

Xenova Group plc

Xenova and FDA reach agreement on SPA Phase III trial programme for TransMID™

Enrolment to Begin Immediately

Slough, UK, 11 May 2004 – Xenova Group plc (LSE: XEN; NASDAQ: XNVA) announced today that it has reached agreement with the US Food and Drug Administration (FDA) under the Special Protocol Assessment (SPA) procedure for the revised Phase III clinical trial programme proposed for TransMID™.

Prior to its acquisition by Xenova, KS Biomedix Holdings plc (KS Biomedix) had obtained FDA agreement for a single Phase III clinical trial for TransMID™ under the SPA process. Following the acquisition of KS Biomedix, Xenova submitted a revised programme involving two smaller sequential Phase III clinical trials rather than one larger study, which has now been agreed with the FDA. The adoption of a two study approach reduces the level of risk associated with a large single study.

The initial Phase III clinical trial is designed to enrol 323 patients with non-resectable, progressive or recurrent Glioblastoma Multiforme (GBM) who have failed conventional therapy. The study will be a randomised, open-labelled, multi-centre trial and will compare TransMID™ against a number of presently used chemotherapeutic agents regarded as “best standard of care” (BSC). The 323 patients will be randomised in a 2:1 ratio of TransMID™:BSC across approximately 50 sites in the EU, Israel and North America.

The primary end-point is overall survival time with a planned interim analysis to be conducted after 50% of the required events have been observed. In an earlier, open label, Phase II study, patients receiving TransMID™ achieved a significant increase in overall survival compared with historical survival figures. In this study, median survival for patients receiving TransMID™ was approximately 37 weeks. This compares to the average life expectancy for these patients which is currently approximately 26 weeks.

Edward Oldfield MD, Chairman of the Surgical Neurology Branch of the National Institute of Neurological Disorders and Stroke (NINDS) at the National Institutes of Health, Bethesda, Maryland said: “Glioblastoma Multiforme has been a very difficult tumour to treat. This novel approach combines a potent new drug with a targeted delivery method that can distribute the drug directly to the region involved with tumour. In earlier Phase I and Phase II clinical trials, the combination produced complete and partial radiographic responses in several patients.”

David A Oxlade, Chief Executive Officer said: “We are pleased to have reached agreement with FDA for the revised programme and we will be starting to enrol patients immediately. People with non-resectable Glioblastoma Multiforme currently have few treatment options and there is a clear need for improved outcomes for these patients.”

TransMID™ received Fast Track status from the FDA in August 2001 and orphan drug status in December 2001. In addition, the European Commission granted TransMID™ orphan designation in March 2002.

Xenova Group plc is a UK-based biopharmaceutical company focused on the development of novel drugs to treat cancer and addiction with a secondary focus in immunotherapy. The Group has a broad pipeline of products in clinical development, including three cancer programmes: its lead product TransMID™, for the treatment of high-grade glioma, now beginning Phase III trials, and the novel DNA targeting agents and XR303 both in Phase I for cancer indications. In addition to its cancer drugs, Xenova is developing two therapeutic vaccines for cocaine and nicotine addiction, in Phase II and Phase I trials respectively. In April 2001 Xenova acquired Cantab Pharmaceuticals plc and in September 2003 it acquired KS Biomedix Holdings plc. Quoted on the London Stock Exchange (XEN) and on NASDAQ (XNVA), Xenova employs approximately 112 people throughout its sites in the UK and North America. (Reuters XEN.L; Bloomberg XEN LN).

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Notes to Editors

TransMID™

TransMID™ is a treatment initially being developed for high-grade glioma (a type of brain cancer), a disease for which improved treatment is essential, as there remains a poor prognosis for patients. TransMID™ is a modified diphtheria toxin conjugated to transferrin. When TransMID™ binds to transferrin receptors on the surface of the cell, the diphtheria toxin gains entry to the cell. Once inside the cell, the diphtheria toxin interferes with protein synthesis and ultimately kills the cell. Transferrin receptors are particularly prevalent on rapidly dividing cells, and the high level of transferrin receptor expression on glioma cells relative to normal brain tissue makes transferrin an appropriate targeting mechanism for the diseased cells.

TransMID™ is pumped directly into the brain tumour using CED (Convection Enhanced Delivery – licensed from the National Institutes of Health, Bethesda, Maryland, USA). CED enhances the distribution of TransMID™ through the tumour mass and produces high local concentrations of drug. TransMID™ is directly infused into the tumour in order to reduce systemic side effects. This also has the benefit of circumventing the usual obstacles present in drug delivery to the brain caused by the blood-brain barrier.

Phase I and Phase II clinical trials for TransMID™ have been successfully completed in patients suffering from inoperable, recurrent high grade gliomas who have failed to respond to other forms of treatment. A Phase I dose-escalating study was performed at the National Institutes of Health in the US and was followed by a Phase II multi-centre study at nine premier US medical centres.

In a Phase II study, 50% or greater reduction in tumour volume was noted in 35% of evaluable patients, with a corresponding increase in life expectancy in those patients that did respond. Median survival time for patients receiving TransMID™ was approximately 37 weeks. This compares to the average life expectancy of approximately 26 weeks for patients with this condition being treated with best standard of care.

TransMID™ is currently licensed to Nycomed Denmark A/S in Europe, Sosei Co Ltd in Japan, Medison Pharma Ltd in Israel and Ranbaxy Laboratories Limited in India. The rights to TransMID™ in North America have been retained.

Convection Enhanced Delivery

Convection enhanced delivery (CED) involves the slow continuous infusion of TransMID™ over several days via one or more catheters directly into the tumour. This technique maximises perfusion of the drug into the target area. Xenova has an exclusive license from the NIH for the use of CED with TransMID™ for cancers of the CNS, head and neck.

Special Protocol Assessment

The Prescription Drug User Fee Act of 1992 (PDUFA) goals for special protocol assessment and agreement provide that, upon request, FDA will evaluate within 45 days certain protocols and issues relating to the protocols to assess whether they are adequate to meet scientific and regulatory requirements identified by the sponsor. Three types of protocols related to PDUFA products are eligible for this special protocol assessment under the PDUFA goals: (1) animal carcinogenicity protocols, (2) final product stability protocols, and (3) clinical protocols for Phase III trials whose data will form the primary basis for an efficacy claim if the trials had been the subject of discussion at an end-of-Phase II/pre-Phase III meeting with the review division. For more information on Special Protocol Assessment, please visit www.fda.gov.

For further information about Xenova and its products please visit the Xenova website at www.xenova.co.uk

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commercialization of products. Various risks may cause Xenova's actual results to differ materially from those expressed or implied by the forward looking statements, including: adverse results in our drug discovery and clinical development programs; failure to obtain patent protection for our discoveries; commercial limitations imposed by patents owned or controlled by third parties; our dependence upon strategic alliance partners to develop and commercialize products and services; difficulties or delays in obtaining regulatory approvals to market products and services resulting from our development efforts; the requirement for substantial funding to conduct research and development and to expand commercialization activities; and product initiatives by competitors. For a further list and description of the risks and uncertainties we face, see the reports we have filed with the Securities and Exchange Commission. We disclaim any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.