Nimotuzumab, a targeted cancer therapy drug with minimal side effects, was approved by the Bureau of Food and Drugs (BFAD) in the Philippines in August 2008 for the treatment of adult and pediatric glioma. The approval for the drug was based on clinical trials conducted in Germany and Cuba.

In Germany, phase II clinical trials were conducted by Oncoscience AG on 47 patients aged four to 17. They had relapsed or resistant high-grade gliomas of World Health Organization (WHO) grade III and IV. Using nimotuzumab as monotherapy saw 37.8% responding to treatment. Among these responders, the median time to progression was 142 days and the median survival time was 189 days. Clinical trials conducted by the Center of Molecular Immunology in Cuba involving 29 patients also showed positive results, with the median overall survival time recorded as 22.17 months and 37.9% of patients showing objective response.

The BFAD approval marks a major milestone for Singapore-based drug development company Innogene Kalbiotech Pte Ltd as it is the first regulatory approval the company has obtained for nimotuzumab. Innogene has been licensed to oversee the clinical development and marketing of nimotuzumab in ASEAN (except Vietnam), Taiwan, South Africa, Nigeria and Congo.

Dr Rikrik Ilyas, director of Innogene Kalbiotech Pte Ltd, said: “We at Innogene are very excited to introduce to the market an additional mode of treatment for brain cancer that can be used alongside with the conventional therapies to offer patients a better chance at containing tumor growth, and a better quality of life due to the low toxicity of nimotuzumab. We continue to work towards developing nimotuzumab and increasing its availability in more Asian and African countries.”

Nimotuzumab is a humanized monoclonal antibody that works by binding and disabling the epidermal growth factor receptor, a protein that is thought to be a pivotal driver in tumor proliferation. It can be used as monotherapy or in combination with chemotherapy and radiotherapy.

As a form of targeted therapy that binds with high specificity, nimotuzumab is thought to affect normal tissues minimally and have fewer toxic side effects. In fact, its proven safety profile allowed nimotuzumab to be the first cancer drug to be used on children (aged 17 and below) with brain tumors in a clinical trial in Germany.

Nimotuzumab has been approved in several countries in Africa, Asia, Eastern Europe and Latin America for various indications such as head and neck cancer, glioma and nasopharyngeal carcinoma. It is also pending marketing approval from the European Medicines Agency for the treatment of glioma in the European Union. Nimotuzumab is available on a named patient basis in Singapore, South Africa, Malaysia, Indonesia, Germany, Canada and the U.S.A.

About Innogene Kalbiotech Pte Ltd
Innogene Kalbiotech Pte., Ltd. is a leading biotechnology company aiming at providing clinically proven and quality guaranteed biopharmaceutical generics as well as developing innovative biopharmaceuticals that requires scientific and clinical development in the global market.