

# Cuban cancer drug undergoes rare U.S. trial

September 4 2009, By John Dorschner

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For the first time since Fidel Castro took power in Cuba over a half-century ago, a drug developed by the Communist regime is going through clinical trials in the United States.

The drug nimotuzumab is designed to target cancer cells including those in rare and deadly types like glioma, the [brain cancer](#) that killed Sen. Ted Kennedy. A researcher at the University of Florida, where one trial is already in progress, calls the drug "exciting, interesting."

The hitch: Even if trials prove successful, nimotuzumab could not be sold in the United States because 20 percent of the company holding the license is owned by the Cuban government.

"We're in the business of developing drugs," said David G.P. Allan, chief of YM Biosciences, based in Canada. "We could care less about the political side."

YM Biosciences owns 80 percent of CIMYM, the company that has the rights to develop nimotuzumab in North America, Europe, Japan and other places. The other 20 percent is owned by the Center of Molecular Immunology, the biotech lab in Havana that developed the drug.

Given by injection, nimotuzumab is already approved for marketing in 20 countries, including India and China, where the licensing was done directly by [Cuba](#), not YM. It is not approved in North America, Europe or Japan, but almost 20 trials are in progress.

Amy Smith, a pediatric neuro-oncologist at the University of Florida, said the theory is that nimotuzumab works by attacking epidermal growth factor receptors, shutting off the growth of [cancer cells](#).

Smith said early studies in Europe indicate the drug showed considerable promise in prolonging the lives of children who have inoperable brain stem glioma. Even with radiation, those children generally survive only eight to 15 months.

To test the Cuban drug in the United States, YM needed an exception from the embargo by applying to the Department of the Treasury's Office of Foreign Assets Control -- a process that Allan called "slow and formal."

Other companies have done this -- Smithkline Beecham for a Cuba-made meningitis vaccine, and CancerVax for a cancer vaccine. In both cases, they obtained the necessary Treasury permission but after research decided not to do [clinical trials](#).

For nimotuzumab, YM received approval in 2006 for trials involving children with inoperable [brain cancer](#). Those tests are still progressing. Results are expected next year.

Several drugs in the same class as nimotuzumab are already approved, including Eli Lilly's Erbitux. These types of drugs do not lead to miracle cures, said Allan, but can help extend life by allowing chemo and radiation therapies to be more effective. YM maintains that nimotuzumab is superior to others in its class because it alone does not lead to toxic skin conditions.

Erbitux has a North American market of more than \$1 billion a year, Allan said, and is used with mixed results on a wide range of cancers. For inoperable brain cancer cases, the U.S. market is about 5,000

patients -- not a large population for a drug manufacturer, especially since treatments could cost \$10,000 to \$50,000 per patient.

That's why YM Biosciences went back to the Treasury and asked to import the Cuban drug to test on patients with all sorts of cancers. That approval came earlier this month.

Not all the nimotuzumab news has been positive. In March, the European Medicines Agency rejected an application to market the drug, listing 27 major objections, including "major deficiencies in the control, consistency and validation of the drug substance" at the Havana manufacturing plant.

Allan said the application was made by a European company that had sub-contracted with YM and was "based on impoverished data" which was bound to be rejected. Next time, the application will be much sounder, he said.

U.S. trials are expected to take three or four years. If the trials succeed, YM would need a change in the embargo law.

Would a life-extending drug be worth an embargo exception? Ana Carbonell, chief of staff for Rep. Lincoln Diaz-Balart, issued a statement Friday, saying the Republican congressman from Miami "supports all efforts to find cures for cancer.

"The medical trials for this drug will take several years. Diaz-Balart hopes that by then the Cuban people will be free."

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