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Breakthrough brain tumour visualisation drug Gliolan to be listed on NZ hospital medicines list from 1 June

Media release from Specialised Therapeutics Group

- GLIOLAN® to be funded in all NZ District Health Board (DHB) hospitals following PHARMAC reimbursement decision
- Listing follows application by leading NZ neurosurgeon
- GLIOLAN has been shown to almost double complete resection rate and progression-free survival in brain cancer patients¹

A NOVEL drug which 'lights up' malignant brain tumours to help surgeons more thoroughly resect the cancer tissue will be widely available to New Zealand patients from 1 June, after a leading neurosurgeon applied for its reimbursement.

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

It is expected around 100 NZ brain cancer patients a year will be operated on using this cutting-edge technology, which has been demonstrated to improve complete resection rates and almost double six-month progression free survival in patients with the most serious form of brain tumours, Glioblastoma Multiforme, or

GBM¹.

It will be made available to newly diagnosed, untreated patients who are eligible for fluorescence-guided surgery.

GLIOLAN will be reimbursed subject to the following hospital restrictions:

- Patient has newly diagnosed, untreated, glioblastoma multiforme
- Treatment to be used as adjuvant to fluorescence-guided resection
- Patient's tumour is amenable to complete resection

Leading New Zealand neurosurgeon Dr Kelvin Woon made an application to PHARMAC seeking reimbursement and ensuring GLIOLAN's broad accessibility.

He has described the PHARMAC decision to list GLIOLAN on the hospital medicines list as "a big step forward".

"This is a great opportunity for NZ patients who are affected by these highly malignant tumours," he said.

"Although not curative, GLIOLAN helps us to better visualise what can be poorly-defined tumour margins, which limits our ability to resect the tumour macroscopically.

"Because we can more clearly see what is brain tissue and what is tumour, it gives us the confidence to be more aggressive and strive for maximum resection. This is important, because the evidence points to maximum (complete macroscopic) resection and increases the chances of overall survival." ²

GLIOLAN is given to patients as a drink prior to surgery. The drug is preferentially taken up by the malignant tumour tissue.

During surgery, a neurosurgical microscope fitted with a specialised blue operating light is used, which causes cancerous tissue containing the drug to glow fluorescent pink whilst normal brain tissue appears blue. This enables neurosurgeons to better visualise these tumours and more completely remove them, whilst sparing the neighbouring healthy brain tissue.

The drug is made available in New Zealand by international biopharmaceutical company Specialised Therapeutics Ltd, an affiliate of Specialised Therapeutics

Asia (ST Asia).

Chief Executive Officer Mr Carlo Montagner said several NZ hospitals had already upgraded operating theatre equipment to enable the use of GLIOLAN and neurosurgeons were preparing to use this technology as soon as the PHARMAC approval and listing takes effect.

“We are delighted to be able to provide another tool for NZ neurosurgeons to use in complex brain tumour cases,” he said.

“In this region and around the world, these patients have a very poor prognosis. With current standard chemotherapy and radiation treatment, these patients have a median overall survival of 12, maybe 15 months.³ GLIOLAN has been shown to help GBM patients survive longer without tumour progression compared to standard surgical procedures. Any drug or technology that enables patients additional time with their families is extremely valuable.”

International studies have shown that the use of GLIOLAN during brain tumour surgery has nearly doubled the rate of achieving a complete resection of the main tumour bulk, 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.

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). Around 500 Australian patients have been operated on using GLIOLAN since 2012.

GLIOLAN will be available to purchase from May 12 from ST’s New Zealand distributor, Healthcare Logistics (HCL).

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.

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About the Specialised Therapeutics Group

The Specialised Therapeutics group of companies collaborates with leading global pharmaceutical and diagnostic companies to bring novel, innovative and life changing healthcare solutions to patients affected by a range of diseases in Australia, New Zealand and throughout South East Asia. ST is committed to making new and novel therapies available to patients around the world, with a broad therapeutic portfolio spanning oncology, hematology, urology and ophthalmology. Additional information can be found at www.STAbiopharma.com

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References

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3. Stupp R, et al. *N Engl J Med* 2005; 352: 987-996