

23 May 2007

## **Vegenics Licensee Announces Early Trial Clearance**

### **US Recombinant DNA Advisory Committee gives early clearance for Trinam<sup>®</sup> Phase III trial**

Vegenics' licensee, UK based Ark Therapeutics Group plc (LSE: AKT), announced today that it has been given clearance by the US Recombinant DNA Advisory Committee for its planned Phase III US clinical study of Trinam<sup>®</sup>. Trinam<sup>®</sup> is a novel gene therapy product which seeks to prevent blood vessels blocking in kidney dialysis patients who have undergone vascular access graft surgery. Ark Therapeutics now intends to undergo Special Protocol Assessment (SPA) for the Phase III study with the United States Food and Drug Administration and Ark expects this trial to commence in the second half of 2007.

Trinam<sup>®</sup> utilises technology licensed from Vegenics Limited. Circadian Technologies established Vegenics to commercialise the vascular endothelial growth factor technology developed by the global Ludwig Institute for Cancer Research and Licentia Limited. Circadian currently owns 67% of Vegenics.

Under the terms of the licence agreement, Vegenics is entitled to receive milestone payments as the Ark product progresses through clinical trials, plus a royalty on sales.

A copy of the announcement by Ark Therapeutics to the London Stock Exchange is attached. Additional information may be found on the Ark website: <http://www.arktherapeutics.com>.

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RNS Number:9884W

Ark Therapeutics Group PLC  
22 May 2007

Ark Therapeutics Group plc

US Recombinant DNA Advisory Committee gives early clearance for Trinam(R)  
Phase III trial

22 May 2007, London, UK: Ark Therapeutics Group plc announces today that it has been given clearance by the US Recombinant DNA Advisory Committee (RAC) for its planned Phase III US clinical study of Trinam(R), Ark's novel gene-based therapy to prevent haemodialysis access graft blockage.

Ark filed its application to the RAC earlier this month and a final decision had been expected by the end of the RAC's public review process scheduled for 19-21 June. After the initial review, the RAC members have determined that the application does not require further review and discussion in a public session and has therefore given clearance for the product to commence the 200+ patient pivotal Phase III study. The Company will now undergo Special Protocol Assessment (SPA) for the Phase III study with the FDA and the trial is expected to commence in the second half of 2007 once this is complete.

Commenting on the announcement Ark's CEO, Dr Nigel Parker, said:

'The rapid granting of this approval without the need for a public hearing illustrates just how far gene-based medicine has advanced in the last year or two. We look forward to giving further updates on the SPA process in due course.'

For further information:

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Notes to Editors

Trinam(R)

Trinam(R) is a combination of a vascular endothelial growth factor gene in an adenoviral vector (Ad-VEGF-D) and Ark's biodegradable local delivery collagen collar device (EG001). At the end of the access graft surgery procedure, the collar is fitted around the outside of the vein/graft join. The Ad-VEGF-D solution, which reduces the likelihood of blood clots and intimal hyperplasia, is then injected into the space between the wall of the collar and the blood vessel. This unique method of administration of the gene localises its delivery to the target tissue site, maximising efficacy, avoiding systemic distribution and thus minimising the potential for side effects.

Trinam(R) has undergone a Phase II clinical study, which has shown encouraging early efficacy results, with grafts of treated patients remaining functional for dialysis on average between two and four times longer than controls. For the primary end point of safety, no quantifiable systemic distribution of Trinam(R) was found and the product is well tolerated. No

serious side effects were exhibited other than those consistent with the nature of the operation and condition.

After consultation with the FDA in January 2007, Ark announced that it intended to undertake a small pre-clinical study on Trinam(R), investigating biodistribution in an 'end-to-side' procedure for surgical placement of the graft. If the results of this study are in line with expectations, it will allow the Phase III trial to include this procedure alongside the 'end-to-end' placement procedure. Pending SPA agreement, the Phase III study is expected to commence around mid-2007 and to last for approximately 18 months.

The Phase III study is being planned as a multi-centre, randomised, controlled trial of up to 250 patients in which the efficacy and safety of Trinam(R) will be investigated in patients with end stage renal disease (ESRD) requiring vascular access for haemodialysis. Patients with ESRD will be randomised to receive either Trinam(R) in addition to standard care or standard care alone at the time of surgical placement of a synthetic PTFE graft for vascular access. The primary endpoint of the trial will be the time to graft failure.

#### Recombinant DNA Advisory Committee

The US National Institutes of Health (NIH) established the RAC on October 7, 1974 in response to public concerns regarding the safety of manipulating genetic material through the use of recombinant DNA techniques. Although the RAC's membership and responsibilities have evolved over time with scientific understanding and developments in this technology, it continues to serve the NIH, as well as the scientific and lay publics, as a critically important forum for open, public deliberation on the panoply of scientific, ethical, and legal issues raised by recombinant DNA technology and its basic and clinical research applications. Over the course of the Committee's existence, transparency and access have been its defining characteristics, enabling public acceptance of a critically important technology and creating an environment in which science can advance in an informed, safe, and ethical manner.

The RAC comprises experts in a wide range of scientific and medical disciplines and also includes ethicists and members of patient and other lay communities. Because of the dedication, effort, and thoughtful contributions of its members over the past 30 years, the RAC has been a vital national forum promoting critically important scientific progress in a transparent, responsible, and safe manner and enhancing public trust in the science.

#### 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 two marketed devices, Kerraboot(R), and Flaminal(R), and three further lead pharmaceutical products in late stage clinical development: CereproTM, VitorTM, and Trinam(R), 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-Herttuala 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.

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