Pfizer Logo

Pfizer Announces Top-line Results From Phase 3 Trial Of INLYTA® (axitinib) In Treatment-Naïve Patients With Advanced Renal Cell Carcinoma

Tuesday, October 16, 2012 - 08:30pm

(BUSINESS WIRE)--Pfizer Inc. announced today that a Phase 3 study of INLYTA® (axitinib) did not meet its primary endpoint of demonstrating statistically significantly longer progression-free survival (PFS), versus sorafenib, in treatment-naïve patients with advanced renal cell carcinoma (RCC).

A preliminary review of the data showed that overall the median PFS for INLYTA exceeded the median PFS for sorafenib, but did not meet statistical significance. In a pre-specified subgroup of patients classified as good Performance Status (ECOG PS 0), the median PFS for INLYTA exceeded the median PFS for sorafenib. In another pre-specified subgroup of patients classified as intermediate Performance Status (ECOG PS 1), there was no difference between INLYTA and sorafenib.

Adverse events for INLYTA were generally consistent with previous findings in INLYTA patients with advanced RCC who had been treated with a prior systemic therapy.

These data will be further analyzed and presented at an upcoming medical congress.

“We narrowly missed the primary endpoint in this trial,” said Dr. Mace Rothenberg, senior vice president of clinical development and medical affairs for Pfizer's Oncology Business Unit. “We are analyzing the study findings to determine whether further evaluation of INLYTA in specific subpopulations of treatment-naïve patients with advanced RCC would be warranted.”

AGILE 1051, a trial of more than 280 treatment-naïve patients with advanced RCC, was powered to show a 78 percent improvement in PFS benefit with INLYTA over sorafenib. The primary endpoint of the study was PFS. The secondary endpoints of the study included overall survival, response rate and safety. Pre-specified subgroups were also analyzed and included patients with either good Performance Status (ECOG PS 0) or intermediate Performance Status (ECOG PS 1). ECOG performance status is a standard measure used to assess functional status of patients and these were stratification factors at randomization.

Earlier this year, INLYTA was approved for patients with previously treated advanced RCC in the U.S., EU, Japan, Switzerland, Canada, Korea, and Australia. In its registrational Phase 3 AXIS trial, INLYTA significantly extended PFS with a median PFS of 6.7 months as compared to 4.7 months for those treated with sorafenib. The differences in PFS observed in the subgroups in the AXIS trial favored INLYTA over sorafenib, including in the ECOG PS 0 and ECOG PS 1 subgroups.

“We set a high bar in our INLYTA trials to understand how it compares to another VEGF-targeted therapy,” said Dr. Rothenberg. “Since approval, INLYTA has established its utility in the second-line setting where it is an important treatment option for many patients with advanced kidney cancer.”

Pfizer is also investigating axitinib in the AGILE 1046 study, a randomized Phase 2 clinical trial in treatment-naïve patients with advanced RCC. Blinded efficacy data from this ongoing study were presented at ASCO earlier this year. Axitinib is also being studied in a randomized Phase 2 clinical trial for the treatment of hepatocellular carcinoma (HCC), which is currently closed to enrollment. Additionally, under a collaborative development agreement between Pfizer and SFJ Pharma Ltd. II, SFJ is conducting a Phase 3 clinical trial in Asia studying axitinib for adjuvant treatment of patients at high risk of recurrent RCC following nephrectomy (kidney removal).

Healthcare professionals who are interested in learning more about Pfizer Oncology clinical trials that are open for enrollment can visit www.PfizerOncology.com/clinicaltrials. Patients with questions should contact their treating physician.

About INLYTA® (axitinib)

INLYTA is indicated for the treatment of advanced RCC after failure of one prior systemic therapy. INLYTA, a kinase inhibitor, is an oral therapy that is designed to inhibit tyrosine kinases, including vascular endothelial growth factor (VEGF) receptors 1, 2 and 3; these receptors can influence tumor growth, vascular angiogenesis and progression of cancer (the spread of tumors).

