

Preliminary Cerepro[®] Phase III results meet primary endpoint

- Secondary endpoints yet to be established with 45% of patients still alive -

London, UK 30 July 2008 - Ark Therapeutics Group plc (AKT:LSE) today announces that the preliminary analysis of Study 904, a Phase III study of Cerepro[®], its novel gene-based therapy being developed as an Orphan Drug for the treatment of operable primary malignant glioma, demonstrates that the trial has met its primary endpoint. Cerepro[®] treatment resulted in significant improvements in median survival on the primary endpoint compared with various control groups. In the secondary endpoints, with 45% of patients still alive, benefits have yet to be established.

Study 904 was a multicentre, standard care controlled, pivotal trial in 236 patients designed, following advice from the EMEA, to confirm the safety and efficacy of Cerepro[®] in patients with operable high grade glioma (brain cancer) against current standard care treatment options. Patients were randomised to either standard care plus Cerepro[®] or standard care alone. Standard care was surgery and radiotherapy or surgery and radiotherapy followed by temozolomide, depending on the investigating centres' standard practice and patient suitability, giving four treatment groups. This allowed comparison of the efficacy of Cerepro[®] and temozolomide in the same trial without denying patients what physicians considered the appropriate established standard care. The primary endpoint was survival, defined as time to death or re-intervention⁽¹⁾. At randomisation, the treatment groups were well matched in terms of demographics and the standard prognostic features (age, Karnofsky Score etc).

The overall combined controls primary endpoint analysis in the Intention to Treat (ITT) population (n=236) compared Cerepro[®] with and without temozolomide against controls with and without temozolomide. It showed a 42 day improvement in median survival (310 days vs 268 days) and the improvement over standard care reached significance (p<0.032). The analysis was performed approximately 14 months after completion of recruitment.

On the primary endpoint, the group given Cerepro[®] and temozolomide showed an improvement of 68% in median survival time compared with standard care surgery and radiotherapy controls (350 days vs 208 days). Against the same controls, treatment with Cerepro[®] alone showed an improved median survival trend approaching 50%, similar to those given treatment with temozolomide alone after surgery and radiotherapy (300 days and 307 days respectively vs 208 days with standard care). Improvements in the combined Cerepro[®] and temozolomide treatment group (n=58) and temozolomide alone group (n=76) were significant (p<0.05). In the smaller Cerepro[®] alone treatment group (n=61), the effect is approaching significance (p<0.065) with 16% still to report an event. Of the total 53 patients still to report an event, only 7 are in the surgery and radiotherapy control group and thus confidence intervals and statistical significance levels in all treatment groups might be expected to improve with time.

On the secondary endpoints, which include MRI based progression, all-cause mortality, safety and quality of life, the effects of Cerepro[®] treatment have yet to be established with around 45% of patients still alive. Data from a further time point analysis are needed to fully elucidate this.

Whilst increases were observed in hemiparesis, aphasia and pyrexia following therapy, the serious adverse event reports for Cerepro® were in line with those in previous studies, indicating that the product has an acceptable safety profile.

An updated analysis will be conducted in January 2009 according to the plan and all patients will be tracked until death in accordance with the gene therapy regulations.

The results of the study are expected to be presented at the European Association of Neuro-Oncology in Barcelona on 11-14 September 2008.

Commenting on the results Dr David Eckland, R&D Director at Ark, said: *“We are very gratified that Cerepro has demonstrated efficacy in this multi-centre Phase III gene therapy study. This is in keeping with our experience and expectation of the product and we now have further evidence to show Cerepro® has an anti-cancer effect. Our next steps are to complete the full analysis and meet with our EMEA rapporteur to determine the way forward.”*

Dr Nigel Parker, CEO at Ark, added: *“This is the first gene therapy product to successfully reach its primary endpoint in a major Phase III trial. With a number of patients in the trial still to report an event, there is a substantial amount of further information to come and we will update the analysis after the turn of the year in parallel with our regulatory activities. Malignant glioma is one of the most aggressive of all human diseases and to have seen a positive effect for Cerepro® in this disease area is very encouraging. Ark’s adenoviral delivery technology has the potential to deliver a new era of gene-based therapies for acute and chronic human disease.”*

⁽¹⁾ Re-intervention is defined as any kind of treatment (surgery, chemotherapy or radiotherapy) given to prolong survival after tumour recurrence.

