Pfizer Receives EU Marketing Authorization for INLYTA® (Axitinib)

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Approved for the treatment of adult patients with advanced renal cell carcinoma after failure of prior treatment with SUTENT® (sunitinib) or a cytokine

"INLYTA is a valuable addition to Pfizer’s portfolio for the treatment of advanced RCC, which includes SUTENT6a and TORISEL® (temsirolimus)7a."

(BUSINESS WIRE)--Pfizer Inc. announced today that the European Commission (EC) has granted marketing authorization for INLYTA® (axitinib) for the treatment of adult patients with advanced renal cell carcinoma (RCC), a type of kidney cancer, after failure of prior treatment with sunitinib or a cytokine.

INLYTA, a kinase inhibitor, is an oral therapy that was designed to selectively inhibit vascular endothelial growth factor (VEGF) receptors 1, 2 and 3,1a which are proteins that can influence tumor growth, vascular angiogenesis and progression of cancer (tumor spread).2a

"INLYTA offers physicians and their patients with advanced kidney cancer a new treatment option following prior treatment with sunitinib or a cytokine. INLYTA data demonstrate statistically significant improvement in progression free survival compared with sorafenib, and support the continued role for VEGFR-targeted therapy, following the first-line standard of care, SUTENT," said Dr. Bernard Escudier, Head of the Immunotherapy Unit, Department of Medical Oncology, Institut Gustave Roussy, France, who served as an investigator on this Pfizer-sponsored study and is a paid consultant to Pfizer Oncology.

The approval is based on data from the Phase 3 AXIS trial, which demonstrated that INLYTA significantly extended progression free survival (PFS) [HR=0.67, 0.56-0.81,

P<0.0001] with a median PFS of 6.8 months (95% CI: 6.4, 8.3) compared with 4.7 months (95% CI: 4.6, 6.3) for those treated with sorafenib, a current second-line standard of care for this patient population, representing a 45 percent improvement in median PFS compared to sorafenib.1b

Renal cell carcinoma is the sixth leading cause of cancer-related death.3a At diagnosis, approximately a third of kidney cancer patients will have advanced disease,4a where the cancer has spread to multiple parts of the body and prognosis is poor. The incidence of RCC in Europe is 102,000 people per year.5a Between 40 and 65 percent of patients worldwide who progress following first-line therapy go on to receive a second-line treatment.9,10

"We are delighted with the decision of the European Commission to approve INLYTA for adult advanced RCC patients whose disease has progressed following failure of SUTENT or a cytokine. Pfizer Oncology recognizes advanced RCC is a complex disease and we are committed to bringing new targeted medicines to physicians and their patients," said Dr. Andreas Penk, Regional President of Europe for the Pfizer Oncology Business Unit. "INLYTA is a valuable addition to Pfizer’s portfolio for the treatment of advanced RCC, which includes SUTENT6a and TORISEL® (temsirolimus)7a."

Notes to Editors

About INLYTA® (axitinib)

In January 2012, INLYTA® was approved by the U.S. Food and Drug Administration (FDA) for the treatment of advanced renal cell carcinoma after failure of one prior systemic therapy. INLYTA has also been approved in a number of other countries, including Switzerland, Japan, Canada, Australia, and Korea.

INLYTA, a kinase inhibitor, is an oral therapy that was designed to selectively inhibit vascular endothelial growth factor (VEGF) receptors 1, 2 and 3, which are proteins that can influence tumor growth, vascular angiogenesis and progression of cancer (tumor spread).1c

Important INLYTA® (axitinib) Safety Information1d

Serious adverse reactions reported in patients receiving INLYTA were arterial embolic and thrombotic events, venous embolic and thrombotic events, haemorrhage (including gastrointestinal haemorrhage, cerebral haemorrhage and haemoptysis), gastrointestinal perforation and fistula formation, hypertensive crisis, and posterior reversible

encephalopathy syndrome.

The most common (≥ 20%) adverse reactions observed following treatment with INLYTA were diarrhoea, hypertension, fatigue, dysphonia, nausea, decreased appetite, and palmar-plantar erythrodysaesthesia (hand-foot) syndrome.

For more information on INLYTA (axitinib), including full prescribing information, please visit www.pfizer.com

About SUTENT® (sunitinib malate)

SUTENT® is approved for gastrointestinal stromal tumors (GIST) after disease progression on or intolerance to imatinib mesylate, for advanced RCC, and for progressive, well-differentiated pancreatic neuroendocrine tumors (NET) in patients with unresectable locally advanced or metastatic disease.8a

SUTENT is an oral multi-kinase inhibitor that works by blocking multiple molecular targets implicated in the growth, proliferation and spread of cancer.8b Two important SUTENT targets, vascular endothelial growth factor receptor (VEGFR) and platelet-derived growth factor receptor (PDGFR) are expressed by many types of solid tumors and are thought to play a crucial role in angiogenesis, the process by which tumors acquire blood vessels, oxygen and nutrients needed for growth. SUTENT also inhibits other targets important to tumor growth, including KIT, FLT3 and RET.8c

Important SUTENT® (sunitinib malate) Safety Information8d

Serious adverse reactions associated with sunitinib are renal failure, heart failure, pulmonary embolism, intestinal perforation, and haemorrhages (e.g. respiratory, gastrointestinal, tumour haemorrhages).

