

## Press Release Details

Title                    09 Nov            Acambis joins forces with Bharat Biotech to address unmet  
                             2005                    need for JE Vaccine in India

### Details

#### **Acambis joins forces with Bharat Biotech to address unmet need for JE Vaccine in India**

Hyderabad, India – 09 November 2005 – Acambis plc (“Acambis”) (LSE: ACM, NASDAQ: ACAM) announces that it has established a manufacturing and marketing agreement with Bharat Biotech International Limited (“Bharat Biotech”) of India relating to Acambis’ ChimeriVax-JE investigational vaccine against Japanese Encephalitis (“JE”).

JE, a virus transmitted to humans by mosquitoes, is the leading cause of childhood encephalitis and viral encephalitis in Asia. Currently, an epidemic is affecting areas of northern India and Nepal, where more than 1,000 people have died since July, most of them children. Every year, there are an estimated 30,000 to 50,000 cases of JE, approximately 25-30% of which are fatal; a high proportion of survivors are left with serious neurological impairment<sup>1</sup>.

Despite the availability of JE vaccines for 60 years, the virus continues to cause death and disease. As a result of this significant unmet public health need and in the absence of a safe, single-dose vaccine, both the World Health Organization’s (WHO’s) Initiative for Vaccine Research and the Gates Foundation have identified a need for development of a second-generation, affordable JE vaccine that has an acceptable safety profile and requires fewer doses than currently available vaccines.

Acambis is preparing to commence pivotal Phase III trials of a single-dose regimen of its ChimeriVax-JE vaccine candidate by the end of 2005, having completed Phase II clinical testing. Current JE vaccines are administered in multiple doses.

Under the agreement announced today, Bharat Biotech will be responsible for end-stage fill/finish processing of ChimeriVax-JE at its facilities in India and, once ChimeriVax-JE is approved, will market and distribute the vaccine in India and neighbouring countries. Bulk vaccine will continue to be manufactured at Acambis’ Canton, Massachusetts facility, where material for Phase III testing has already been produced following technology transfer and scale-up to commercial scale manufacture.

Bharat Biotech is one of India’s leading biotechnology companies. Based in Hyderabad, it manufactures and sells a polysaccharide typhoid vaccine (launched in 2003) and a recombinant vaccine for Hepatitis B (launched in 1998), which is also sold in Latin America and Africa. Both were developed in-house. Bharat Biotech’s manufacturing plant is the largest in the Asia-Pacific region and it has an established sales force and distribution network serving the Indian subcontinent.

Gordon Cameron, Chief Executive Officer of Acambis, said:

“The scale of the current epidemic in India has highlighted the critical need for a safe, efficacious and cost-effective vaccine against JE. We believe that the forthcoming Phase III trials of ChimeriVax-JE will demonstrate our vaccine can meet that need and Bharat Biotech is the ideal partner to help us maximise ChimeriVax-JE’s reach in India and neighbouring countries. This collaboration is part of our strategy to establish ChimeriVax-JE as the optimum vaccine in endemic countries and I look forward to a long and fruitful relationship with Bharat Biotech.”

Dr Krishna M. Ella, Chairman and Managing Director of Bharat Biotech International Ltd, said:

“It is Bharat Biotech's endeavour to provide vaccines based on the most up-to-date technology platforms and of the highest quality to people living in developing countries. We aim to market vaccines that are affordable to the common man and yet manufactured under the globally recognised Good Manufacturing Practices. We are already manufacturing vaccines against Hepatitis B and typhoid, and vaccines against rotavirus and malaria are also in development. This partnership with Acambis will enable us to bring a much-needed and improved JE vaccine to children in the Indian subcontinent, a region currently suffering from an epidemic that has so far killed over 1,000 children.”

## References

1. WHO Initiative for Vaccine Research ([www.who.int](http://www.who.int))

About Bharat Biotech International Limited: Bharat Biotech

Bharat Biotech is a multi-dimensional biotechnology company specialising in product-oriented research, development and manufacturing of vaccines and biotherapeutics. It is the first bio-pharma company in the country to be audited and approved by Korean Food & Drugs Administration and has set a new benchmark in quality standards that epitomizes the tremendous progress of Indian biotechnology in the global arena.

About Acambis

Acambis is a leading developer of vaccines to prevent and treat infectious diseases. Recognised internationally as the leading producer of smallpox vaccines, Acambis is developing an investigational smallpox vaccine, ACAM2000, and is manufacturing emergency-use stockpiles of this investigational vaccine for the US Government and other governments around the world. It is also developing an attenuated smallpox vaccine, MVA3000, under contracts with the US National Institutes of Health. Acambis is establishing a travel vaccines franchise through its US-based subsidiary Berna Products Corporation, which markets Vivotif®, the world's only licensed oral typhoid vaccine, in North America. Acambis has other potential travel vaccines in development and is also developing an investigational vaccine against the West Nile virus, which has spread to 48 US States in the last six years.

