In: Niederhuber JE, Armitage JO, Kastan MB, Doroshow JH, Tepper JE, eds. Abelloff's Clinical Oncology. 6th o.p. Philadelphia, Pennsylvania: Elsevier; 2020:chap 77.Di Bisceglie AM, Befeler AS. Liver tumors and cysts. In: Feldman M, Friedman L.S., Brandt LJ, eds. Sleisenger and Fordtran gastrointestinal and liver disease: pathophysiology/diagnosis/management. 10th o. Philadelphia, PA: Elsevier Saunders; 2016:chap 96.National Cancer Institute website. Adults primary treatment for liver cancer (PD) - health professional version. www.cancer.gov/types/liver/hp/adult-liver-treatment-pdq. Updated March 24, 2019 Access to The National Comprehensive Cancer Network website. NCCN Clinical Practice Guidelines in Oncology: Hepatobiliary Cancers. Version 3, 2019. www.nccn.org/professionals/physician_gls/pdf/hepatobiliary.pdf. Last Updated Aug 1, 2019 : August 27, 2019.Page 2Mc'uaid KR. Approach to a patient with gastrointestinal diseases. In: Goldman L, Schafer AI, Ed. Goldman-Cecil Medicine. 26th. Philadelphia, Pennsylvania: Elsevier; 2020:chap 123.Smith KA. Pain in the abdomen. In: Walls RM, Hockberger RS, Goshe Hill M, eds. Rosen Emergency Medicine: Concepts and Clinical Practices. 9th o.p. Philadelphia, Pennsylvania: Elsevier; 2018:chap 24.Squires R, Carter SN, Postier RG. A sharp belly. In: Townsend CM Jr., Beauchamp RD, Evers BM, Mattox KL, eds. Sabiston is a textbook surgery. 20th o.p. Philadelphia, Pennsylvania: Elsevier; 2017:chap 45.Page 3Mayer EA. Functional gastrointestinal disorders: irritable bowel syndrome, dyspepsia, chest pain of the alleged origin of the oesophagus and heartburn. In: Goldman L, Schafer AI, Ed. Goldman-Cecil Medicine. 25th. Philadelphia, PA: Elsevier Saunders; 2016:chap 137.Tack J. Dyspepsia. In: Feldman M, Friedman L.S., Brandt LJ, eds. Sleisenger and Fordtran in gastrointestinal and liver disease. 10th o. Philadelphia, PA: Elsevier Saunders; 2016:Chap 14.Page 4Updated by: Michael M. Phillips, MD, Clinical Professor of Medicine, George Washington University School of Medicine, Washington, D.C. Also reviewed are David Sive, MD, MHA, Medical Director, Brenda Conaway, Editorial Director, and A.D.A.M. Editorial Team. Other names: HCC; Liver cancer; Malignant hepatoma O hepatocellular carcinoma: Hepatocellular carcinoma is a malignant liver tumor that develops in chronic liver disease or cirrhosis of the liver. The following list of medications is in some way related to, or used in the treatment of this condition. Learn more about Hepatocellular Carcinoma Symptoms and TreatmentMayo Clinic ReferenceHepatocellular CarcinomaLiver CancerICD-10 CM Clinical Codes (external) See ICD10 codes for carcinomas on icd-codes.com Rx Prescription Only over-the-counter prescription counter Rx/OTC or over the Counter Off Label This drug may not be approved by the FDA for the FDA this state. Pregnancy Category A Adequate and well-controlled studies have failed to demonstrate the risk to the fetus in the first trimester of pregnancy (and there is no evidence of risk in

later trimesters). B Animal reproduction studies have failed to demonstrate risk to the fetus and there are no adequate and well-controlled studies in pregnant women. C Animal Reproduction Studies have shown adverse effects on the fetus and there are no adequate and well-controlled studies in humans, but potential benefits may require use in pregnant women despite the potential risks. D There is positive evidence of a person's fetal risk based on adverse reaction data from research or marketing experience or human studies, but potential benefits may require use in pregnant women despite potential risks. X Studies on animals or humans have shown fetal abnormalities and/or there is positive evidence of human fetal risk based on adverse reaction data from research or marketing experience, and the risks associated with use in pregnant women clearly outweigh the potential benefits. N FDA has not classified the drug. The Controlled Substances Act (CSA) Schedule N is not subject to the Controlled Substances Act. 1 has a high potential for abuse. It does not currently have accepted medical use in treatment in the United States. There is no accepted security for use under medical supervision. 2 Has a high potential for abuse. Has currently accepted medical use in treatment in the United States or is currently accepted medical use with serious limitations. Abuse can lead to severe psychological or physical dependence. 3 Has the potential for less abuse than in charts 1 and 2. Has now accepted medical use in treatment in the United States. Abuse can lead to moderate or low physical dependence or high psychological dependence. 4 Has a low potential for abuse compared to those in schedule 3. He has now accepted medical use in treatment in the United States. Abuse can lead to limited physical dependence or psychological dependence compared to those in chart 3. 