Fact Sheet

CELESTIAL - Phase 3 Pivotal Trial

of Cabozantinib in Previously Treated Advanced Hepatocellular Carcinoma

CELESTIAL CLINICAL TRIAL

The CELESTIAL global phase 3 clinical trial tested the effects of cabozantinib compared with placebo in patients with advanced hepatocellular carcinoma (HCC) who had already received treatment with sorafenib (Nexavar®), the standard of care for first-line HCC treatment. The main objective of the CELESTIAL trial was to determine whether cabozantinib can improve survival in this patient population.

WHAT IS HEPATOCELLULAR CARCINOMA (HCC)?

- HCC is the most common type of liver cancer.[1]
- In 2018, it is estimated that 42,000 new cases will be diagnosed and approximately 30,000 people will die from HCC in the U.S.[2]
- This type of liver cancer is the third leading cause of cancer-related deaths worldwide.[3]

Cabozantinib is not indicated for the treatment of advanced HCC.

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EXELIXIS®

GLOBAL PHASE 3, MULTICENTER, RANDOMIZED, DOUBLE-BLINDED, INTERNATIONAL TRIAL

- Designed to compare cabozantinib with placebo in 760 patients ages 18 years and older with advanced HCC whose disease had spread or grown after treatment with sorafenib (Nexavar®), the standard of care for first-line treatment of advanced HCC.
- Patients had received up to two prior systemic cancer therapies for HCC and had adequate liver function.
- Conducted at more than 100 sites in 19 countries

PATIENTS WERE RANDOMLY ASSIGNED TO:

- Oral cabozantinib 60 mg tablet once daily
- A placebo tablet once daily

STUDY ENDPOINTS:

Primary endpoint

- **Overall survival:** average length of time from randomization until death from any cause

Secondary endpoint

- **Objective response rate:** percentage of patients whose tumors respond to treatment (complete or partial confirmed response)
- **Progression-free survival:** time until either death or disease worsening, per investigator review

For additional information on the study, visit https://clinicaltrials.gov

References: **1.** National Cancer Institute. Liver and Bile Duct Cancer—Patient Version. (https://www.cancer.gov/types/liver). Accessed January 2018. **2.** American Cancer Society. Cancer Facts & Figures 2018. (https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2018/cancer-facts-and-figures-2018.pdf). Accessed January 2018. **3.** Hepatocellular Carcinoma – United States, 2001-2006. (7 May 2010). Morbidity and Mortality Weekly Report. Centers for Disease Control and Prevention. (http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5917a3.htm). Accessed January 2018.