

FDA licenses Acambis' ACAM2000™ vaccine for protection against smallpox

Cambridge, UK and Cambridge, Massachusetts – 31 August 2007 – Acambis plc (Acambis) (LSE: ACM), a leading vaccine company, announces that the US Food and Drug Administration (FDA) has approved its ACAM2000 (Smallpox (Vaccinia) Vaccine, Live) vaccine for active immunisation against smallpox disease for persons determined to be at high risk for smallpox infection. This approval is a key step towards Acambis finalising a long-term “warm-base manufacturing” contract with the US Government.

Acambis developed ACAM2000 under contracts with the US Centers for Disease Control and Prevention (CDC) as part of its preparations for a public health emergency. ACAM2000, which is a single-dose vaccine, is the primary smallpox vaccine for use in an emergency and forms the majority of the US Government's smallpox vaccine Strategic National Stockpile (SNS). To date, Acambis has supplied 192.5 million doses of ACAM2000 to the CDC for the SNS.

Acambis is currently in advanced negotiations with the CDC for a “warm-base manufacturing” contract to provide the US Government with a long-term ACAM2000 production capability that is located entirely in the US. The contract would also cover licence maintenance activities.

Ian Garland, Acambis' Chief Executive Officer, said:

“The licensure of ACAM2000 is a significant milestone not only for Acambis but also for the US Government in its plans to ensure a state of readiness against the threat of smallpox. This has been a highly successful collaboration between Acambis and the CDC, and we look forward to finalising the warm-base manufacturing contract to secure this vaccine production capability for the US Government for the long term.”

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About ACAM2000

- § ACAM2000 is a live, vaccinia virus smallpox vaccine indicated for active immunisation against smallpox disease for persons determined to be at high risk for smallpox infection.
- § It is a single-dose vaccine administered percutaneously.
- § It was derived by plaque purification from the previously licensed calf lymph-produced vaccine that was extensively used in the smallpox eradication programme.
- § ACAM2000 is manufactured in Vero cells using modern cell-culture techniques designed to comply with current Good Manufacturing Practice standards.
- § Acambis has supplied more than 200 million doses of ACAM2000 under an FDA Investigational New Drug application to 15 governments around the world, including the US.

ACAM2000 was developed to be a modern smallpox vaccine with a safety and efficacy profile comparable to the US's licensed previous vaccine but manufactured using the latest production techniques. Until the development of ACAM2000, smallpox vaccines were last manufactured in the US in 1982 and were produced from calf lymph.

The clinical trial data generated on ACAM2000 were reviewed by the FDA's Vaccines and Related Biological Products Advisory Committee in May 2007, which voted unanimously (11-0) in favour of the vaccine's safety and efficacy. The FDA has licensed ACAM2000 for persons determined to be at high risk for smallpox infection. In addition to being stockpiled for emergency use, ACAM2000 will be used by the US Department of Defense for protection of military personnel.

Important Safety Information

ACAM2000 may not protect all persons exposed to smallpox. ACAM2000 is contraindicated for individuals with severe immunodeficiency who are not expected to benefit from the vaccine. These individuals may include persons who are undergoing bone marrow transplantation or persons with primary or acquired immunodeficiency states who require isolation.

§ The most serious adverse events associated with smallpox vaccination are myocarditis, pericarditis, encephalitis, encephalomyelitis, encephalopathy, progressive vaccinia, generalised vaccinia, severe vaccinia skin infections, and erythema multiforme major (including STEVENS-JOHNSON SYNDROME) and eczema vaccinatum resulting in permanent sequelae or death, ocular complications, blindness and foetal death have occurred following either primary vaccination or revaccination with smallpox vaccines.

§ The most common side effects following smallpox vaccination include itching, swollen lymph nodes, sore arm, fever, headache, body ache, mild rash and fatigue.

Full prescribing information may be obtained by calling Acambis at +1 866 440 9440 (toll free) or +1 617 866 4500.

About smallpox

Smallpox is a highly contagious disease caused by the variola virus, a member of the Orthopox virus family. It is one of the most devastating diseases known to humanity, with a mortality rate as high as 30%. In 1967, the World Health Organization embarked upon an intensified vaccination campaign to eradicate smallpox, which culminated in the successful eradication of the disease globally by 1980.⁽¹⁾

By the mid-1980s, there were only two known repositories of variola virus: the Institute of Virus Preparations in Russia and the US Centers for Disease Control and Prevention (CDC). The events in the US in September and October 2001 highlighted the risk that the variola virus might be used as an agent of bioterrorism.⁽²⁾ Governments around the world are taking precautionary measures to be ready to deal with a potential smallpox outbreak.

Notes and references

⁽¹⁾ WHO: <http://www.who.int/mediacentre/factsheets/smallpox/en/>

⁽²⁾ CDC: <http://www.bt.cdc.gov/agent/smallpox/overview/disease-facts.asp>

About Acambis

Acambis is a leading vaccine company developing novel vaccines that address significant unmet medical needs or substantially improve standards of care. ChimeriVax™-JE, Acambis' most advanced vaccine candidate in its non-biodefence pipeline, has completed Phase 3 trials and is currently undergoing paediatric trials in India. It is partnered with sanofi pasteur and Bharat Biotech. Acambis' proprietary ChimeriVax technology, developed in association with St Louis University, has also been used to develop Acambis' ChimeriVax-West Nile vaccine candidate, which is undergoing Phase 2 clinical testing, making it the most advanced investigational vaccine against the West Nile virus. Acambis also has the only vaccine in development against *Clostridium difficile* bacteria, a leading cause of hospital-acquired infections. Acambis' influenza programme aims to develop a universal vaccine against influenza, for which a universal 'A' strain vaccine, ACAM-FLU-A™, is currently being tested in a Phase 1 trial, and also includes various further vaccine candidates in the research and pre-clinical stages.

Recognised internationally as the leading producer of smallpox vaccines, Acambis manufactured its smallpox vaccine, ACAM2000, for emergency-use stockpiles held by the US Government and 14 other governments around the world under a US FDA IND application. ACAM2000 is licensed for active immunisation of persons determined to be at high risk for smallpox infection.



Acambis is based in Cambridge, UK and Cambridge, Massachusetts, US, and is listed on the London Stock Exchange (ACM). More information is available at www.acambis.com.

“Safe Harbor” statement under the Private Securities Litigation Reform Act of 1995:

The statements in the news release that are not historical facts are forward-looking statements that involve risks and uncertainties, including the timing and results of clinical trials, product development, manufacturing and commercialisation risks, the risks of satisfying the regulatory approval process in a timely manner, and the need for and the availability of additional capital. For a discussion of these and other risks and uncertainties, see the relevant risk sections in the Company’s latest Annual Report, in addition to those detailed on the Company’s website and in the Company’s filing made with the Securities and Exchange Commission prior to Acambis’ deregistration. These forward-looking statements are based on estimates and assumptions made by the management of Acambis and are believed to be reasonable, though are inherently uncertain and difficult to predict. Actual results or experience could differ materially from the forward-looking statements.