5 Has a low potential for abuse compared to those in Schedule 4. Has now accepted medical use in treatment in the United States. Abuse can lead to limited physical dependence or psychological dependence compared to those in chart 4. Alcohol X interacts with alcohol. See Treatment Options A B C D E F G H J J K K N N O P s T U V W X Y - Always consult with your health care provider to make sure that the information displayed on this page relates to your personal circumstances. Medical failure Medical Review Drugs.com. Updated May 4, 2019, the Hepatocellular Carcinoma (HCC) review is the most common type of primary liver cancer. Hepatocellular carcinoma is most common in people with chronic liver disease, such as cirrhosis of the liver caused by hepatitis B or hepatitis C Risk factors risk hepatocellular carcinoma, the most common type of liver cancer, is higher in people with long-term liver disease. It is also higher if liver scars from hepatitis B infection or hepatitis C. Hepatocellular carcinoma is more common in people who drink large amounts of alcohol and who have a buildup of fat in the liver. Diagnostic Tests and procedures used to diagnose hepatocellular carcinoma include: Blood tests to measure liver function Imaging tests such as CT and MRI liver biopsies, in some cases to remove a liver tissue sample for laboratory testing Treatment Which treatment is better for you will depend on the size and location of hepatocellular carcinoma, how well your liver functions are functioning. Hepatocellular carcinoma treatments include: Surgery. Surgery to remove cancer and margin healthy tissue that surrounds it may be an option for people with early stage liver cancer who have normal liver function. Liver transplant surgery. Surgery to remove the entire liver and replace it with a liver from a donor may be an option for otherwise healthy people whose liver cancer has not spread beyond the liver. Destruction of cancer cells with heat or cold. Ablative procedures for destroying cancer cells in the liver using extreme heat or cold may be recommended for people who cannot undergo surgery. These procedures include radiofrequency ablation, cryoablation and ablation using alcohol or microwave. Delivery of chemotherapy or radiation directly to cancer cells. Using a catheter that has passed through blood vessels and into the liver, doctors can deliver chemotherapy drugs (chembolyzization) or tiny glass spheres containing radiation (radioembolization) directly to cancer cells. Radiation therapy. Radiation therapy using the energy of X-rays or protons may be recommended if surgery is not an option. A specialized type of radiation therapy, called stereotactic body radiation therapy (SBRT), involves focusing many radiation rays simultaneously at one point in your body. Targeted drug therapy. Targeted drugs attack specific weaknesses in cancer cells, and they can help slow the progression of the disease in people with liver cancer progress. Immunotherapy. Immunotherapy drugs use your body's germ-fighting immune system to attack cancer cells. Immunotherapy may be an option for treating liver cancer. Clinical trials. Clinical trials give you the opportunity to try new treatments for liver cancer. Ask your doctor if you are eligible to participate in clinical trials. © 1998-2019, the Foundation for Medical Education and Mayo (MFMER). All rights are reserved. Terms of use. Learn more about hepatocellular carcinoma Associate DrugsIBM Watson MicromedexSymptoms and TreatmentMayo Clinic Handbook Podcast Cabozantinib FDA Medical Oncologists discuss January 14, 2019, 2019, cabosantinib for patients with hepatocellular carcinoma (HCC) who were previously treated with sorafenib. Dr. Sanjeeve Bala: Welcome back to DISCO, FDA Drug Info Soundcast's Clinical Oncology From The Cancer Center excellence. During our soundcasts, we discuss recent FDA approvals of cancer drugs and therapies. We hope that this information will help you better understand these claims and how new drugs and treatments benefit cancer patients. Today we will discuss the recent approval of cabozantinib for the treatment of patients with hepatocellular carcinoma who progressed after systemic therapy. I am Dr. Sanjevie Bala, a medical oncologist and clinical team leader at the FDA, and I am joined by my colleague Dr. Abhi Nair, also a medical oncologist at the Cancer Center of Excellence. Dr. Abhi Nair: Hello everyone. Thank you for joining us. Patients with hepatocellular carcinoma that progressed after initial systemic therapy have a median survival rate of less than one year, despite having three drugs to use in this setting, namely, regorafenib, nivolumab, and pembrolizumab. It is obvious that the treatment of fireproof hepatocellular carcinoma is an unmet medical necessity. SB: Cabozantinib is an oral inhibitor of tyrosine tyrosine cMET and VEGFR2, as well as a number of others, and was initially approved for the treatment of patients with medullary thyroid cancer in 2012 and patients with progressive renal carcinoma in 2016. Current authorization for the treatment of