

## **Acambis' ACAM2000 receives positive recommendations from Advisory Committee**

17 May 2007

Acambis plc (Acambis) (LSE: ACM) announces that the Vaccines and Related Biological Products Advisory Committee of the US Food and Drug Administration yesterday voted unanimously that Acambis' ACAM2000 is both safe and efficacious.

**CAMBGIDGE, UK and CAMBRIDGE, MA, USA | May 17, 2007** | Acambis plc (Acambis) (LSE: ACM) announces that the Vaccines and Related Biological Products Advisory Committee of the US Food and Drug Administration yesterday voted unanimously that Acambis' ACAM2000 is both safe and efficacious.

The Advisory Committee was asked to review whether the clinical data demonstrated that ACAM2000 was safe and effective for use in persons at high risk of exposure to smallpox virus. It voted 11-0 in favour on both the safety and efficacy of ACAM2000.

The FDA has the final decision on licensure of ACAM2000. It has identified 31 August 2007 as the target date for its response to Acambis' ACAM2000 licence application under the Prescription Drug User Fee Act.

Ian Garland, Acambis' Chief Executive Officer, said:

"We are delighted with the outcome of the Advisory Committee meeting and look forward to the FDA's decision on our licence application. This positive vote further reinforces our confidence in the potential for ACAM2000 to be licensed, which is a necessary prerequisite to finalising a warm-base manufacturing contract with the CDC and securing a long-term revenue stream that will underpin Acambis' continued growth."

Acambis developed ACAM2000 under contracts with the US Centers for Disease Control and Prevention (CDC) in response to the US Government's need for a stockpile of smallpox vaccine to counter the threat of smallpox being used as a biological weapon. To date, Acambis has supplied 192.5 million doses of ACAM2000 to the US's Strategic National Stockpile under an FDA Investigational New Drug (IND) application.

ACAM2000 is intended to be used for protection of persons determined by the US Government to be at high risk for smallpox infection, which currently includes vaccination of military personnel being deployed to certain regions. The CDC and Acambis are discussing provision by Acambis of a long-term production capability and licence maintenance activities under a 'warm-base manufacturing' contract, which would provide smallpox vaccine production entirely in the US.

**SOURCE: Acambis plc**