GLIOLAN® Granted Orphan Drug Status by the Therapeutic Goods Administration

Melbourne, Australia April 2012: A drug which aids neurosurgeons to better visualise and more completely remove malignant brain tumours has been granted orphan drug status by the Therapeutic Goods Administration (TGA).

The drug, Gliolan, is currently in-licensed by Melbourne biopharmaceutical company, Specialised Therapeutics Australia (STA) and is currently only available to neurosurgeons via the federal government's Special Access Scheme (SAS).

Gliolan has been granted orphan drug designation for photodynamic diagnosis of gliomas that are glioblastoma multiforme (GBM) (malignant) on preoperative imaging, and intended for gross macroscopic resection of all visible tumour. STA will lodge an application for TGA approval later this year. Orphan drug designation also means TGA application fees are waived.

STA chief executive officer, Mr Carlo Montagner, said orphan drug status is an important milestone as the company progressed plans to register the drug with the TGA.

"After we submit our documentation for registration by the TGA, approval for Gliolan could take 12 to18 months. We look forward to making this product broadly available to patients as it has been shown to significantly improve outcomes in glioma patients."

Gliolan is administered to patients three hours prior to surgery and causes cancerous tissue to glow fluorescent red during brain surgery. This enables improved visualisation of the boundary between healthy and diseased brain tissue, and aids the surgeon to more thoroughly remove the tumour. International studies have shown the use of Gliolan during surgery has nearly doubled the rate of achieving a complete resection, which has resulted in a doubling of the number of patients without progression of their brain cancer six months after their 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]

Gliolan has been accessed via the SAS and used in five brain tumour (high grade glioma) operations to date in Australia, at the Royal Melbourne Hospital and the Wesley Hospital in Brisbane.

The drug has been approved for use in 29 countries since 2007, including the United Kingdom, France, Germany, and Korea. Gliolan is used in adult patients with malignant glioma. The active substance in Gliolan, 5-aminolevulinic acid, is a photoreceptive compound which is predominantly absorbed by highly proliferative cells in the body and 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 visualise the tumour more clearly during brain surgery and to remove it more completely and accurately, sparing healthy brain tissue.[2]

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

About Gliolan®

The active substance in Gliolan is 5-aminolevulinic acid. It 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 5-ALA or porphyrins, 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, 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 negotiating the rights to several more important therapeutic agents for release in Australasia and other regional markets.