Specialised Therapeutics' Breakthrough Brain Tumour Visualisation Drug GLIOLAN® Approved for Use in New Zealand

Melbourne, Australia, 17 September 2015: A NOVEL drug which helps neurosurgeons to better visualise and remove malignant brain tumours has been approved for marketing and distribution in New Zealand by Medsafe.

The drug, GLIOLAN (aminolevulinic acid HCl), assists neurosurgeons to better visualise and more completely remove malignant brain tumours (gliomas) by causing them to become fluorescent and glow during surgery.

GLIOLAN is given to the patient as a drink three hours before surgery. During surgery, a neurosurgical microscope fitted with a specialised blue operating light is used, which causes cancerous tissue to glow fluorescent pink whilst normal brain tissue appears blue. This enables neurosurgeons to better visualise these tumours and more completely remove them, without damaging the neighbouring healthy brain tissue.

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**.[2]

The drug will be made available in New Zealand by Australian based bio-pharmaceutical company Specialised Therapeutics (ST). ST in-licenses the drug from German partner photonamic GmbH and Co. KG. According to New Zealand Ministry of Health 2012 figures, around 260 people in New Zealand are diagnosed with brain cancer each year, with nearly half of these being GBM.[3]

Specialised Therapeutics' Chief Executive Officer Mr Carlo Montagner said regulatory approval by Medsafe is the first step in having GLIOLAN broadly

available for New Zealand patients with GBM.

“Our next step is to have this important drug reimbursed and listed on the Pharmaceutical Schedule in New Zealand as soon as possible, to make this high class compound available to all patients with GBM. GLIOLAN is already under consideration for reimbursement as a high priority by PHARMAC, the New Zealand reimbursement authority” he said.

“Using GLIOLAN for complicated brain tumour surgery can lead to substantially improved outcomes for patients, as it improves the chances of the tumour being more completely removed. In Australia, more than 230 patients have had their surgery done using GLIOLAN, where it has been approved since November 2013.

Leading New Zealand neurosurgeon Dr Kelvin Woon described glioblastoma as a very aggressive brain tumour and said it had been proven that maximum (complete macroscopic) resection of the tumour increased the chances of overall survival. “Achieving this in surgery is often difficult, as the brain and tumour look similar,” he said. “Trying to find tumour margins is challenging, which can limit maximum resection.

“GLIOLAN has enabled neurosurgeons to find the ill-defined tumour margin, and gives us the confidence to go further to achieve maximum resection. Having Medsafe approval provides New Zealand patients and neurosurgeons with another weapon to treat these very aggressive tumours.”

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

The pivotal Phase III study published in The Lancet Oncology Medical Journal reported complete resection of malignant brain tumour tissue in 65% of patients receiving GLIOLAN compared to 36% of patients in the study’s control arm (difference between groups 29% [95% CI 17–40], p<0•0001). Six-month progression-free survival was achieved in 41% of patients receiving GLIOLAN compared to 21% of patients who were operated on without the use of the drug (difference between groups 20% [95% CI 9•1–30•7], p=0•0003).[1]

The Chief Executive Officer of photonamic, Mr Ulrich Kosciessa, said that GLIOLAN is already approved for use in 33 countries, including Germany, United Kingdom, Japan, South Korea, and Australia, and the approval in New Zealand is another milestone in the global development of the drug.

“We are delighted that ST has been able to successfully achieve an approval from Medsafe and that GLIOLAN will be available also for GBM patients in New Zealand,” he said. “Approximately 60,000 patients globally have already benefited from the use of GLIOLAN in brain tumour resection.”

GLIOLAN was first approved in Europe in 2007 and is marketed by medac GmbH in Europe, Africa, South America and Asia (excepting Japan and Korea). The following hospitals in New Zealand have fluorescence-guided surgery capabilities:

1. Wellington Hospital, Wellington
2. Dunedin Hospital, Dunedin
3. Christchurch Hospital, Christchurch
4. Waikato Hospital, Hamilton

The following Australian hospitals currently perform fluorescence-guided surgery using GLIOLAN:
1. Royal Brisbane and Woman’s Hospital, Queensland
2. Princess Alexandra Hospital, Queensland
3. Prince of Wales Hospital, New South Wales
4. John Hunter Hospital, New South Wales
5. Wollongong Hospital, New South Wales
6. Calvary Hospital, Tasmania
7. The Royal Melbourne Hospital, Victoria
8. Flinders Medical Centre, South Australia

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.

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 international pharmaceutical and diagnostic companies to provide patient access to innovative healthcare solutions. The STA therapeutic portfolio and pipeline at present encompasses oncology, haematology, supportive care and genomics. STA also has interests in the therapeutic areas of ophthalmology, 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, a privately held company, was established in 2002 to develop photosensitisers in the field of fluorescence guided diagnostics and photodynamic therapy. photonamic has developed ALA (GLIOLAN) for the fluorescence guided resection of glioblastoma and for the photodynamic therapy of non melanoma skin cancer (NMSC) with a transdermal patch formulation (ALACARE). Both products are approved in Europe and will further be developed for the global market. photonamic is based in Wedel/Hamburg, Germany.

- Medsafe has approved GLIOLAN® for marketing and distribution in New Zealand
- GLIOLAN is under consideration for reimbursement as a “high priority” for use in all New Zealand public hospitals
- Phase III study shows complete resection rates and 6-month progression-free survival is doubled in patients receiving GLIOLAN[1]

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. GLIOLAN Product Information
3. New Zealand Ministry of Health 2012. Cancer: New registrations and deaths 2009.