New PBS listing for patients with advanced soft tissue sarcoma

Treatment options for advanced Soft Tissue Sarcoma (STS) have been broadened with a new Pharmaceutical Benefits Scheme (PBS) listing for Votrient® (pazopanib hydrochloride)1 providing a targeted treatment option for physicians and their patients.

From 1 March 2014, VOTRIENT will be reimbursed on the PBS for advanced (unresectable and/or metastatic) soft tissue sarcoma in patients who have received prior chemotherapy including an anthracycline treatment.1 This PBS listing adds to VOTRIENT’s existing use in the treatment of advanced and/or metastatic renal cell carcinoma (RCC).2,3

Soft tissue sarcomas currently present a significant treatment challenge for oncologists. The disease is associated with poor survival rates and there has been little progress in the development of new systemic treatments for STS in the past few decades.4-6 The approval and reimbursement of VOTRIENT is based on the results of a phase 3 randomised placebo-controlled clinical study (PALETTE) in patients that had received prior chemotherapy.2,5

"I am very pleased that we will now have pazopanib available for our patients with sarcomas. It has literally been decades since we have had a new reimbursed treatment option for advanced soft tissue sarcomas patients in Australia, so this is a welcome addition for us” said Jayesh Desai, Medical Oncologist at the and Bone and Soft Tissue Sarcoma Unit at the Peter MacCallum Cancer Centre in Melbourne, Australia.

Richard Vines, Director of Rare Cancers Australia, welcomed the PBS listing for patients with STS.

“Access to medicines for rare cancers is crucial to our ability to manage them better,” said Mr Vines.

“Rare cancers exert a terrible toll on the community. They may not have the high media profile of some other diseases but our efforts to find and reimburse treatments are very important for those affected,” concluded Mr Vines.

Dr Andrew Yeates, GSK’s Medical Director in Australia said the PBS listing was part of GSK’s ongoing commitment to make more treatment options available to Australian cancer patients.

“Patients with this disease are dealing with a rare but debilitating cancer. So we are very pleased to be playing our part in helping them get access to another medicine, “said Dr Yeates.

About VOTRIENT
VOTRIENT belongs to a class of drugs that are targeted (a multi-target tyrosine kinase inhibitor).2 This targeted therapy interferes with cell processes, including cell signalling and the formation of new blood vessels to the tumour.2,6

About Soft Tissue Sarcoma
STS is a rare type of cancer, accounting for 1% of all human cancers, which forms in muscles, blood vessels and other tissues that support, surround and protect organs. There are over 70 different types of STS, named after the abnormal cells making up the tumour. It can develop at any age, although it is more likely to occur in people over the age of 55. The cause of most sarcomas is not known.

For further information about advanced soft tissue sarcoma and treatment options please speak with your healthcare professional. For Consumer Medicine Information (CMI) on VOTRIENT, please see www.gsk.com.au/votrient

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**Dose Modifications:** should be in 200 mg increments based on individual tolerability. Daily dose should not exceed 800 mg/day orally without food (at least one hour before or two hours after meal), taken whole with water.

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**Indications:** VOTRIENT is indicated for the treatment of advanced and/or metastatic renal cell carcinoma (RCC); treatment of advanced (unresectable and/or metastatic) soft tissue sarcoma (STS) in patients who, unless otherwise contraindicated, have received prior chemotherapy including an anthracycline treatment. The Phase III trial population excluded patients with gastrointestinal stromal tumour (GIST) or adipocytic soft tissue sarcoma.*

**Contraindications:** Hypersensitivity to pazopanib hydrochloride or any excipients.

**Precautions:** Hepatic Effects: Monitor serum liver tests before initiating treatment, at weeks 3, 5, 7 and 9, and at month 3 and month 4, then monitor periodically after month 4.* Caution concomitant use with simvastatin for risk of ALT elevations and monitor closely. Hypertension: Blood pressure should be well controlled prior to initiating treatment, monitored within 1 week and hypertension treated promptly.* Cardiac dysfunction: Monitor for signs and symptoms. Baseline and periodic LVEF assessment recommended if at risk of cardiac dysfunction*. Other precautions: QT Prolongation and Torsade de Pointes, arterial thrombotic events, venous thromboembolic events*, thrombotic microangiopathy, haemorrhagic events, gastrointestinal perforations and fistula, wound healing, cardiomyopathy, proteinuria, infections*, posterior reversible encephalopathy syndrome/reversible posterior leukoencephalopathy syndrome*, juvenile toxicity*. Effects on fertility, pregnancy (category D), lactation.* Refer to full PI for details.

