Optimising Metastatic Renal Cell Carcinoma (mRCC) Treatment: Lessons from the Real World

15:30–16:30
Friday 25 April 2014
Room: The Liffey A

9th European International Kidney Cancer Symposium,
Convention Centre, Dublin,
Ireland

Not intended for US Healthcare Professionals

This symposium is sponsored by GSK. GSK has been involved in selecting the faculty and in the creation of the agenda and the content. This meeting will have promotional content.

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We are delighted to invite you to the GSK-sponsored satellite symposium

Optimising mRCC Treatment: Lessons from the Real World

There are several options for the treatment of metastatic renal cell carcimona (mRCC), and in recent years results from a number of randomised clinical trials have been reported. Despite this wealth of data, we still need a better understanding of the patient experience in real-world settings. This interactive symposium with a panel of experts will explore ways to optimise the treatment of mRCC by drawing upon lessons from real-world data and the experts' own experiences. We are confident that you will find the session stimulating, informative and that it will help you optimise patient care in your own clinic.

I hope that you will be able to join us for what will be an exciting symposium.

Thomas Hutson
Professor of Medicine and Director of the Genitourinary Oncology Program at Texas Oncology-Baylor A. Sammons Cancer Center, USA

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Agenda

15:30–15:40	**Welcome**	Thomas Hutson
15:40–15:55	**Do we need more first-line treatment options for mRCC?**	Stéphane Oudard Patrick Schöffski
15:55–16:10	**From clinical trial to clinical practice: evidence from the real world**	Ignacio Durán Thomas Hutson
16:10–16:25	**What have we learned? Expert perspectives**	All faculty
16:25–16:30	**Closing remarks**	Thomas Hutson

Thomas Hutson
Texas Oncology-Baylor A. Sammons Cancer Center, USA

Stéphane Oudard
Georges Pompidou European Hospital, Paris, France

Patrick Schöffski
University Hospitals Leuven, KU Leuven, Belgium

Ignacio Durán
Hospital Universitario Virgen del Rocio, Seville, Spain

Prescribing Information (Please refer to full SmPC before prescribing)

