Headlines in Cuban Health

US Company Licenses Three Cuban Cancer Vaccines

CancerVax Corporation, a California company, has entered into a licensing, development and marketing agreement for three innovative cancer vaccines developed by Cuba’s Center for Molecular Immunology (CIM). The agreement was signed on July 15, between CancerVax and CIMAB, S.A., the commercial arm of CIM.

Authorization for the deal from the U.S. government represents a limited breakthrough in the tough sanctions the United States has imposed on Cuba for more than 40 years, prohibiting such cooperation between a US and Cuban company in the development of biotechnology. In 1999, the U.S. government granted a license to the British company SmithKline Beecham PLC (now GlaxoSmithKline) to market a Cuban vaccine against meningitis B, once the product receives FDA approval (Medic Review, July 1999).

Since the early 1990s, Cuba has sold millions of doses in Latin America, including Brazil, Argentina and Columbia.

According to specialists, the vaccines could prove valuable to fight breast, lung and colon cancer, among others. Published data from early Phase 1 and 2 studies of the lead candidate among the three vaccines, SAI-EGF, showed promising results in increasing the survival of patients with advanced stage non-small-cell lung cancer (Source: Journal of Clinical Oncology, Vol 22, No. 14S, July 15 Supplement, 2003:2514; Abstract No: 2514; Annals of Oncology, Vol 14, 2003). Based on these results, David Hale, chief executive of CancerVax, has expressed confidence that the SAI-EGF vaccine could be approved for marketing as early as 2008 or 2009. The other two vaccines, SAI-TGF-alpha and SAI-EGFR-ECD, are currently in preclinical development.

The vaccines consist of immunotherapies designed to stimulate the body’s immune system to recognize and attack cancer cells. The SAI-EGF vaccine is designed to attack epidermal growth factor receptor, one of the receptors related to the regulation of cell growth. Research has shown that the EGF signaling pathway is linked to cancer cell growth in the development of many solid tumor cancers, including lung, breast, ovarian, pancreatic and prostate cancers. The other two, SAI-TGF-alpha and SAI-EGFR-ECD are in preclinical development.

Under the agreement, CancerVax’s wholly owned subsidiaries Tarcanta, Inc. and Tarcanta, Ltd. (Ireland) will carry out the clinical trials of the vaccines in the United States and Europe necessary for the marketing and distribution of the drugs. According to Dr. Augstin Lage Davila, Director of CIM, if the clinical trials prove successful and the vaccines are approved for distribution, they will be produced both by CancerVax and CIM in the United States and Cuba, respectively. CancerVax will have rights under license to market the vaccines in the United States, Canada, Europe, Japan, Australia, New Zealand and Mexico.

The two preclinical vaccines were previously licensed by CIMAB, S.A. to the Canadian firm YM BioSciences Inc. for development. Under a three-way agreement with CancerVax the licenses held by YM Biosciences will be transferred to CancerVax.

CancerVax won bipartisan support for the project in Congress as well as the endorsement of top oncology researchers, convincing the Bush administration to approve the license for what are considered to be “revolutionary life-saving medications.” As stated by Senator Christopher J. Dodd, Democrat from Connecticut, “saving lives shouldn’t be a political issue.”

However, as a condition of the U.S. Treasury Department authorization, initial payments in the amount of US$6 million by CancerVax to Cuba’s CIMAB during the three-year developmental stage cannot be made in cash, but rather must be in food and medicines.
At the signing of the agreement, David F. Hale, chief executive of Cancer Vax Corporation, lauded the Cuban advances in biotechnology research: "I think there are other product candidates and technology in Cuba that could be helpful to the American people, not just the American people but people around the world.”