**Interactions:** CYP3A4, Pgp, breast cancer resistance protein (BCRP) Inhibitors: Combination with strong CYP3A4 and Pgp inhibitors should be avoided.* Caution with grapefruit juice, co-administration of pazopanib with Pgp or BCRP inhibitors.* CYP3A4 Inducers: CYP Substrates: Concomitant agents with narrow therapeutic windows metabolised by CYP3A4, CYP2D6, or CYP2C8 not recommended. Other: May increase concentrations of drugs primarily eliminated through UGT1A1 and OATP1B1. Concomitant use with simvastatin increases the incidence of ALT elevations. Not indicated for use in combination with other systemic anti-cancer agents*.

**Adverse Events (RCC):** Very common: anorexia, headache, hypertension, diarrhoea, nausea, vomiting, abdominal pain, ALT/AST increased, hair depigmentation, fatigue, asthenia, arthralgia*. Common: neutropenia thrombocytopenia, hypothyroidism, weight decreased, dysgeusia, transient ischaemic stroke*, bradycardia*, myocardial ischaemia, QT prolongation, epistaxis, haematuria, dysphonia, dyspepsia, lipase elevations, hepatic function abnormal, hyperbilirubinaemia, alopecia, palmar-plantar erythrodysesthesia syndrome, rash, skin degeneration, proteinuria, chest pain, flatulence*, gamma-glutamyl transpeptidase increase*, Uncommon: ischaemic stroke, Torsade de Pointes, cardiac dysfunction, haemorrhage* (cerebral, gastrointestinal or pulmonary), venous thromboembolic events*, myocardial infarction, gastrointestinal perforation, gastrointestinal fistula, pancreatitis*. Adverse Events (STS)*: Very common: anorexia, weight decreased, dizziness, dysgeusia, headache, hypertension, cough, dysphoea, abdominal pain, diarrhoea, nausea, stomatitis, vomiting, alopecia, exfoliative rash, hair depigmentation, palmar-plantar erythrodysesthesia syndrome, skin degeneration, musculoskeletal pain, myalgia, chest pain, fatigue, peripheral oedema, arthralgia*. Common: hypothyroidism, cardiac dysfunction, bradycardia, myocardial infarction, QT prolongation, epistaxis, pulmonary haemorrhage, venous thromboembolic events, dysphonia, pneumothorax, dyspepsia, ALT/AST increased, dry skin, nail disorder; chills, blurred vision, flatulence*, gamma-glutamyl transpeptidase increase*. Uncommon: ischaemic stroke, cerebral haemorrhage, gastrointestinal haemorrhage, cerebral haemorrhage, gastrointestinal fistula, proteinuria. Not a full list; for more details, refer to full PI. Dosage and Administration: Recommended dose for the treatment of RCC or STS is 800 mg/day orally without food (at least one hour before or two hours after meal), taken whole with water.

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**PBS Information:** Authority required for the treatment of stage IV renal cell carcinoma. Authority required for the treatment of advanced soft tissue sarcoma. Refer to PBS Schedule for full information.

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VOTRIENT (pazopanib hydrochloride) Minimum Product Information

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Severe and fatal hepatotoxicity has been observed in clinical studies. Monitor hepatic function and interrupt, reduce, or discontinue dosing as recommended. [See PRECAUTIONS.]

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exceed 800 mg. **Children:** Not recommended for use in children and adolescents below 18 years of age. **Hepatic Impairment:** VOTRIENT should be reduced to 200 mg/day with moderate hepatic impairment. Not recommended in severe hepatic impairment. For further details, please refer to Full Product Information. *Please note changes in Product Information*

For full product information, information on GSK products or to report an adverse event involving a GSK product, please contact GSK Medical Information on 1800 033 109. GlaxoSmithKline Australia Pty Ltd. ABN 47 100 162 481. Melbourne, VIC. Votrient® is a registered trade mark of the GSK group of companies.

Dr Desai has served on advisory boards sponsored by GSK for which compensation was received. In relation to this GSK media announcement, no compensation was provided to Dr Desai or Mr Vines and the opinions expressed are their own. Dr Desai and Mr Vines have been briefed on the approved use of this product.

**Issued on behalf of GSK Australia by Palin Communications**

For more information or interviews contact Martin Palin (martin@palin.com.au; 0418 419 258) or George Anderson (george@palin.com.au; 0404 855 758) at Palin Communications (612 9412 2255) in Sydney.

**References:**
1. Pharmaceutical Benefits Division letter to GSK (dated 7 February 2014)
2. Approved VOTRIENT Product Information
4. FDA News Release – FDA approves Votrient for advanced soft tissue sarcoma FDA Statement, April 2012