Ceres Oncology Selected to Present VGX-100 Phase I Clinical Data at ASCO 2014

Ceres Oncology Pty Ltd, a clinical stage biotechnology company and wholly owned subsidiary of Circadian Technologies Limited (ASX: CIR, OTCQX: CKDXY), is pleased to announce that it has been selected to present Phase 1 clinical patient data of VGX-100, its anti-VEGF-C targeted therapy to treat solid tumors, at the American Society of Clinical Oncology’s 50th Annual Meeting, May 30-June 3, 2014, in Chicago, Illinois.

The VGX-100 Phase 1 trial was chosen for presentation as part of a Poster Highlights Session which features selected abstracts of clinical research in the Developmental Therapeutics: Clinical Pharmacology and Experimental Therapeutics Section of the ASCO meeting. The presentations are displayed by topic followed by a discussion session in which clinical oncology experts provide commentary on the research findings. The ASCO 2014 conference will bring together over 25,000 international oncology professionals from a wide range of specialties to review the latest scientific and clinical developments in cancer research. In celebration of ASCO’s 50th anniversary, the 2014 Annual Meeting will highlight the progress made against cancer in the last 50 years while identifying challenges and advances to come in the future.

Dr Gerald Falchook from MD Anderson, Texas, USA, will present the detailed VGX-100 patient data. The Phase 1 oncology clinical trial, run under an Investigational New Drug (IND) program with the Food and Drug Administration (FDA), was conducted at 2 major sites in the USA as a dose escalation study of VGX-100 alone or in combination with bevacizumab (Avastin®). In Q4, 2013 the trial completed enrolment of 43 patients with advanced or metastatic solid tumors as follows:

- 19 patients received weekly intravenous (IV) infusions of VGX-100 at doses ranging from 1–30 mg/kg (Phase 1a);
- Another 24 patients received weekly IV dosing of VGX-100 (2.5-20 mg/kg) in combination with bevacizumab (5 or 10 mg/kg) given IV every two weeks (Phase 1b).

The schedule for the VGX-100 Phase 1 Poster Highlights presentation at ASCO is as follows:

Date / Time: Friday, May 30, 2014, Poster Display 1:00-4:00PM (CT) & Discussion Session 4:30-5:45PM (CT)
Session: Developmental Therapeutics: Clinical Pharmacology and Experimental Therapeutics
Session Type: Poster Highlights Session
Abstract ID: 2524
Title: Phase I study of VGX-100, an anti-VEGF-C monoclonal antibody, with or without bevacizumab, in patients (pts) with advanced solid tumors
Presenter: Gerald Falchook, M.D., (MD Anderson Cancer Center)

The abstract can be found on the ASCO 2014 Annual Meeting website at: http://abstracts.asco.org/ and additional information on the VGX-100 clinical trial (Study ID: NCT01514123) can be found at www.clinicaltrials.gov.

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About Ceres Oncology Pty Ltd

Ceres Oncology Pty Ltd is a 100% owned subsidiary of Circadian Technologies Limited based in Melbourne, Australia. Ceres is developing VGX-100, which is a fully human monoclonal antibody that specifically and potently blocks the activity of vascular endothelial growth factor C (VEGF-C) which is involved in tumour angiogenesis (blood vessel growth), lymphangiogenesis (lymphatic vessel growth) and vascular leakage. By targeting and inhibiting the effects of VEGF-C, VGX-100 may have a broad utility in a range of oncology related disease states characterised by aberrant blood and/or lymphatic vessel growth, vascular leakage or edema, and/or inflammation, including solid tumours and lymphedema.

About Circadian Technologies Limited

Circadian (ASX:CIR; OTCQX:CKDXY)) is developing cancer and cancer related biologic therapies through its subsidiary Ceres Oncology and ophthalmic disease therapies through its subsidiary Opthea. It controls exclusive worldwide rights to a significant intellectual property portfolio around Vascular Endothelial Growth Factor (VEGF)-C and −D and VEGFR-3. 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 include VGX-100 (a human antibody against VEGF-C) for cancer therapy and OPT-302 (soluble VEGFR-3) for ‘back of the eye’ disease including “wet” Age Related Macular Degeneration. Circadian 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 anti-lymphatic antibody-based drug IMC-3C5 targeting VEGFR-3.

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 statements

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.