Eisai are pleased to invite you to attend a Breakfast Symposium at AGW:

The early experience with Lenvima in HCC: A Case Study Discussion Forum

Tuesday 10th September 2019
7:15am to 8:15 am (breakfast included)

Gilbert Suite, Adelaide Convention Centre
North Terrace, Adelaide SA 5000

Presenters
Associate Professor Simone Strasser
Professor Stuart Roberts
Dr Michael Wallace
ABOUT
Lenvima (lenvatinib) has been PBS reimbursed in Australia for the first-line treatment of uHCC since 1st of March 2019 before which time there was very minimal local experience with Lenvima. This breakfast symposium will cover the latest data with Lenvima including recently presented sub-analyses from REFLECT. Two case studies that look at the early experience with Lenvima from two different transplant centres in Australia will also be presented.

PRESENTERS
Associate Professor Simone Strasser
Professor Stuart Roberts
Dr Michael Wallace

CHAIRPERSON
Associate Professor Simone Strasser

AGENDA
7:15am Welcome
7:20am TKIs for unresectable HCC: a Roadmap for Management, Prof Stuart Roberts
7:40am Case 1, Dr Michael Wallace
7:55am Case 2, A/Prof Simone Strasser
8:10am Discussion
8:15am Close

REGISTRATION
To register for this breakfast please RSVP your details to: contact_australia@eisai.net by the 5th of September 2019 or fill in the information below and fax to 03 8678 3946.

Name: ____________________________
Email: ____________________________
Phone: ____________________________
Dietary Requirements: ____________________________

REFLECT: A Multicenter, Randomized, Open-Label, Phase 3 Trial to Compare the Efficacy and Safety of Lenvatinib Vs Sorafenib in First-Line Treatment of Subjects With Unresectable Hepatocellular Carcinoma
ASSOCIATE PROFESSOR SIMONE STRASSER

Associate Professor Simone Strasser is a Senior Staff Specialist in the AW Morrow Gastroenterology and Liver Centre, and the Australian National Liver Transplant Unit at Royal Prince Alfred Hospital and the University of Sydney. She has a major clinical and research interest in primary liver cancer, viral hepatitis, non-alcoholic fatty liver disease, advanced liver disease, and liver transplantation. She is Director of Hepatology Clinical Trials at RPAH, and is site principal investigator on multiple clinical trials of new therapies for patients with liver disease and liver cancer. She is a regular speaker in national and local educational programmes and sits on multiple educational, advisory, editorial and administrative boards and committees in Australia and internationally. She is currently President-Elect of the Gastroenterological Society of Australia. Her publications include many book chapters and over 120 publications in peer reviewed journals.

PROFESSOR STUART ROBERTS

Professor Stuart Roberts is the Head of Hepatology and a consultant gastroenterologist at The Alfred, Melbourne. Having completed a Hepatology Fellowship at the Mayo Clinic in the USA, Professor Roberts was awarded a Doctorate of Medicine by the University of Melbourne for his liver research. More recently, he completed a Master of Public Health at Monash University with High Distinction. His main research interests are hepatocellular carcinoma, viral hepatitis, autoimmune hepatitis, fatty liver disease, and non-invasive markers of liver disease. Professor Roberts has been Principal Investigator in over 165 sponsored and investigator-initiated clinical trials from phase I-IV. Professor Roberts has published more than 170 original articles across a range of high-impact journals including the New England Journal of Medicine, Lancet, Annals of Internal Medicine, Gastroenterology, Gut, Hepatology, and Journal of Hepatology.

DR MICHAEL WALLACE

Michael Wallace is a consultant Hepatologist at Sir Charles Gairdner Hospital in Perth, Western Australia. He completed his medical degree at UWA, his training in gastroenterology and hepatology in Perth and fellowship at the Mount Sinai School of Medicine in New York. His main research interests are in hepatocellular carcinoma, in particular, epidemiological trends, the use of emerging functional imaging techniques such as 18F-fluorocholine PET and refining SIRT response prediction.
CONTRAINDICATIONS: Hypersensitivity to the active substance or to any of the excipients. SPECIAL WARNINGS AND PRECAUTIONS: Gastrointestinal toxicity: diarrhoea and dehydration (actively manage before commencing therapy); hypertension; proteinuria (discontinue in event of nephrotic syndrome); renal failure and impairment (initial dose should be adjusted with severe impairment); cardiac dysfunction; posterior reversible encephalopathy syndrome (PRES)/Reversible Posterior Leuencephalopathy Syndrome (RPLS); hepatotoxicity (LFT monitoring recommended; no recommended dose in moderate impairment, not studied or recommended in severe impairment); haemorrhagic events and thrombocytopenia; arterial thromboembolic events (caution if within previous 6 months, discontinue following any event); wound healing complications (interruption for major surgery recommended); gastrointestinal (GI) perforation and fistula formation; non-gastrointestinal fistula; QT interval prolongation (monitor EEGs with special attention in patients with congenital long QT syndrome, congestive heart failure, bradyarrhythmias and those taking drugs known to prolong the QT interval including Class Ia and III antiarrhythmics); impairment of TSH suppression/Thyroid dysfunction; no data on use immediately following sorafenib or other anticancer treatments (risk for potential additive toxicities without adequate washout period); benefit-risk in patients with poor ECOG performance status not evaluated; limited data in elderly; pregnancy (Category D). Unknown effect on hormonal contraceptives therefore use barrier method; should not be used during breast feeding; no data available in children 2-<18 years. INTERACTIONS: Inhibitor effects on OAT1, OAT3, OCT1, OCT2, OATP1B1 and BSEP. ADVERSE EFFECTS: Very common: Hypothyroidism, diarrhoea, abdominal pain, nausea, vomiting, constipation, ascites, stomatitis/oral inflammation, fatigue, pyrexia, peripheral edema, weight decreased, decreased appetite, arthralgia/myalgia, headache, proteinuria, dysphonia, palmar-plantar erythrodysaesthesia syndrome, rash, hypertension, haemorrhagic events. DOSAGE AND METHOD OF ADMINISTRATION: 4 and 10 mg hard capsules. Adults: recommended dose 8 mg for patients with a body weight < 60 kg and 12 mg once daily for ≥ 60 kg taken once daily at same time each day, with or without food, swallowed whole with water (if unable to swallow, dissolve whole capsule in 25 mL water or apple juice). Management of adverse reactions, including hepatotoxicity, may require dose interruption, adjustment or discontinuation—refer to PI for dose modifications. Optimal management for nausea, vomiting and diarrhea should be initiated prior to any interruption or dose reduction (actively manage GI toxicity to reduce risk of dehydration and renal failure). No recommended dose for patients with HCC with moderate or severe hepatic impairment or severe renal impairment. Use in ESRD has not been studied. Must not be used in children <2 years; no data available in children 2-<18 years. Date of most recent amendment: 15 January 2019.

PBS Information: Authority required (STREAMLINED). Advanced ( unresectable) Barcelona Clinic Liver cancer stage B or stage C hepatocellular carcinoma. Refer to PBS Schedule for full authority information.