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Circadian Licensee Ark Therapeutics Announces Trinam® Phase III Study Enrols First Patient

Circadian Technologies Limited (ASX:CIR) announces that its licensee Ark Therapeutics Group plc has enrolled the first patient into its US Phase III study for Trinam®, a novel treatment to improve quality of care and quality of life for kidney dialysis patients.

Trinam® is a gene-based medicine to prevent blood vessels from blocking in kidney dialysis patients who have undergone vascular access graft surgery. The product is an adenovirus-mediated VEGF-D gene delivered with a novel biodegradable local delivery device.

Rights to employ the VEGF-D gene in Trinam® are licensed from Circadian (through its wholly owned subsidiary Vegenics) to Ark. Under the terms of the license agreement, Vegenics is entitled to receive milestone payments on clinical development achievements and royalties on product sales.

Circadian owns extensive intellectual property rights for the use of VEGF-D and other VEGF family members for diverse therapeutic applications. Circadian's internal product programs are focused on the development of novel therapeutics for cancer.

Robert Klupacs, CEO of Circadian commented, "This is a further significant milestone for Trinam® in the path towards commercialisation, and we congratulate Ark on their pioneering role in advancing this important and novel technology. We look forward to the ongoing enrolment of patients in this trial and are hopeful that Trinam® will continue to demonstrate the considerable benefits for patients undergoing kidney dialysis."

"We believe that progression of this application is a reflection of the significant commercial value of our VEGF intellectual property."

Additional information is provided in the announcement below submitted by Ark Therapeutics Group plc to the London Stock Exchange. Additional information on Ark Therapeutics may be found on its web-site www.arktherapeutics.com.

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About Circadian Technologies Limited

Circadian (ASX:CIR) is a biologics drug developer utilising the significant intellectual property portfolio around Vascular Endothelial Growth Factor (VEGF) C and D that it has accumulated in its unlisted wholly owned subsidiary Vegenics. The applications for the VEGF technology, which functions in regulating blood supply, are substantial and broad. Circadian's internal product development programs are focussed on novel anti-cancer therapeutics for large unmet needs. Circadian has also licensed rights to some parts of its intellectual property portfolio for the development of other products to UK company Ark Therapeutics Group plc (LSE: AKT) and ImClone Systems (a wholly owned subsidiary of Eli Lilly & Company - NYSE: LLY). Ark is developing Trinam®, a treatment for vascular grafts associated with renal dialysis based upon Circadian intellectual property which has commenced Phase 3 clinical trials. ImClone Systems is currently developing an antibody-based drug targeting VEGFR-3 for the treatment of solid tumours.

The VEGF patent portfolio developed by LICR and Licentia has been assigned to Vegenics. Vegenics also has rights to CoGenesys Inc/Human Genome Sciences Inc's VEGF-C intellectual property.

About VEGF Technology

In Cancer

The clinical and outstanding commercial success of Avastin®, an antibody that blocks the activity of VEGF-A, clinically validated anti-angiogenic drugs as an effective means of inhibiting solid tumour growth. By blocking the interaction of VEGF-A with its receptors, primarily VEGFR-2, the multi-billion dollar cancer therapeutic slows tumour growth by inhibiting blood vessel recruitment into the tumour, effectively starving tumours of essential nutrients and oxygen required for growth. Avastin, which is sold by Genentech, now part of Roche, and Hoffman-La Roche, had U.S. sales in 2007 of US$2.3 billion and worldwide sales in excess of US$6 billion.

VEGF-C and VEGF-D inhibitors, key therapeutics in the portfolio of Circadian's unlisted subsidiary Vegenics, blocks the alternative ligands for VEGFR-2. As such, they have the potential to block blood vessel growth in tumours resistant to anti-VEGF-A therapy and, when used in combination with drugs like Avastin, may completely shut down angiogenesis (the growth of blood vessels) mediated by VEGFR-2, resulting in greater clinical efficacy.

VEGF-C and VEGF-D also bind and activate VEGFR-3 which drives lymphatic vessel and tumour-associated blood vessel growth. Inhibitors of VEGF-C, VEGF-D and VEGFR-3 thus have therapeutic potential to inhibit not only primary tumour growth through their anti-angiogenic activities, but to also inhibit tumour spread or metastasis via the lymphatic vessels - a mechanism of tumour dissemination that is often the deadliest aspect of many tumour types and a mechanism that is not effectively blocked by anti-VEGF-A or anti-VEGFR-2 therapeutics.

Other Disease Applications

VEGF Technology also has applications in other diseases, where shutting down angiogenesis and/or lymphatic vessel growth is important, such as eye diseases including age related macular degeneration and diabetic retinopathy.

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Ark Therapeutics Group plc

Trinam® Phase III Study Enrols First Patient

London, UK, 21 May 2009 - Ark Therapeutics Group plc ('Ark' or the 'Company') announces today that the first patient has been enrolled into the US Phase III study for Trinam®. Trinam® is Ark's novel gene-based medicine to prevent blood vessels blocking in kidney dialysis patients who have undergone vascular access graft surgery. The product is an adenovirus-mediated VEGF D gene delivered with a novel biodegradeable local delivery device (EG001).

The Phase III study is a US multi-centre, randomised, controlled trial, in which the efficacy and safety of Trinam® 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® in addition to standard care or standard care alone at the time of surgical placement of a synthetic PTFE graft for vascular access. Primary Unassisted Patency (time to any first intervention) will be the primary regulatory endpoint. Overall patency and a number of other important pre-defined clinical endpoints will also be measured.

The safety of the trial will be assessed by an independent Data and Safety Monitoring Board (DSMB) against a pre-specified set of stopping rules defined during the Special Protocol Assessment (SPA). The DSMB will also undertake a blinded 'sizing' analysis after 150 patients have been enrolled to determine the final trial size. This type of adaptive design assists groundbreaking drugs to ensure robust efficacy data are available to satisfy regulatory requirements as approval standards evolve.

Results from a Phase II open-label, non-randomised, standard-care controlled trial of Trinam®, reported in March 2007, indicated that the access grafts of patients given Trinam® remained functional for dialysis, on average, up to three times longer than in untreated controls. Trinam® was well tolerated with no quantifiable systemic distribution of the product found and no serious side effects were exhibited other than those consistent with the nature of the operation and underlying condition.

Trinam® was awarded Fast Track Status by the FDA earlier this month and has been granted Orphan Drug Status in both the US and Europe. US regulatory review for the product comes under the responsibility of the Centre for Biologics Evaluation and Research (CBER), the specialist biologics division of the FDA.

Dr David Eckland, Research and Development Director of Ark, commented: *"We are very pleased to commence enrolment into the Phase III study for Trinam® which follows the Fast Track Status gained from the FDA earlier this month. There is a significant unmet therapeutic need in this indication and today's news brings us a step closer to gaining approval for a product which we believe will transform the prognosis for many patients suffering from kidney failure."*

Dr Nigel Parker, CEO of Ark, added: *"First patient enrolment is a significant milestone for this very important gene-based medicine and reflects the good progress we continue to make at Ark. Our whole portfolio is growing in strength and we look forward to announcing details of Trinam®'s continued progress in due course."*

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Notes to Editors

Trinam®

Trinam® 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.

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 five marketed devices, Kerraboot®, Kerraped®, Flaminal®, Neuropad® and KerraMax® 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 both 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, where 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 Ylä-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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