ASX / Media Release

Circadian commences first Phase 1 clinical trial of VEGF-C antibody VGX-100 in cancer patients

Melbourne, Australia January 9 2012 – Circadian Technologies Limited (ASX:CIR, OTCQX:CKDXY) announced today that it has commenced the first Phase 1 clinical trial of its fully human monoclonal antibody against VEGF-C, VGX-100, at a leading US-based cancer treatment centre.

The Phase 1 study will examine the safety and tolerability of escalating doses of VGX-100 in patients with advanced solid tumours who have no other standard treatment options both as a monotherapy and also when used in combination with other anti-angiogenic agents. Results from the trial are expected to be available in the second half of 2012.

"We are extremely proud to have completed the translation of VGX-100 from early discovery to the clinical development stage. We are committed to improving outcomes for patients suffering from cancer, and believe that VGX-100, especially when combined with existing therapies could make a significant difference. Commencing clinical trials with VGX-100 is an extremely important achievement for Circadian and a major step in our goal to develop VGX-100 as a new therapeutic agent in the fight against cancer" said Robert Klupacs, CEO of Circadian Technologies Limited.

VGX-100 is a human antibody that acts against the human VEGF-C protein. Treatment for cancers, particularly glioblastoma and metastatic colorectal cancers, are the first target indications for VGX-100. Additionally, Circadian is developing VGX-100 for a number of other cancer indications, as well as an agent to treat front-of the-eye diseases.

Studies in animal model studies across a wide range of tumour types have shown that when combined with Avastin® and/or chemotherapy, VGX-100 can significantly reduce tumour growth and tumour spread as well as significantly improve tumour inhibition over and above that of Avastin® and/or chemotherapy alone. Recent studies have also implicated VEGF-C as a key mediator of disease progression during Avastin® treatment, implying that combination therapy with VGX-100 and Avastin® could significantly improve treatment outcomes in cancer patients.

Circadian's wholly owned subsidiary, Vegenics Pty Ltd, owns worldwide rights to an extensive intellectual property portfolio covering the angiogenesis and lymphangiogenesis targets VEGF-C, VEGF-D and the receptor protein VEGFR-3. Vegenics has also been granted exclusive worldwide rights to intellectual property filed by Schepens Eye Research Institute covering the use of anti-lymphangiogenic molecules for the treatment of Dry Eye Disease.

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About Circadian Technologies Limited

Circadian (ASX:CIR; OTCQX:CKDXY) is a biologics drug developer focusing on cancer and 'front of the eye' disease therapies. It controls exclusive worldwide rights to a significant intellectual property portfolio around Vascular Endothelial Growth Factor (VEGF)-C and -D. The applications for the VEGF technology, which functions in regulating blood and lymphatic vessel growth, are substantial and broad. Circadian's internal product development programs are primarily focussed on developing VGX-100 (a human antibody against VEGF-C) as a treatment for solid tumours, in particular glioblastoma and colorectal cancer, as well as for 'front of the eye' disease such as corneal neovascularisation and/or corneal allograft rejection. Circadian has also licensed rights to some parts of its intellectual property portfolio for the development of other products to ImClone Systems, a wholly-owned subsidiary of Eli Lilly and Company, including the antibody IMC-3C5 targeting VEGFR-3.

About Circadian's pipeline of treatments for cancer

The clinical and 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. However after a short period of time tumors can begin to grow again in the presence of Avastin®. Avastin® is approved by the US FDA in the following indications: metastatic colorectal cancer, non-squamous-cell lung cancer, glioblastoma, and metastatic renal cell carcinoma. In Europe it is approved for the additional indications of ovarian cancer and breast cancer.

The angiogenic receptor VEGFR-2 can also be stimulated by VEGF-C and hence an inhibitor such as VGX-100, a key therapeutic in Circadian's portfolio, can produce greater blockade of this receptor pathway when used in combination with VEGF-A inhibitors. As such, VGX-100 has the potential to block blood vessel growth in tumours which grow despite ongoing Avastin® therapy and hence may completely shut down angiogenesis (the growth of blood vessels) mediated by VEGFR-2.

VEGF-C, along with the molecule VEGF-D, are also the only known proteins to bind and activate VEGFR-3 which drives lymphatic vessel and tumour-associated blood vessel growth. Inhibitors of VEGF-C 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.

Inherent risks of Investment in Biotechnology Companies

There are a number of inherent risks associated with the development of pharmaceutical products to a marketable stage. The lengthy clinical trial process is designed to assess the safety and efficacy of a drug prior to commercialisation and a significant proportion of drugs fail one or both of these criteria. Other risks include uncertainty of patent protection and proprietary rights, whether patent applications and issued patents will offer adequate protection to enable product development, the obtaining of necessary drug regulatory authority approvals and difficulties caused by the rapid advancements in technology. Companies such as Circadian are dependent on the success of their research and development projects and on the ability to attract funding to support these activities. Investment in research and development projects cannot be assessed on the same fundamentals as trading and manufacturing enterprises. Thus investment in companies specialising in drug development must be regarded as highly speculative. Circadian strongly recommends that professional investment advice be sought prior to such investments.

Forward-looking statement

Certain statements in this ASX announcement may contain forward-looking statements regarding Company business and the therapeutic and commercial potential of its technologies and products in development. Any statement describing Company goals, expectations, intentions or beliefs is a forward-looking statement and should be considered an at-risk statement. Such statements are subject to certain risks and uncertainties, particularly those risks or uncertainties inherent in the process of developing technology and in the process of discovering, developing and commercialising drugs that can be proven to be safe and effective for use as human therapeutics, and in the endeavour of building a business around such products and services. Circadian undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise. Actual results could differ materially from those discussed in this ASX announcement.