Inlyta®
axitinib

The Second-line TKI

Proven efficacy and superiority in 2nd line mRCC vs. Sorafenib[1]

- Demonstrated **significant PFS** superiority[2]

6.7 MONTHS FOR **INLYTA** *n*=361

4.7 MONTHS WITH **SORAFENIB** *n*=362

43% improvement in median PFS[2]

95% CI: 6.3 - 8.6 and 4.6 - 5.6, respectively; HR=0.665 (95% CI: 0.544 - 0.812; *P*<.0001); primary endpoint

- More than doubled ORR -19% INLYTA *vs* 9% with sorafenib[2]

95% CI: 15.4 – 23.9 and 6.6 – 12.9, respectively; *P*=.0001; secondary endpoint

- Overall survival (OS) was 20.1 months with INLYTA *vs* 19.2 months with sorafenib[3]

95% CI: 16.7-23.4 and 17.5-22.3, respectively; *P*=.0.3744; secondary endpoint

- Recommended by NCCN (category 1), ESMO (level 1) and EAU (Grade A) guidelines[1,4,5]

Safety Statement: Treatment related hypertension, nausea, dysphonia, and hypothyroidism were more common with axitinib whereas hand–foot syndrome, alopecia, and rash were more common with sorafenib.

mRCC: metastatic renal cell cancer. **TKI:** Tyrosine kinase inhibitors. **PFS:** Progression free survival. **ORR:** Objective response rate. **OS:** Overall survival. **NCCN:** National Comprehensive Cancer Network. **ESMO:** European society for medical oncology. **AE:** Adverse events.

Reference: 1. Ljungberg B, Bensalah K, Bex A, *et al.* Guidelines on renal cell carcinoma. European association of Eurology 2014 Available at http://www.uroweb.org. Accessed on 2nd Feb 2015. **2.** 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):1931-9. **3.** Motzer RJ, Escudier B, Tomczek P, *et al.* Axitinib versus sorafenib as second-line treatment for advanced renal cell carcinoma: overall survival analysis and updated results from a randomised phase 3 trial. *Lancet Oncol.* 2013;14: 552–62. **4.** Escudier B, Eisen T, Porta C, *et al.* Renal cell carcinoma: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. *Ann Oncol.* 2012;23(7):vii65-vii71. **5.** Kidney cancer. NCCN (National Comprehensive Cancer Network) Clinical Practice Guidelines in Oncology Version 3.2015. Available at http://www.nccn.org. Accessed on January 24th 2015.

SUMMARY OF PRESCRIBING INFORMATION FOR AXITINIB (Version 1.0, SPI_ LPDAXT042012) Composition: Film-coated tablet containing 1 mg or 5 mg axitinib **Indication:** Treatment of patients with advanced renal cell carcinoma (RCC) after failure of one prior systemic therapy. **Contraindications:** None. **Adverse Reactions:** The most common (≥20%) adverse reactions with axitinib are diarrhea, hypertension, fatigue, decreased appetite, nausea, dysphonia, palmar-plantar erythrodysaesthsia (hand- foot) syndrome, weight decreased, vomiting, asthenia, and constipation. Other adverse reactions include anaemia, hypothyroidism, dehydration, hyperkalemia, hypercalcemia, headache, dysgeusia, dizziness, tinnitus, dyspnoea, cough, pulmonary embolism, haemoptysis, epistaxis, abdominal ain, stomatitis, constipation, dyspepsia, haemorrhoids, rectal haemorrhage, rash, dry skin, erythema, pruritus, alopecia, arthralgia, pain in extremity, myalgia, proteinuria, haematuria, fatigue, asthenia, mucosal inflammation, increase liver enzymes. **Warnings and Precautions:** Hypertension was reported in 40% of patients receiving axitinib in clinical study. Blood pressure should be well-controlled prior to initiating axitinib and monitored thereafter. Anti-hypertensive medications and decrease in the dose of Axitinib dose should be used for managing hypertension. Periodic monitoring of thyroid function and treatment according to standard medical practice should be given to maintain euthyroid state. Axitinib should be used with caution in patients who are at risk for, or who have a history of, arterial or venous thromboembolic events. If hemoglobin or hematocrit becomes elevated above the normal level, patients should be treated according to standard medical practice to decrease hemoglobin or hematocrit to an acceptable level. Hemorrhagic events were reported in 16% patients receiving axitinib. Axitinib should not be used in patients who have evidence of untreated brain metastasis or recent active gastrointestinal bleeding. If any bleeding requires medical intervention, temporarily interrupt the axitinib dose. Gastrointestinal perforation occurred in <1% patients, periodic monitoring is required. Treatment with axitinib should be stopped at least 24 hours prior to scheduled surgery. In patients with signs/symptoms of RPLS, temporarily interrupt or permanently discontinue axitinib. In patients with moderate to severe proteinuria, reduce the dose or temporarily interrupt axitinib treatment. No dose adjustment is required for elderly, renal impairment or mild hepatic impairment patients (Child-Pugh class A). A dose decrease is recommended when administering Axitinib to patients with moderate hepatic impairment (Child-Pugh class B). Axitinib has not been studied in patients with severe hepatic impairment (Child-Pugh class C). The safety and efficacy of axitinib in children (<18 years) have not been established. Use of Axitinib in pregnant and lactating patients should be avoided. **Dosage:** Starting dose of axitinib is 5 mg twice daily orally with or without food. Patients with no adverse reactions >Grade 2 for two consecutive weeks, are normotensive, and are not receiving anti-hypertension medication, may have their dose increased from 5 mg twice daily to 7 mg twice daily and subsequently, using the same criteria, to a maximum of 10 mg twice daily. To manage adverse drug reactions axitinib dose may be reduced to 3 mg twice daily and further to 2 mg twice daily. Axitinib dose should be adjusted when used concurrently with strong CYP3A4/5 inducers or inhibitors. See Full PI for details.

For the use of Registered Medical Practitioner or a Hospital or a Laboratory only.

For full prescribing information available on request

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