Pfizer Presents Promising New Immunotherapy Combination Data With INLYTA® (axitinib) In Advanced Renal Cell Carcinoma (RCC)

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Data From a Trial of INLYTA With Pembrolizumab Provides Additional Support for Novel Immunotherapy Combinations in RCC Preliminary Results from an Ongoing Trial of INLYTA with Avelumab in RCC Were Also Presented

Pfizer Inc. (NYSE:PFE) today announced data from an ongoing, investigational Phase 1b study of INLYTA® (axitinib) combined with the checkpoint inhibitor pembrolizumab (A4061079, NCT02133742), a PD-1 inhibitor known as KEYTRUDA® and marketed by Merck, known as MSD outside the United States and Canada, in treatment-naïve patients with advanced renal cell carcinoma (RCC). The study was designed to establish dosing and evaluate the safety and anti-tumor activity of INLYTA when combined with pembrolizumab in first-line treatment of advanced RCC.

Preliminary results from a similar, separate study combining INLYTA with avelumab (JAVELIN Renal 100, NCT02493751), an investigational, fully human anti-PD-L1 IgG1 monoclonal antibody that is being co-developed by Merck KGaA, Darmstadt, Germany, and Pfizer were also presented. The data suggest evidence of anti-tumor activity for INLYTA in combination with avelumab and were presented during a poster discussion session at the ESMO 2016 Congress, the annual meeting of the European Society for Medical Oncology being held in Copenhagen, Denmark.

Based on these Phase 1 results, two independent global Phase 3 trials evaluating these combinations - INLYTA plus pembrolizumab and INLYTA plus avelumab – each compared with SUTENT® (sunitinib) in first-line advanced RCC are now enrolling patients.

“Combining immunotherapy agents with currently approved therapies such as INLYTA may provide a meaningful improvement in outcome for patients with renal cancer,” said Chris Boshoff, M.D., Ph.D., head of immuno-oncology, early development and translational oncology, Pfizer Global Product Development. “The results presented today indicate that there is a potential additive or synergistic effect between INLYTA and a checkpoint inhibitor in RCC.”

Early indicators from the A4061079 study point to strong response rates with the INLYTA/pembrolizumab combination, with 37 patients (71.2%, confidence internal 56.9, 82.9) achieving objective responses (three complete responses and 34 partial responses); 10 patients had stable disease and 5 patients had disease progression.

Separately, in the JAVELIN Renal 100 study of INLYTA in combination with avelumab, five out of six patients treated so far had confirmed partial responses (objective response rate 83.3%, 95% confidence interval: 35.9, 99.6) and one patient with tumor shrinkage not meeting partial response criteria had stable disease.

INLYTA is an oral vascular endothelial growth factor (VEGF) receptor inhibitor for the treatment of patients with advanced RCC after failure of one prior systemic therapy approved in 63 countries. It was the first treatment to demonstrate superior progression-free survival benefit in a Phase 3 study versus sorafenib, a tyrosine kinase inhibitor, in second-line treatment of advanced RCC.

About Avelumab

Avelumab (also known as MSB0010718C) is an investigational fully human anti-PD-L1 IgG1 monoclonal antibody. By inhibiting PD-L1 interactions, avelumab is thought to enable the activation of T-cells and the adaptive immune system. By retaining a native Fc-region, avelumab is thought to potentially engage the innate immune system and induce antibody-dependent cell-mediated cytotoxicity (ADCC). In November 2014, Merck KGaA, Darmstadt, Germany, and Pfizer announced a strategic alliance to co-develop and co-commercialize avelumab.

About INLYTA® (axitinib)

INLYTA 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). In the U.S., INLYTA is approved for the treatment of advanced renal cell carcinoma (RCC) after failure of one prior systemic therapy. INLYTA is also approved by the European

Medicines Agency (EMA) for use in the EU in adult patients with advanced RCC after failure of prior treatment with sunitinib or a cytokine.

INLYTA Important 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.

Cardiac failure has been observed and can be fatal. Monitor for signs or symptoms of cardiac failure throughout treatment with INLYTA. Management of cardiac failure may require permanent discontinuation of INLYTA.

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.

No formal studies of the effect of INLYTA on wound healing have been conducted. 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 ALT, 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 (55% vs 53%), hypertension (40% vs 29%), fatigue (39% vs 32%), decreased appetite (34% vs 29%), nausea (32% vs 22%), dysphonia (31% vs 14%), hand-foot syndrome (27% vs 51%), weight decreased (25% vs 21%), vomiting (24% vs 17%), asthenia (21% vs 14%), and constipation (20% vs 20%).

The most common (≥10%) grade 3/4 AEs occurring in patients receiving INLYTA (vs sorafenib) were hypertension (16% vs 11%), diarrhea (11% vs 7%), and fatigue (11% vs 5%).

The most common (≥20%) lab abnormalities occurring in patients receiving INLYTA (all grades, vs sorafenib) included increased creatinine (55% vs 41%), decreased bicarbonate (44% vs 43%), hypocalcemia (39% vs 59%), decreased hemoglobin (35% vs 52%), decreased lymphocytes (absolute) (33% vs 36%), increased ALP (30% vs 34%), hyperglycemia (28% vs 23%), increased lipase (27% vs 46%), increased amylase (25% vs 33%), increased ALT (22% vs 22%), and increased AST (20% vs 25%).

For more information and full Prescribing Information, visit www.pfizer.com.

About Pfizer Oncology

Pfizer Oncology is committed to pursuing innovative treatments that have a meaningful impact on those living with cancer. As a leader in oncology speeding cures and accessible breakthrough medicines to patients, Pfizer Oncology is helping to redefine life with cancer. Our strong pipeline of biologics, small molecules and immunotherapies, 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. By working collaboratively with academic institutions, individual researchers, cooperative research groups, governments and licensing partners, Pfizer Oncology strives to cure or control cancer with its breakthrough medicines. Pfizer Oncology knows that success in oncology is not measured solely by the medicines you manufacture, but rather by the meaningful partnerships you make to have a more positive impact on people’s lives. Learn more about how Pfizer Oncology is applying innovative approaches to improve the outlook for people living with cancer athttp://www.pfizer.com/research/therapeutic_areas/oncology.

Pfizer Inc.: Working together for a healthier worldTM

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of healthcare products. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer healthcare products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, Pfizer has worked to make a difference for all who rely on us. For more information, please visit us at www.pfizer.com. In addition, to learn more, follow us on Twitter at @Pfizer and@Pfizer_News, LinkedIn, YouTube, and like us on Facebook at Facebook.com/Pfizer.

DISCLOSURE NOTICE: The information contained in this release is as of October 9, 2016. 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 INLYTA (axitinib), including a potential indication for INLYTA in combination with pembrolizumab (A4061079, NCT02133742) for the treatment of advanced renal cell carcinoma (RCC) and a potential indication for INLYTA in combination with avelumab (MSB0010718C) for the treatment of advanced RCC, including their potential benefits, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical study commencement and completion dates as well as the possibility

of unfavorable study results, including unfavorable new clinical data and additional analyses of existing clinical data; risks associated with preliminary data; the risk that clinical trial data are subject to differing interpretations, and, even when we view data as sufficient to support the safety and/or effectiveness of a product candidate, regulatory authorities may not share our views and may require additional data or may deny approval altogether; whether and when drug applications may be filed in any jurisdictions for any potential indications for the combination therapies; whether and when any such applications may be approved by regulatory authorities, which will depend on the assessment by such regulatory authorities of the benefit-risk profile suggested by the totality of the efficacy and safety information submitted; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of the combination therapies; 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, 2015, and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results," as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

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