A conference call for analysts will be held at 9.00am today, 30 July 2008. Please call Claire Rowell on 0207 269 7285 for details.

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Notes to Editors

High grade glioma

High grade glioma (malignant glioma) is a devastating and fatal form of tumour that is usually confined to the brain. The current standard therapy involves surgically removing the solid tumour mass (when possible) and initiating radiotherapy and/or chemotherapy. Even with the latest approved treatments, most patients die within 12-15 months of diagnosis. Little therapeutic progress has been made in recent years and the prognosis for malignant glioma patients is poor. A high unmet clinical need exists for new treatments that prolong life in this devastating disease. It is estimated that there are approximately 16,000 cases of malignant glioma in the EU which are operable.

Cerepro®

Cerepro® is an adenoviral mediated gene based medicine (ad.HSV tk) given by multiple injections into the healthy brain tissue of patients following surgical removal of the solid tumour mass. In the following days ganciclovir is given intravenously. Once treated, healthy brain cells surrounding the site where the tumour was removed express the enzyme thymidine kinase. This converts the ganciclovir to a substance which specifically kills dividing cells. The healthy neurones surrounding the tumour in the brain are non-dividing and are therefore not susceptible to this substance. In this way Cerepro® harnesses healthy brain cells to help prevent a new tumour from growing.

Ark Therapeutics Group plc

Ark Therapeutics Group plc is a specialist healthcare group (the "Group") addressing high value areas of unmet medical need within vascular disease, wound care and cancer. These are large and growing markets, where opportunities exist for effective new products to generate significant revenues. With four marketed devices, Kerraboot®, Kerraped®, Flaminal® and Neuropad®, and three further lead pharmaceutical products in late stage clinical development: Cerepro®, Vitor™, and Trinam®, the Group is transitioning from an R&D company to a commercial, revenue generating business.

Ark's own products are sourced from related but largely non-dependent technologies within the Group and have been selected to enable them to be taken through development within the Group's own means and to benefit from Orphan Drug Status and/or Fast Track Designation, as appropriate. This strategy has allowed the Group to retain greater value and greater control of clinical development timelines, and to mitigate the risks of dependency on any one particular programme or development partner. Ark has secured patents or has patent applications pending for all its lead products in principal pharmaceutical markets.

Ark has its origins in businesses established in the mid-1990s by Professor John Martin and Mr Stephen Barker of University College London and Professor Seppo Yla-Herttua of the AI Virtanen Institute at the University of Kuopio, Finland, all of whom play leading roles in the Company's research and development programmes.

Ark's shares were first listed on the London Stock Exchange in March 2004 (AKT.L).

This announcement includes "forward-looking statements" which include all statements other than statements of historical facts, including, without limitation, those regarding the Group's financial position, business strategy, plans and objectives of management for future operations (including development plans and objectives relating to the Group's products and services), and any statements preceded by, followed by or that include forward-looking terminology such as the words "targets", "believes", "estimates", "expects", "aims", "intends", "will", "can", "may", "anticipates", "would", "should", "could" or similar expressions or the negative thereof. Such forward-looking statements involve known and unknown risks, uncertainties and other important factors beyond the Group's control that could cause the actual results, performance or achievements of the Group to be materially different from future results, performance or achievements expressed or implied by such forward-looking statements. Such forward-looking statements are based on numerous assumptions regarding the Group's present and future business strategies and the environment in which the Group will operate in the future. Among the important factors that could cause the Group's actual results, performance or achievements to differ materially from those in forward-looking statements include those relating to Ark's funding requirements, regulatory approvals, clinical trials, reliance on third parties, intellectual property, key personnel and other factors. These forward-looking statements speak only as at the date of this announcement. The Group expressly disclaims any obligation or undertaking to disseminate any updates or revisions to any forward-looking statements contained in this announcement to reflect any change in the Group's expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based. As a result of these factors, readers are cautioned not to rely on any forward-looking statement.