Important INLYTA® (axitinib) Safety Information

Hypertension including hypertensive crisis has been observed. Blood pressure should be well controlled prior to initiating INLYTA. Monitor for hypertension and treat as needed. For persistent hypertension, despite use of antihypertensive medications, reduce the dose. Discontinue INLYTA if hypertension is severe and persistent despite use of antihypertensive therapy and dose reduction of INLYTA, and discontinuation should be considered if there is evidence of hypertensive crisis.

Arterial and venous thrombotic events have been observed and can be fatal. Use with caution in patients who are at increased risk or who have a history of these events.

Hemorrhagic events, including fatal events, have been reported. INLYTA has not been studied in patients with evidence of untreated brain metastasis or recent active gastrointestinal bleeding and should not be used in those patients. If any bleeding requires medical intervention, temporarily interrupt the INLYTA dose.

Gastrointestinal perforation and fistula, including death, have occurred. Use with caution in patients at risk for gastrointestinal perforation or fistula. Monitor for symptoms of gastrointestinal perforation or fistula periodically throughout treatment.

Hypothyroidism requiring thyroid hormone replacement has been reported. Monitor thyroid function before initiation of, and periodically throughout, treatment.

Stop INLYTA at least 24 hours prior to scheduled surgery.

Reversible Posterior Leukoencephalopathy Syndrome (RPLS) has been observed. If signs or symptoms occur, permanently discontinue treatment.

Monitor for proteinuria before initiation of, and periodically throughout, treatment. For moderate-to-severe proteinuria, reduce the dose or temporarily interrupt treatment.

Liver enzyme elevation has been observed during treatment with INLYTA. Monitor alanine aminotransferase (ALT), aspartate aminotransferase (AST), and bilirubin before initiation of, and periodically throughout, treatment.

For patients with moderate hepatic impairment, the starting dose should be decreased. INLYTA has not been studied in patients with severe hepatic impairment.

Women of childbearing potential should be advised of potential hazard to the fetus and to avoid becoming pregnant while receiving INLYTA.

Avoid strong CYP3A4/5 inhibitors. If unavoidable, reduce the dose. Grapefruit or grapefruit juice may also increase INLYTA plasma concentrations and should be avoided.

Avoid strong CYP3A4/5 inducers and, if possible, avoid moderate CYP3A4/5 inducers.

The most common (?20%) adverse events (AEs) occurring in patients receiving INLYTA (all grades, vs sorafenib) were diarrhea, hypertension, fatigue, decreased appetite, nausea, dysphonia, hand-foot syndrome, weight decreased, vomiting, asthenia, and constipation.

The most common (?10%) grade 3/4 AEs occurring in patients receiving INLYTA (vs sorafenib) were hypertension, diarrhea, and fatigue.

The most common (?20%) lab abnormalities occurring in patients receiving INLYTA (all grades, vs sorafenib) included increased creatinine, decreased bicarbonate, hypocalcemia, decreased hemoglobin, decreased lymphocytes (absolute), increased ALP, hyperglycemia, increased lipase, increased amylase, increased ALT and increased AST.

About Pfizer Oncology

Pfizer Oncology is committed to the discovery, investigation and development of innovative treatment options to improve the outlook for cancer patients worldwide. Our strong pipeline, one of the most robust in the industry, is studied with precise focus on identifying and translating the best scientific breakthroughs into clinical application for patients across a wide range of cancers, including breast, lung, prostate, sarcoma, melanoma, and various hematologic cancers. Pfizer Oncology has biologics and small molecules in clinical development and more than 100 clinical trials underway. By working collaboratively with academic institutions, individual researchers, cooperative research groups, governments, and licensing partners, Pfizer Oncology strives to cure or control cancer with breakthrough medicines, to deliver the right drug for each patient at the right time. For more information please visit www.Pfizer.com.

DISCLOSURE NOTICE: The information contained in this release is as of October 17, 2012. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about a potential indication for axitinib, including its potential benefits, that involves substantial risks and uncertainties. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development; decisions by regulatory authorities regarding whether and when to approve any drug applications that may be filed for any such oncology product

or any such additional indications as well as their decisions regarding labeling and other matters that could affect the availability or commercial potential of such indications; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2011 and in its reports on Form 10-Q and Form 8-K.

Pfizer Inc. Media: Victoria Davis, 484-865-5194 or Investors: Jennifer Davis, 212-733-0717