Acambis is based in Cambridge, UK and Cambridge, Massachusetts, US. Its primary listing is on the London Stock Exchange (ACM) and its shares are listed in the form of American Depositary Receipts on NASDAQ (ACAM). More information is available at [www.acambis.com](http://www.acambis.com).

“Safe Harbor” statement under the Private Securities Litigation Reform Act of 1995: The statements in this 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, the need for and the availability of additional capital. For a discussion of these and other risks and uncertainties see “Risk management” in the Company’s 2004 Annual Report and “Risk factors” in its Form 20-F, in addition to those detailed on the Company’s website and in the Company’s filings made with the Securities and Exchange Commission from time to time. 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.

For Enquires:

Bharat Biotech International Ltd.  
Seema Kumar  
Tel: +91 40 23480567  
Mobile: 9848887845  
Email: seema@bharatbiotech.com

Acambis plc  
Gordon Cameron,  
Chief Executive Officer  
David Lawrence,  
Chief Financial Officer  
Lyndsay Wright,  
VP, Communications and IR  
Tel +44 (0) 1223 275 300

Financial Dynamics David Yates/Davina Langdale: Tel +44 (0) 20 7831 3113

Japanese Encephalitis (JE)

The Japanese encephalitis (JE) virus, world's most significant cause of viral encephalitis, is found across China, Korea, the Indian sub-continent, south-east Asia and parts of Australia.

Three billion people live in JE-endemic regions and more than 70 million children are born each year in endemic countries<sup>1</sup>. According to the US Centers for Disease Control and Prevention (CDC), approximately 30,000-50,000 human cases of JE are reported annually, although the true incidence is likely higher as surveillance and reporting rates are poor. Upto 30% of affected people die of this virus and many survivors have permanent neurological disabilities.

The JE virus is transmitted to humans via the bite of an infected mosquito. The mosquitoes usually get infected when feeding on domestic pigs and wild birds that are already carrying the virus. The *Culex tritaeniorhynchus* group of mosquito is the primary transmitter of JE to humans and can be found breeding in flooded rice fields, marshes and standing water pools in planted fields. The disease cannot be transmitted from person-to-person.

The majority of JE virus infections are mild, being characterised initially by flu-like symptoms appearing 5 to 15 days after being bitten by an infected mosquito. These symptoms include the sudden onset of fever, chills, headache, tiredness, nausea and vomiting.

An estimated 1 in 300 cases becomes more severe and develops into encephalitis - a serious infection of the brain with symptoms such as disorientation, tremors, occasional convulsions (especially in children), coma and paralysis. The disease is fatal in 30% of cases and, of the survivors; a further 30% are left with permanent neurological problems, such as brain damage and paralysis.

Indian states affected by JE are West Bengal, Bihar, Karnataka, Tamil Nadu, Andhra Pradesh, Assam, Uttar Pradesh, Manipur and Goa. This year over 2000 people in Eastern Uttar Pradesh have fallen prey to the disease. 24 districts have been affected so far in the region, which will require over 70 million dosages of vaccination. According to CDC, the transmission season in the affected Indian

states is as follows:

State Transmission Season

Goa May – October

Tamil Nadu October – January

Karnataka August – December

Andhra Pradesh September – December

North India July - December

## Corporate Profile

Acambis was established in 1992 as Peptide Therapeutics. In 2000, the Company changed its name to Acambis to reflect the merger of the UK and US operations. In 2001, Acambis listed its shares on the NASDAQ stock exchange in the form of American Depositary Receipts. Its employees are based at facilities in Cambridge, UK, Cambridge and Canton, Massachusetts, and Miami, Florida.

In September 2000, Acambis was awarded the first of a number of contracts with the US Centers for Disease Control and Prevention to manufacture and supply its investigational smallpox vaccine. Following the events of 9/11 and the anthrax-related attacks shortly thereafter, the US Government procured a smallpox vaccine stockpile from Acambis at a cost of more than USD \$428 million.

The majority of Acambis' operational activities, such as manufacturing and clinical trials, take place in the United States, where they are regulated by the US Food and Drug Administration (FDA). In Europe, Acambis is regulated in Europe by the regulatory body European Medicines Agency, previously known as the EMEA.

Acambis have invested in developing the manufacturing facility in Canton, USA. This 47,000 sq ft plant is now a state-of-the-art facility that has already been used in the production of more than 200 million doses of Acambis' investigational ACAM2000 smallpox vaccine and is manufacturing supplies of investigational vaccines against Japanese encephalitis and West Nile.

Research and development of new vaccines lies at the heart of Acambis' business. The Company recognizes that the long-term growth of the company depends on the introduction of new, commercially viable vaccines. Research and development has always been core to Acambis' business, and the Company has also strengthened clinical, regulatory and quality functions to meet the requirements of the ever-advancing product pipeline, the more demanding regulatory environment and the manufacturing facility.

Acambis using its proprietary ChimeriVax™ technology is developing an investigational vaccine against Japanese Encephalitis (JE). Known as ChimeriVax-JE, the investigational vaccine candidate is a live, attenuated, injectable vaccine, which is currently undergoing phase-III clinical trials.