Votrient®(pazopanib) 200mg and 400mg film-coated tablets. Each tablet contains pazopanib hydrochloride, equivalent to 200mg and 400mg of pazopanib, respectively. **Indication** Adults for first-line treatment of advanced renal cell carcinoma (RCC) and those with prior cytokine therapy. **Dosage and administration** Only to be initiated by physician experienced in use of anti-cancer agents. 800mg once daily. Take without food (≥1 hour before or ≥2 hours after a meal). Take tablets whole; do not break or crush. *Dose modification*: In 200mg steps based on individual tolerability to manage ADRs. Not to exceed 800mg. *Renal impairment*: No dose adjustment required in patients with CrCl >30ml/min. Caution advised in patients with CrCl <30ml/min. *Hepatic impairment*: Severe hepatic impairment - Not recommended. Undertake with caution and close monitoring in mild/moderate impairment. Mild impairment - 800mg once daily; Moderate impairment - 200mg once daily. *Elderly*: Limited data in patients ≥ 65 yrs. *Paediatrics*: Not to be used in children <2 yrs. No data available in children 2-18 yrs. **Contra-indications** Hypersensitivity to active substance or excipients. **Special Warnings and Precautions** *Hepatic effects*: Hepatic failure reported during pazopanib use; increases in serum transaminases (ALT, AST) and bilirubin also observed. Monitor liver function before initiation of pazopanib and at weeks 3, 5, 7 and 9; then months 3 and 4 and as clinically indicated; and periodically thereafter. If transaminases rise between 3 and ≤8xULN, continue pazopanib with weekly monitoring until return to ≤Grade 1. If transaminases >8xULN, interrupt pazopanib until return to ≤Grade 1. If re-introduced, reduce dose to 400mg with weekly monitoring for 8 weeks. If transaminases >3xULN occur following re-introduction, discontinue pazopanib. If transaminases >3xULN occur concurrently with bilirubin >2xULN, discontinue pazopanib. Concomitant use of pazopanib and simvastatin increases risk of ALT elevations: undertake with caution and close monitoring. *Hypertension*: Hypertension, including hypertensive crisis, has occurred in pazopanib studies. Control BP prior to initiating pazopanib. Monitor for hypertension early (≤1 week after starting treatment) and frequently thereafter. Manage elevated BP with anti-hypertensives and pazopanib dose modification. Discontinue pazopanib if there is evidence of hypertensive crisis or if hypertension is severe and persists despite anti-hypertensive therapy and dose reduction. *Posterior reversible encephalopathy syndrome (PRES) / Reversible posterior leukoencephalopathy syndrome (RPLS)*: reported in association with pazopanib. Permanently discontinue pazopanib if PRES/RPLS develops. *Cardiac dysfunction/heart failure*: Cardiac dysfunction (e.g. CHF and LVEF decline) has occurred in pazopanib trials. Consider risks/benefits of pazopanib in patients with pre-existing cardiac dysfunction; baseline and periodic LVEF evaluation recommended. Monitor patients for signs and symptoms of CHF. *QT prolongation and Torsades de Pointes*: Use with caution in patients (i) with history of QT interval prolongation, (ii) taking antiarrhythmics or other medications that may prolong QT interval or (iii) with relevant pre-existing cardiac disease. Baseline and periodic ECGs, and maintenance of electrolytes within normal range recommended. *Arterial thrombotic events*: Use with caution in patients at increased risk for these events based on individual patient's benefit/risk assessment. *Venous thromboembolic events (VTEs)*: including venous thrombosis and fatal PE have occurred in pazopanib trials. *Thrombotic microangiopathy (TMA)*: including thrombotic thrombocytopenic purpura and haemolytic uraemic syndrome reported in pazopanib clinical trials. Permanently discontinue pazopanib if TMA develops; reversal of TMA effects has been observed after discontinuation. *Haemorrhagic events*: Not studied in patients with history of haemoptysis, cerebral, or significant GI haemorrhage in past 6 months. Use with caution in patients with significant risk of haemorrhage. *GI perforations and fistula*: Use with caution in patients at risk for GI perforation or fistula. *Wound healing*: Stop treatment ≥7 days prior to surgery. Resume after surgery based on clinical judgement of adequate wound healing. Discontinue in patients with wound dehiscence. *Hypothyroidism*: Baseline measurement of thyroid function recommended prior to start of pazopanib; monitor periodically during treatment. Monitor for signs and symptoms of thyroid dysfunction and manage appropriately. *Proteinuria*: Baseline and periodic urinalysis recommended. Monitor for worsening proteinuria. Discontinue pazopanib if nephrotic syndrome develops. *Pneumothorax*: Observe closely for signs and symptoms of pneumothorax. *Infections*: Cases of serious infection (with/without neutropenia) reported. **Interactions** Avoid concomitant use with strong inhibitors of CYP3A4 (including grapefruit juice) and CYP3A4 inducers. Hyperglycaemia observed during concomitant administration with ketoconazole. Avoid co-administration with medicines that increase gastric pH (e.g. PPIs and H2 receptor antagonists) unless medically necessary. Undertake concomitant administration with uridine diphosphate glucuronosyl transferase 1A1 (UGT1A1) substrates and simvastatin (and other statins) with caution. **Undesirable effects** Most important serious ADRs identified in pazopanib clinical studies were: TIA, ischaemic stroke, myocardial ischaemia, myocardial and cerebral infarction, cardiac dysfunction, GI perforation and fistula, QT prolongation; pulmonary/GI/cerebral haemorrhage. All events occurred in <1% of patients. Fatal events possibly related to pazopanib included: GI haemorrhage, pulmonary haemorrhage/haemoptysis, abnormal hepatic function, intestinal perforation, ischaemic stroke. Treatment-related events reported with pazopanib in advanced RCC patients with following frequencies: *Very common*: Decreased appetite; Dysgeusia, headache; Hypertension; Diarrhoea, nausea, vomiting, abdominal pain; Hair colour changes, PPE, alopecia, rash; Fatigue; Increased ALT and AST. *Common*: Tumour pain; Thrombocytopenia, neutropenia, leucopenia; Hypothyroidism; Hypophosphataemia, dehydration; Insomnia; Dizziness, lethargy, paraesthesia, peripheral sensory neuropathy; Blurred vision; VTE; Hot flush/flushing; Epistaxis, dysphonia, dyspnoea; Dyspepsia, stomatitis, mouth ulceration, dry mouth, flatulence, abdominal distension; Abnormal hepatic function/hepatotoxicity, hyperbilirubinaemia; Skin hypo/de-pigmentation, erythema, pruritus, dry skin, hyperhidrosis; Arthralgia/myalgia, muscle spasms; Proteinuria; Asthenia, mucosal inflammation, oedema, chest pain; Decreased weight/WBC, Increased creatinine/bilirubin/lipase/BP/TSH/GGT/amylase/urea. *Uncommon events* include: Infections (with/without neutropenia), gingival infection, infectious peritonitis; Hypomagnesaemia; Hypoaesthesia, somnolence, CVA; Eyelash discolouration; Myocardial infarction, bradycardia, cardiac dysfunction; Hypertensive crisis; Frequent bowel movements, haematochezia/melaena, haematemesis, pancreatitis; Hepatic failure, DILI, jaundice; Photosensitivity reaction, skin disorders/exfoliation, nail disorders; Menorrhagia, metrorrhagia, Retroperitoneal/urinary tract/vaginal/rectal haemorrhage; Chills, mucous membrane disorder; Decreased blood glucose, abnormal thyroid function test. **Basic NHS Cost** 200mg x 30 tablet pack £560.50. 400mg x 30 tablet pack £1121.00. **Marketing authorisation (MA) nos.** EU/1/10/628/001-4. **MA holder** Glaxo Group Ltd., 980 Great West Road, Brentford, Middlesex TW8 9GS. **Legal category** POM. UK/PAZ/0234/13. December 2013.

Adverse events should be reported. Adverse events should be reported by the HCP in their country of origin according to local guidelines.

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