The most common (≥20%) adverse events (AEs) in patients receiving SUTENT were decreased appetite, taste disturbance, hypertension, fatigue, gastrointestinal disorders, skin discoloration, and hand-foot syndrome. Fatal events, other than those listed, included multi-system organ failure, disseminated intravascular coagulation, peritoneal hemorrhage, rhabdomyolysis, cerebrovascular accident, dehydration, adrenal insufficiency, renal failure, respiratory failure, pleural effusion, pneumothorax, shock, and sudden death.

For more information on SUTENT (sunitinib malate), including full prescribing information, please visit www.pfizer.com

About TORISEL® (temsirolimus)

TORISEL® is the only intravenous mammalian target of rapamycin (mTOR) inhibitor approved for the treatment of advanced renal cell carcinoma (RCC).7b

TORISEL inhibits the activity of mTOR, an intracellular protein implicated in multiple growth-related cellular functions including proliferation, growth and survival. The inhibition of mTOR also reduces levels of certain growth factors, such as vascular endothelial growth factor(VEGF), which are overexpressed in solid tumors like kidney cancer and are thought to play a crucial role in angiogenesis, the process by which tumors acquire blood vessels, nutrients and oxygen needed for growth.7c

Important TORISEL® (temsirolimus) Safety Information7d

Renal Cell Carcinoma

Serious reactions observed with TORISEL are hypersensitivity/infusion reactions (including some life threatening and rare fatal reactions), hyperglycaemia/glucose intolerance, infections, interstitial lung disease (pneumonitis), hyperlipaemia, intracerebral bleeding, renal failure, bowel perforation, and wound healing complication.

The most common (≥30%) adverse reactions (all grades) observed with TORISEL include anaemia, nausea, rash (including rash, pruritic rash, maculopapular rash, pustular rash), anorexia, oedema (including facial oedema and peripheral oedema), and asthenia.

Cataracts have been observed in some patients who received the combination of temsirolimus and interferon α.

Mantle Cell Lymphoma

The occurrence of undesirable effects following the dose of 175 mg TORISEL/week for MCL, e.g. grade 3 or 4 infections or thrombocytopaenia, is associated with a higher incidence than that observed with either 75 mg TORISEL/week or conventional chemotherapy.

The most serious reactions observed with TORISEL are thrombocytopaenia, neutropaenia, infections, interstitial lung disease (pneumonitis), bowel perforation, hypersensitivity reactions, and hyperglycaemia/glucose intolerance.

The most common (≥30%) adverse reactions (all grades) observed with TORISEL include thrombocytopaenia, asthenia, anaemia, diarrhoea, bacterial and viral infections

(including infection, cellulitis, bronchitis, sinusitis, herpes zoster, herpes simplex), rash (including rash, pruritic rash, maculopapular rash, pustular rash, eczema), pyrexia, anorexia, epistaxis, mucositis, oedema (including oedema, facial oedema, peripheral oedema, scrotal oedema, genital oedema, generalised oedema), and stomatitis (including aphthous stomatitis, mouth ulceration, stomatitis, glossitis, oral pain).

Serious adverse reactions observed in clinical trials of TORISEL for advanced renal cell carcinoma, but not in clinical trials of temsirolimus for mantle cell lymphoma include: anaphylaxis, impaired wound healing, renal failure with fatal outcomes, and pulmonary embolus.

Based on the results of a phase 3 study in renal cell carcinoma, elderly patients (≥ 65 years of age) may be more likely to experience certain adverse reactions, including oedema, diarrhoea, and pneumonia. Based on the results of a phase 3 study in mantle cell lymphoma, elderly patients (≥ 65 years of age) may be more likely to experience certain adverse reactions, including pleural effusion, anxiety, depression, insomnia, dyspnoea, leukopaenia, lymphopaenia, myalgia, arthralgia, taste loss, dizziness, upper respiratory infection, mucositis, and rhinitis

For more information on TORISEL (temsirolimus), including full prescribing information, please visit www.pfizer.com

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 of biologics and small molecules, 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 breakthrough medicines, to deliver the right drug for each patient at the right time.

As a leader in the treatment of advanced RCC, Pfizer Oncology is dedicated to offering multiple treatments and investigating new agents in different populations and stages of disease. Pfizer Oncology has helped transform treatment expectations for advanced kidney cancer, providing confidence and options to physicians, allowing them to better tailor treatment for different patient populations.

For more information please visit www.pfizer.com

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10Pfizer Data on File

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