Specialised Therapeutics to License Brain Tumour Visualisation Drug GLIOLAN® in Australia & NZ

Melbourne, Australia and Hamburg, Germany, 17 June 2011: A new drug which aids neurosurgeons to better visualise and operate on high grade glioma, a type of brain tumour which has a poor prognosis, has been in-licensed by Melbourne bio-pharmaceutical company Specialised Therapeutics Australia Pty Ltd (STA).

STA has signed a binding term sheet with German company photonamic GmbH and Co. KG to in-license the drug Gliolan. The drug is used in brain surgery to selectively induce fluorescence in brain tumour cells to assist surgeons in defining and resecting gliomas.

An article published in The Lancet Oncology medical journal indicated complete resection of the malignant brain tumour tissue was achieved in 65% of patients receiving Gliolan, compared to 36% of patients in the control arm. Additionally, 6-month progression-free survival was achieved in 41% of patients receiving Gliolan compared to 21.1% of patients who received surgery without the use of the drug.[1]

The drug is already approved for use in 27 countries, including the United Kingdom, France and Germany. STA plan to lodge an application later this year with the Therapeutic Goods Administration to have the drug formally approved for widespread use in Australia.

Announcing the plan, STA chief executive officer Mr Carlo Montagner said STA would be responsible for marketing and clinical/regulatory development of the product in Australia and NZ. Photonamic would receive a confidential upfront payment, as well as milestone and royalty payments.

“The widespread adoption of Gliolan in Europe as a result of the Phase III randomised study published in The Lancet clearly demonstrates that patients significantly benefit from its use during surgery,” Mr Montagner said.

“Australian neurosurgeons will welcome the opportunity to access Gliolan.

“For our part, we have made clear our strategy of building Specialised Therapeutics Australia through the acquisition and growth of specialist medicines that offer unique clinical benefits to patients.

“Gliolan is an excellent fit in our growing portfolio and we look forward to driving its growth.”

Photonamic managing director, Mr Ulrich Kosciessa, said Gliolan which has recently been approved in Korea was now widely available and phase III trials of the drug had demonstrated “extremely positive” data.

“We anticipate similar results when the drug is used on patients with malignant gliomas in Australia and New Zealand,” he said. “We are delighted this drug is now being made available in Australia.”

Gliolan is used in adult patients with malignant glioma. Gliolan helps surgeons to visualise brain tumours more clearly during surgery which enables improved complete resection of the malignant tissue in the brain.

The active substance in Gliolan is 5-aminolevulinic acid, a natural biochemical precursor of heme, which is absorbed by cells in the body, where it is converted by enzymes into fluorescent chemicals, particularly protoporphyrin IX (PPIX). [2]

Since glioma cells take up more of the active substance and convert it more rapidly into PPIX, higher levels of PPIX accumulate in the cancer cells than in normal tissue. When illuminated under blue light of a specific wavelength, the PPIX in the tumour glows an intense red, while the normal brain tissue appears blue which enables the surgeon to literally see the tumour more clearly during brain surgery and to remove it more accurately, sparing healthy brain tissue.[2]

Gliolan was first approved in Europe in 2007 and is marketed by medac in Europe, Africa, South America and Asia (excepting Japan and Korea).

References:

1. Stummer W, Pichlmeier U, Meinel T, et al., Fluorescence-guided surgery

with 5-aminovulinec acid for resection of malignant glioma: a randomised controlled multicentre phase III trial, Lancet Oncol, 2006;7:392-401
2. European Public Assessment Report Gliolan; http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Summary_for_the_public/human/000744/WC500021786.pdf

About Gliolan®

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About Specialised Therapeutics Australia, Pty Ltd

Specialised Therapeutics Australia Pty Ltd (STA) was established to identify, develop and commercialise innovative anti-cancer and other specialised therapies for the Australasian market. Currently STA markets two world leading cancer and cancer supportive care therapies, ABRAXANE® (nanoparticle albumin-bound paclitaxel) and ALOXI® (palonosetron) respectively. Based in Melbourne, Australia, the privately held company is currently developing several more important therapeutic agents for release in Australasia and other regional markets.

About photonamic GmbH and Co KG

photonamic GmbH and Co KG was established in 2003 to develop photosensitizers in the field of fluorescence guided diagnostics and photodynamic therapy. photonamic has developed 5-ALA for the fluorescence guided resection of glioblastoma (Gliolan) and for the photodynamic therapy of skin lesions

(Alacare). Both products are approved in Europe and will further be developed for the global market. photonamic is based in Hamburg, Germany.

- Phase III study shows 6-month progression-free survival is doubled in patients receiving Gliolan® (5-aminolevulinic acid, 5-ALA) [1]
- Drug improves visualisation and resection of brain tumour cells