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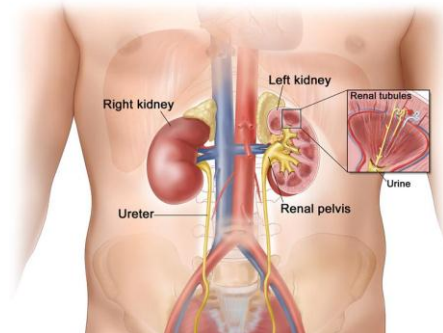
Pfizer launches INLYTA® as second line treatment for kidney cancer

First treatment to demonstrate superior benefit in a Phase 3 study compared with another targeted agent in advanced RCCⁱ

Kuala Lumpur, March 27, 2014: Pfizer Inc. today announced the launch of INLYTA® (axitinib) as second-line of treatment for adult patients with advanced renal cell carcinoma (RCC) after failure of one prior systemic therapy with sunitinib or a cytokine. Second-line of treatment is recommended when initial treatment (first-line therapy) does not work, or stops working.ⁱⁱ

Renal cell carcinoma is a type of kidney cancer that forms in the lining of very small tubes in the kidney that filter and clean the blood, taking out waste products and making urine.ⁱⁱⁱ RCC is the most common form of cancer starting in the kidney. When the cancer spreads to other parts of the body it is called metastatic renal cell carcinoma. It occurs mostly in adults between ages 50 to 70. Renal cancer incidence is 1.9 per 100,000 in the Malaysian population^{iv}.

Some of the symptoms that characterise renal cell carcinoma include, blood in the urine, abdominal mass, back or flank pain, weight loss, low blood count (anaemia) and tumour calcification on x-ray.^v At diagnosis, approximately a third of kidney cancer patients will have advanced disease,^{vi} where the cancer has spread to multiple parts of the body and prognosis is poor.



Genetic factors have been linked to an increased risk of developing kidney cancer such as Von Hippel-Lindau disease (a hereditary disease that affects blood vessels in the brain, eyes, and other body parts), family history of kidney cancer; other external factors includes smoking and obesity.^{vii}

Source: Cancer.org

<http://www.cancer.gov/cancertopics/pdq/treatment/renalcell/Patient/page1>

The Phase 3 AXIS (Comparative effectiveness of axitinib versus sorafenib in advanced renal cell carcinoma) trial demonstrates INLYTA as the first agent to exhibit superior efficacy in a head-to-head trial^{viii}. This means, INLYTA significantly extended progression free survival (PFS), with a median PFS of 6.7 months compared with 4.7 months for those treated with sorafenib, a current standard of care for this patient population, representing a 43 percent improvement in median progress free survival in patients compared to sorafenib. In a clinical trial, measuring the progression-free survival is one way to see how well a new treatment works in the patient.^{ix}

“Despite the advances made in recent years in the treatment of advanced RCC, there is a need for additional therapies for this patient population, particularly for patients whose disease has progressed with first-line medications. Axitinib is a drug with true data for second-line treatment of kidney cancer to date.” said past president of Malaysian Oncological Society, Datuk Dr Mohamed Ibrahim Wahid.



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 receptors that can influence tumour growth, vascular angiogenesis and progression of cancer (the spread of tumours).^{x,xi} It reduces the blood supply to the tumour and slowing down the growth or stop the spread of cancer cells.

Azwar Kamarudin, Director, Corporate Affairs, Health and Value – Pfizer (Malaysia) Sdn Bhd said “In the area of oncology, Pfizer has been at the forefront of the evolution of care for advanced kidney cancer and is dedicated to offering multiple treatments and investigating new agents in different populations and stages of disease. INLYTA is an important addition to Pfizer’s robust product portfolio of therapies for the treatment of advanced RCC, along with sunitinib malate (2007) and temsirolimus (2009), which collectively will continue to have a significant impact on the way the disease is treated.”

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 sunitinib or cytokine. INLYTA has also been approved in European Union and countries like Japan, Canada, Singapore, Hong Kong, Indonesia, Taiwan and Korea.

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INLYTA® (axitinib) Indication

INLYTA is indicated for the treatment of advanced renal cell carcinoma (RCC) after failure of one prior treatment with sunitinib or cytokine.

Important INLYTA® (axitinib) Safety Information

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 ($\geq 20\%$) adverse reactions observed following treatment with INLYTA were diarrhoea, hypertension, fatigue, dysphonia, nausea, decreased appetite, and palmar-plantar erythrodysesthesia (hand-foot) syndrome. For more information on INLYTA (axitinib), including full prescribing information, please visit www.pfizer.com.

About Pfizer Inc.: Working together for a healthier world®

At Pfizer, we apply science and our global resources to improve health and well-being at every stage of life. We strive to set the standard for quality, safety and value in the discovery, development and manufacturing of medicines for people and animals. Our diversified global health care portfolio includes human and animal biologic and small molecule medicines and vaccines, as well as many of



the world's best-known consumer 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 the world's leading biopharmaceutical company, we also 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.

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REFERENCES

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- ⁱ Data are from a multicenter, open-label, phase 3 trial of 723 patients with advanced RCC after failure of 1st-line therapy (sunitinib-, temsirolimus-, bevacizumab-, or cytokine-containing regimen). Patients were randomized to either INLYTA (5 mg twice daily) or sorafenib (400 mg twice daily) with dose adjustments allowed in both groups.
- ⁱⁱ National Cancer Institute <http://www.cancer.gov/dictionary?cdrid=346513>
- ⁱⁱⁱ National Cancer Institute <http://www.cancer.gov/cancertopics/types/kidney>
- ^{iv} Clinical Characteristics of Renal Cancer in Malaysia : A Ten Year Review
- ^v Kidney Cancer - <http://www.kidneycancer.org/knowledge/learn/about-kidney-cancer/>
- ^{vi} 4Najjar YG, Rini BL. Novel agents in renal carcinoma: a reality check. Ther Adv Med Oncol. 2012;4(4):183-94 - <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3384093/>
- ^{vii} Kidney Cancer Causes - <http://www.kidneycancer.org/knowledge/learn/about-kidney-cancer/>
- ^{viii} Rini BI, Escudier B, Tomczak P, et al. Comparative effectiveness of axitinib versus sorafenib in advanced renal cell carcinoma (AXIS): a randomised phase 3 trial. Lancet. 2011;378(9807):1931-1939
- ^{ix} National Cancer Institute <http://www.cancer.gov/dictionary?cdrid=44782>
- ^x INLYTA [Package Insert]. New York, NY: Pfizer, Inc. 2012.
- ^{xi} Hicklin DJ, Ellis LM. Role of VEGF in Tumour Growth and Angiogenesis. JCO. 2007;23:1011-1027.