US government awards $132.5 million for flu vaccine production.

Vaccine makers MedImmune and Sanofi Pasteur have been awarded $132.5 million to retrofit their manufacturing facilities for the production of a pandemic influenza vaccine.

Sanofi Pasteur was given $77.4 million, while MedImmune's contract was approximately $55.1 million.

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According to Reuters, the government is keen to get vaccine factories up and running in the US as most vaccines for the US market come from abroad. If an influenza pandemic were to happen, countries may nationalize their own vaccine supplies.

"The contract covers costs for design, retrofit and the maintenance of the facilities at a state of readiness so the company can switch to pandemic influenza vaccine manufacture at the HHS' request," Sanofi said in a statement.

Sanofi's existing facility has been modified over the years to produce approximately 50 million doses of vaccine for the US market during the course of the past several influenza seasons. When both facilities are validated, the company's capacity will approximately triple from its current capacity.

The department of health and human services (HHS) estimates that upon completion, the new facilities will expand domestic pandemic vaccine manufacturing capacity by 16%.

Fuente: Business Review

No safety concerns found for Biovest vaccine.

An independent monitoring panel has found no safety concerns in its analysis of Biovest's anticancer vaccine BiovaxID, a conclusion that the company is hoping will support its application for an accelerated approval.

Biovest International, a majority owned subsidiary of Accentia Biopharmaceuticals, added that the independent safety panel has requested an interim analysis of all primary and secondary endpoints. The company said it believes that BiovaxID's strong safety record will be supportive of its planned application for accelerated conditional approval of BiovaxID.

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BiovaxID is an anticancer vaccine that is in phase III trials for the indication of non-Hodgkins lymphoma. BiovaxID is a personalized, patient specific vaccine designed to stimulate the patient's own immune system to recognize and destroy cancerous B-cells that may remain in the body or may arise after the patient has been treated with chemotherapy.
The chairman of the Data Monitoring Committee (DMC), Dr Gerry Messerschmidt, said: "There are no identifiable safety concerns in the current BiovaxID phase III pivotal clinical trial at this time in our data review."
Applications for accelerated conditional approval of BiovaxID are planned to be submitted to both the FDA and European Medicines Agency (EMEA) by mid-2008. The DMC has agreed to serve as a liaison between the Company and the FDA and the EMEA. If conditionally approved by the target date of mid-June 2008, BiovaxID would be commercially available in early 2009.

Fuente: Business Review

FDA delays decision on Sanofi vaccine

The FDA has delayed giving a decision on Sanofi-Pasteur's pediatric combination vaccine for technical reasons to November 2, according to the company.
The vaccine is designed to prevent diphtheria, pertussis or whooping cough, polio, tetanus and Haemophilus influenzae type b. It is sold in nine countries including Canada. A spokesperson for Sanofi said that the delay was nothing to do with the vaccine itself, and said that it was a technical matter.
The FDA had asked Sanofi earlier in the year about the way it is conducting analysis in its new lab in the US, after moving production from Canada.

Fuente: Business Review

IDM reports encouraging results for cancer vaccine

IDM Pharma has released results showing that its experimental cancer vaccine was well tolerated with evidence of efficacy and induction of immune response in patients with progressive metastatic melanoma in a phase II trial.
Out of 30 patients evaluable for efficacy, nine (30%) showed evidence of clinical benefit with duration of response ranging from 9.4 to 26.5 months. Progression free survival was 4.8 months with a median follow-up of 12 months. Overall survival has not yet been reached as 21 patients are still alive.

The survival rate at 9 months was 70%. The vaccine, Uvidem, was well tolerated with toxicity limited to mild events with only one possibly related serious adverse event reported (age related macular degeneration).
Merrick Ross from The University of Texas MD Anderson Cancer Center, said: "The preliminary analysis of the phase II clinical trial with IDM Pharma's cancer vaccine, Uvidem, suggests that several patients with advanced melanoma attained durable control of their disease after a treatment stimulating their own immune system cells. Additionally, the side effects experienced by our patients were minimal."
IDM is jointly developing the vaccine with Sanofi-Aventis

Fuente: Business Review
Bavarian Nordic wins US smallpox vaccine contract

Danish company Bavarian Nordic has won a contract from the US government to manufacture and deliver 20 million doses of its smallpox vaccine Imvamune. The five-year contract is valued at more than $500 million, with options that if exercised extend the value to $1.6 billion and the performance period of the contract. The department of health and human services (HHS) is procuring the vaccine for the protection of individuals considered to be at risk for exposure to smallpox. The contract options allow for the government to procure up to an additional 60 million doses and would support additional clinical studies for extending the license to include HIV-infected, pediatric, and geriatric populations. This contract is the first next-generation, or completely new, product procured by HHS under the government's BioShield program, enacted after the terrorist attacks of 9/11 to guard against bioterrorism.

Peter Wulff, Bavarian Nordic's president and CEO, says that while the only way to prevent smallpox infection is through vaccination, traditional smallpox vaccines used or stockpiled today are live replicating viruses that can pose serious side effects and lead to complications in up to 25% of the population. Imvamune, on the other hand, is based on the Modified Vaccinia Ankara (MVA) virus, which is also a live virus but one that does not replicate in the body and is expected to be safe for both healthy as well as immuno-compromised individuals. Additionally, the MVA virus cannot be accidentally transferred to others who might be immuno-compromised, because it is administered by injection.

According to Wulff, "Our Imvamune clinical development program consists of 10 completed or ongoing trials, which have investigated the vaccine in persons who are immuno-compromised as well as healthy individuals. Results in more than 1,500 persons (atopic dermatitis, HIV-infection and healthy subjects) vaccinated with Imvamune show that the vaccine was safe and well-tolerated."

Bavarian Nordic has invested $60 million of its own financial capital to put into operation a manufacturing facility in Denmark that has the capacity to produce a minimum of 40 million doses of Imvamune per year, with the capacity of being expanded to 180 million doses per year.

Fuente: Business Review

AstraZeneca entra en el mercado de las vacunas.

La compañía farmacéutica británica AstraZeneca ha decidido entrar en el mercado de las vacunas. Para ello va a adquirir por 15,200 millones de dólares la empresa estadounidense MedImmune.

Con la venta de la vacuna contra la gripe FluMist que producía MedImmune, AstraZeneca tendrá a partir de ahora una mayor participación en este segmento del mercado.

Fuente: Time