Specialised Therapeutics Australia Receives Therapeutic Goods Administration Approval for Brain Tumour Visualisation Drug – GLIOLAN®

Melbourne, Australia and Hamburg, Germany, November 2013: A novel drug which assists neurosurgeons to better visualise and remove malignant brain tumours has been approved by the Therapeutic Goods Administration (TGA).

Until now, GLIOLAN (aminolevulinic acid HCl) has only been available via the Federal Government's Special Access Scheme (SAS). It will now be made widely available for use by neurosurgeons to treat patients with high grade glioma, specifically glioblastoma multiforme (GBM), which are tumours that typically have a very poor prognosis.

GLIOLAN is indicated in adult patients for **visualisation of malignant tissue during surgery for malignant gliomas that are glioblastoma multiforme (GBM) on preoperative imaging, and who are intended for resection of the tumour**.

GLIOLAN causes brain tumours (gliomas) to become fluorescent and glow during surgery. This enables neurosurgeons to better visualise these tumours and more completely remove them. GLIOLAN is given to the patient as a drink three hours before surgery. During surgery, a modified neurosurgical microscope fitted with a specialised blue operating light is used, which causes cancerous tissue to glow fluorescent red whilst normal brain tissue appears blue.

Melbourne bio-pharmaceutical company Specialised Therapeutics Australia Pty Ltd (STA) in-licenses the drug from German partner photonamic GmbH and Co. KG.

Announcing the TGA approval, STA chief executive officer Mr Carlo Montagner said GLIOLAN had already been used to treat over 100 Australian patients via the

SAS and a number of hospitals have been quick to upgrade neurosurgical microscopes with fluorescence capability.

“We are pleased with the positive response from neurosurgeons since GLIOLAN was made available via the SAS and this approval from the TGA is an extremely positive outcome,” he said.

“It has always been our intention to make this high class compound available to all patients who may benefit. Brain tumour surgery using GLIOLAN has been widely adopted throughout Europe and we expect a similar uptake in Australia to improve outcomes for all GBM patients.”

The chief executive officer of photonamic Mr Ulrich Kosciessa said: “The approval in Australia is another milestone in our global development of GLIOLAN, which is now registered in more than 30 countries world wide.

“GLIOLAN was developed to provide neurosurgeons with an effective tool to increase radicality of brain tumour resection without compromising safety for the patients. We are pleased that our partner STA has successfully been able to achieve an approval from the TGA.”

International studies have shown that use of GLIOLAN during brain tumour surgery has nearly doubled the rate of achieving a complete resection, which in turn has resulted in a doubling of the number of patients without progression of their brain cancer six months post surgery.[1]

The pivotal Phase III registration study published in The Lancet Oncology medical journal reported 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. This resulted in 6-month progression-free survival being achieved in 41% of patients receiving GLIOLAN compared to 21.1% of patients who received surgery without the use of the drug.[1]

Brisbane neurosurgeon, Lindy Jeffree, has used GLIOLAN in 36 patients since the drug was first made available via the SAS. She regards fluorescence guided surgery as an important tool in helping surgeons distinguish parts of a tumour which would otherwise be invisible to the naked eye.

She commented: “It makes it much easier to distinguish tumour from normal

brain tissue, which has undoubtedly assisted during some complex surgical procedures. Our aim is to provide optimal patient benefit. Using GLIOLAN to see tumour tissue more clearly enables better and more thorough resection which can make a big difference to a patient's response to subsequent treatment and ultimately to survival."

"I am extremely pleased to see this drug being made more widely available to improve surgical outcomes for patients with GBM around the country."

The approval by the TGA approval brings the number of countries where GLIOLAN is registered to 31, including 27 in the EU as well as Japan, Korea and Taiwan. GLIOLAN was first approved in Europe in 2009 and is marketed by medac in Europe, Africa, South America and Asia (except Japan and Korea).

- Novel drug which improves visualisation and resection of malignant brain tumours now widely available
- Twice as many patients are without progression of brain cancer six months after surgery with GLIOLAN
- To date over 100 Australian patients have been treated with GLIOLAN via the Federal Government's Special Access Scheme

The following Australian hospitals currently perform fluorescence-guided resection of brain tumours using GLIOLAN:

1. Royal Brisbane and Woman's Hospital, Queensland
2. The Wesley Hospital, Queensland
3. The Mater Private Hospital, Queensland
4. Princess Alexandra Hospital, Queensland
5. Prince of Wales Hospital, New South Wales
6. Newcastle Private Hospital, New South Wales
7. Calvary Hospital, Tasmania
8. The Royal Melbourne Hospital, Victoria
9. St Vincent's Private Hospital, Victoria

About GLIOLAN®

The active substance in GLIOLAN, aminolevulinic acid (ALA), is a photoreceptive compound which is absorbed by cells in the body, where it is converted by enzymes into fluorescent chemicals, particularly protoporphyrin IX (PPIX). 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. This enables the surgeon to see the tumour more clearly during brain surgery and to remove it more accurately, sparing healthy brain tissue.[2]

Like all medications GLIOLAN may cause side effects. GLIOLAN should not be used in patients with hypersensitivity to ALA or porphyrins, or in cases of acute or chronic porphyria, or in pregnancy. Cardiac disorders, gastrointestinal disorders and skin and subcutaneous disorders are all reported as being uncommon.

About Specialised Therapeutics Australia

Specialised Therapeutics Australia Pty Ltd (STA) is a biopharmaceutical company dedicated to working with leading pharmaceutical companies worldwide to provide acute care therapies for high unmet medical needs to people living in Australia and New Zealand. The STA therapeutic portfolio and pipeline at present encompasses oncology and infectious diseases. STA also has interests in the therapeutic areas of respiratory, dermatology, endocrinology and central nervous system (CNS). Additional information can be found at www.specialisedtherapeutics.com.au

About photonamic GmbH and Co KG

photonamic GmbH and Co KG was established in 2003 to develop photosensitisers in the field of fluorescence guided diagnostics and photodynamic therapy. photonamic has developed 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.

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

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