patients with hepatocellular carcinoma who were previously treated with sorafenib. The recommended dose is 60 mg orally, once a day. It should be noted that this is a statement for Cabometyx tablets, not Cometriq capsules used to treat medullary thyroid cancer in a different dosage regimen. AN: Cabozantinib received an orphan drug designation from the FDA during development and has now received regular approval for this indicator. Sanjeev, tell us about the trial and the end points. SB: Cabozantinib was evaluated in the CELESTIAL trial, a double-blind trial in 707 patients with hepatocellular carcinoma previously treated with sorafenib, which were randomized 2:1 to cabozantinib, 60 mg orally once a day, or placebo. AN: These patients also had a Class A liver function disorder, right? S.B.: Right, Abhi. And they were stratified to study the etiology of diseases, i.e. hepatitis B and/or hepatitis C, against hepatitis C alone, against other etiology. Additional stratification factors include a geographic region with categories of Asia compared to other regions and the presence of extrahepatic spread and/or microvascular intrusion. AN: And this test used overall survival as the primary that strengthens the interpretation of these results. SB: Additional endpoints included progression of free survival and objective response, with assessments by investigators Eight weeks. AN: Of the enrolled patients, the average age was 64 years; 82% were male, 56% were white and 34% were Asian. As for the etiology of their HCC, 38% were classified as hepatitis B virus infection, 21% were associated with hepatitis C infection, and 40% had other etiology; 27% of patients also had two previous systemic treatments. Okay, now let's hear the results of the trial. SB: The average overall survival rate of patients, semi-unincied cabozantinib was 10.2 months, while it was 8 months for those receiving a placebo. The median progression-free survival was 5.2 months for patients on the arm of the treatment, and 1.9 months on the placebo arm. The total response rate was 4% for hand treatment, and 0.4% on a placebo hand. AN: Sanjeev, how about banishing the most important security signals during the trial? SB: Cabozantinib has been on the market since 2012. Compared to placebo patients, patients with hepatocellular carcinoma who received cabosantinib in the CELESTIAL trial had more hepatotoxicity. Elevated transaminase has occurred more frequently in patients with hepatocellular carcinoma receiving cabozantinib compared to renal cell carcinoma and medullary signs of thyroid cancer, which is not unexpected given the underlying disease. Observed hepatotoxicity was largely controlled by dose modifications. The most common adverse reactions were diarrhea, fatigue, decreased appetite, palmar-saugenium erythrodycesia, nausea, hypertension and vomiting. Practitioners recognize these symptoms as common for many tyrosine kinase inhibitors. There are some additional rare, more serious toxicities, including osteonecrosis of the jaw, fistula, and reversible posterior leukoencephalopathy. AN: What about lowering the dose and stopping? SB: Doses have been reduced for 62% of patients, and 33% of patients required a dose reduction of up to 20 mg daily from a starting dose of 60 mg per day. They were usually caused by palmar-soles of erythrodiesia, diarrhea, fatigue, and an increase in aspartate aminotransferase (AST). Details of the safety are available on the product label. AN: Why don't you give us three hireds for this DISCO. SB: 1) Cabozantinib was recently approved for the treatment of patients with advanced hepatocellular carcinoma after treatment with sorafenib; 2) The clinical trials that led to the approval demonstrated the overall survival advantage; and 3) safety on this test is usually similar to previous studies, with diarrhea, fatigue, and decreased appetite occurring more often. More information about appointment and security can be found in approved appointment information, also available online drugs@fda. For a transcript of this Soundcast, visit the FDA Cancer Center of Excellence D.I.S.C.O. www.fda.gov/DISCO. Fda analysis and review were conducted by the FDA's interdisciplinary team More information can be found on the FDA website. AN: Thank you Sanjeje. Are there other FDA oncology drug approvals that you would like to hear about? Leave us your questions and comments on Twitter @FDAOncology and, as always, we welcome your feedback to our email address FDAOncology@fda.hhs.gov. I'm Abhi Nair, thanks for tuning in to DISCO today. S.B.: And until the next time on DISCO I'm Sanjeev Bala. Confessions of This Drug Info Soundcast in Clinical Oncology was developed by Sanjeeve Bala, Abhilasha Nair, Martha Donoghue, Kirsten B. Goldberg, and Richard Pazdur, Cancer Center of Excellence and Office of Hematology and Oncology Products. Stephen Jackson of the Drug Information Division was a sound engineer. 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