

Chronocort™ granted second Orphan Medicinal Product Designation by European Commission, for adrenal insufficiency

Diurnal Limited ("Diurnal"), one of Biofusion plc's portfolio companies, announces that the European Commission has granted Orphan Medicinal Product Designation to Chronocort™ for the treatment of adrenal insufficiency ("AI"). This is the second indication for which Chronocort™ has received Orphan Medicinal Product Designation from the European Commission. Orphan Medicinal Product Designation was originally granted in respect of the genetic disorder congenital adrenal hyperplasia ("CAH") in 2005.

The EU Orphan Medicinal Product Designation is intended to promote the development of drugs that may provide significant benefit to patients suffering from rare diseases identified as serious or life-threatening. Under EMEA guidelines, Orphan Medicinal Product Designation provides the sponsor access to free protocol assistance to aid the development of clinical trials, waivers of fees relating to the marketing approval process, centralised registration procedure and ten years of marketing exclusivity once the product is approved for the designated indication in the European Union. Early discussions are now underway with the US Food and Drug Administration ("FDA") to seek equivalent orphan drug designations in the US.

Chronocort™ is being developed by Phoqus Pharmaceuticals Limited ("Phoqus"), a drug delivery company based in Kent, England. This follows the exclusive licencing by Phoqus of a Diurnal patent that relates to delayed and sustained release therapy. Chronocort™ is a modified release tablet containing hydrocortisone for both AI, the failure of the adrenal glands to produce sufficient steroid hormones, and congenital CAH. CAH is a serious genetic disorder caused by the deficiency of an enzyme responsible for cortisol production.

Chronocort™ is designed to provide a new form of corticosteroid hormone replacement therapy by releasing hydrocortisone in a manner that will enable doctors to achieve a daily cycle (circadian rhythm) of cortisol levels in patients that closely matches that of the normal population. This in turn should improve disease symptom control and may also increase the accuracy of the disease treatment and monitoring regimen, potentially reducing the incidence of over or under exposure to steroids.

Planning is underway for the full clinical development programme which includes pivotal pre-registration studies in both CAH patients and patients suffering from AI that are scheduled to commence in the latter half of 2007 in both the EU and the US, subject to regulatory approval. Chronocort™ is currently under evaluation in healthy volunteer studies to confirm its pharmacokinetic profile.

In the EU and US combined there are estimated to be between 78,000 and 206,000 patients with acquired AI (due to conditions such as Addison's Disease and hypopituitarism) and a further 44,000 to 53,000 patients with the genetic disorder CAH.

Phoqus' CEO, Dr. Richard Mason, commented:

"Adrenal insufficiency is a disease of significant unmet therapeutic need and results in patients having a quality of life similar to chronic congestive heart failure. Subject to regulatory approval, we are planning to commence pivotal pre-registration clinical trials for

both adrenal insufficiency and congenital adrenal hyperplasia in the second half of this year, and the orphan drug designation granted by the EMEA will be of great benefit to our clinical programme. Based on reasonable assumptions, we believe that Chronocort has the potential to generate peak annual sales in excess of \$200m from use in these two orphan indications."

Notes to Editors

About Diurnal

Founded in November 2004, Diurnal has already entered into an agreement to develop a tablet that delivers hydrocortisone in a manner that mimics the normal physiological circadian rhythm. This clearly defined rhythm, with high levels in the morning and low levels at night, is lost in patients with adrenal insufficiency. Current therapies are steroid-based, and cannot adequately control the condition, so the Diurnal management team believes that their product should offer a much needed improvement in treatment for patients with congenital adrenal hyperplasia.

This product is being developed by Phoqus, a UK drug delivery company, which has an exclusive licence of the 'delayed and sustained release therapy' patent. In 2005 Diurnal received Orphan Medicinal Product designation for this product from the European Medicines Agency, which affords 10 years of market exclusivity after the grant of a marketing authorisation in Europe. The product has successfully completed Phase 1 clinical studies.

Diurnal anticipates that the new product will provide a more efficacious therapy, with improved compliance from patients.

About Biofusion

Biofusion was established in 2002 to commercialise university-generated IP. Biofusion has signed long term agreements with two of the UK's top ten research intensive universities (University of Sheffield and Cardiff University) giving a combined R&D spend attributable to Biofusion of approximately £114 million a year.

Biofusion's first agreement was a ten-year exclusive arrangement with the University of Sheffield for the commercialisation of IP owned by the University in the area of medical life sciences. Biofusion has shareholdings in a portfolio of 18 Sheffield University spin-out companies including Asterion, Axordia, Celltran, Lifestyle Choices, Diurnal and Phase Focus. The University of Sheffield was ranked 5th in the UK for the quality of its life sciences research and will be spending an estimated £0.5bn of research funding over the lifetime over the life of the Sheffield Agreement.

In January 2007, Biofusion completed a long-term exclusive agreement with Cardiff University, to commercialise 100% of all Cardiff University's research-generated IP. Biofusion has shareholdings in a portfolio of seven Cardiff University spin-out companies including Abcellute, Q-Chip and Cardiff Protides. Cardiff University was ranked 7th in the UK in the most recent research rankings and will be spending over £1.0bn of research funding over the lifetime over the life of the Cardiff Agreement.

Further background on the Company can be found at www.biofusion.co.uk.

About Phoqus

Phoqus is an oral drug delivery and development company. It creates new therapeutic products for both in-house and collaborative development programmes using its proprietary electrostatic powder coating technology, LeQtracoat®. This technology provides Phoqus with an extensive range of innovative drug delivery systems that are applied to pharmaceuticals to provide benefits such as controlling the release of a drug into the body, enhancing patient compliance and improving the performance and efficacy of an existing drug. In turn, these benefits enable the development of new products that better meet the unmet medical needs of patients. They can also allow pharmaceutical companies to extend the life cycles of their products, strengthen their patent protection and thereby enhance the value of their marketed products and development pipelines. Phoqus is the only company using electrostatic powder coating technology for pharmaceutical applications and has over 120 granted patents.

Based in Kent, Phoqus was established in 1998 as a spin-out from Colorcon, a division of Berwind Pharmaceutical Services Inc. The Company was admitted to trading on AIM in November 2005 and is listed under the symbol "PQS".

Further background on the Company can be found at www.phoqus.com.