

MEDICC Review

Cuba Health Reports

Cuban Cancer Drug Headed for US Clinical Trials

By Conner Gorry

November 6, 2006 – The Cuban monoclonal antibody nimotuzumab, an anti-epidermal growth factor receptor (EGFr), has received the requisite license from the US Treasury's Office of Foreign Assets Control (OFAC) to begin clinical trials in the United States. Nimotuzumab is slated for testing to treat pediatric glioma – a type of brain tumor that strikes children.

David Allan, Chairman and CEO of YM BioSciences explained in a press release that "diffuse pontine glioma is an inoperable malignant brain cancer that only affects children and...is a treatment-resistant tumor so that children currently suffering from it have few treatment options."

Until now perhaps.

Nimotuzumab is already in Phase III clinical trials (combined with chemotherapy) for pontine glioma in Europe[1] and has been approved and is available to cancer sufferers in several countries including India, China and Argentina. Furthermore, the monoclonal antibody is in Phase II trials for lung cancer in Canada. Research has shown that the epidermal growth factor receptor is linked to the growth of cancer cells in many types of cancer including lung, ovarian, breast and prostate.

Still, children in the US suffering from pontine glioma have had to wait while the treatment – because it is Cuban – secures licensing specific to US embargo rules. The license recently obtained by YM Biosciences for nimotuzumab only permits the importation of the antibody to begin clinical trials; marketing the treatment requires a distinct license from OFAC. These licenses are wholly separate from, and in addition to, the standard testing and approval procedures set out by the Food and Drug Administration (FDA).

"In essence, a biotech product of Cuban origin has to undergo double approval," says Dr Normando Iznaga, Chief Development Officer for the Center for Molecular Immunology. "It must be approved by OFAC and by the FDA regulatory agency."

Response to the application for trial design is currently before the FDA, with a decision expected soon. The agreement between YM Biosciences and the Cuban Center for Molecular Immunology (CIM) established a joint venture for testing and marketing nimotuzumab in the USA and Canada, Europe, Japan and other countries of the Pacific Rim.

Other products developed at the Center for Molecular Immunology include monoclonal antibodies for tumor imaging; chemotherapy treatments; an anti-CD3 antibody for patients with organ transplant rejection; human recombinant therapy for anemia in patients with chronic kidney disease; and granulocyte Colony Stimulating Factor for neutropenia treatment in cancer patients. ■

Medical Education Cooperation with Cuba

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