

BIOFUSION plc

DIURNAL RECEIVES EMEA ORPHAN MEDICINAL PRODUCT DESIGNATION FOR A NOVEL THERAPY FOR CONGENITAL ADRENAL HYPERPLASIA

Diurnal Limited ("Diurnal"), a Sheffield -based medical therapeutics Biofusion portfolio company, today announced it has received Orphan Medicinal Product designation for a modified release hydrocortisone tablet for the treatment of congenital adrenal hyperplasia. This product 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.

Orphan Medicinal Product designation affords 10 years market exclusivity after the grant of a marketing authorisation in Europe. Other benefits include protocol assistance, access to the centralised procedure for the application for marketing authorisation and fee reductions. The Directors' believe that the global market for this product is estimated to be worth £100m. The product is expected to enter human studies in Q4 2005.

The tablet formulation developed by Phoqus will allow for the controlled and sustained release of hydrocortisone, a steroid normally released from the adrenal gland, in a manner which mimics the normal physiological circadian rhythm. This marked rhythm, with high levels in the morning and low levels at night, is lost in patients with adrenal insufficiency. The Diurnal management believe that their product will offer a potential much needed improvement in steroid treatment for patients with congenital adrenal hyperplasia, a form of adrenal insufficiency. Current therapies cannot adequately control the condition and Diurnal anticipates that the new product will provide a more efficacious therapy with improved compliance from patients.

Diurnal also intends to explore additional opportunities in areas in which steroid levels may be implicated in other diseases such as inflammatory conditions.

Professor Richard Ross of Diurnal said: "Orphan Medicinal Product designation is a great boost for our development of modified released hydrocortisone and recognition of the potential of the product to benefit sufferers of this rare but serious condition."

David Baynes, CEO of Biofusion, said: "This is excellent news for Diurnal allowing the company to push ahead with its development plan, which includes tests in humans by the end of this year. The company will benefit from guidance given by the EMEA in its development plan and we look forward to working with Diurnal and Phoqus in progressing this product to the market as quickly as possible.

"This is an exciting time for Biofusion as we are starting to see the value and potential of Sheffield's world class IP."

Andy Jones, CEO of Phoqus, said: "This is an exciting opportunity to apply Phoqus' innovative Qtrol™ controlled release technology to develop a product that will benefit patients through simplified dosing regimens and reduced side effects."

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About Biofusion

Biofusion was established in 2002 to commercialise university-generated IP. In February 2005 Biofusion listed on Aim and raised £8.2m for the commercialisation of IP owned by the University of Sheffield in the area of medical life sciences. It has agreed a ten-year exclusive arrangement with the University which also gives Biofusion shareholdings in an existing portfolio of eight spin-out companies. The University of Sheffield is a world class life sciences research centre, spending £30m in 2002/3 on research in medical life sciences. This spending level is expected to grow year on year giving an estimated £0.5bn of research funding over the next ten years. The University, which celebrates its centenary this year, can count five Nobel Prize winners among its alumni and researchers, and data from the latest UK Government's Research Assessment Exercise 2001 ("RAE 2001") showed it ranked fifth in the UK for the quality of its life sciences research.

About Diurnal

Founded in 2004, Diurnal seeks to develop means for the controlled and sustained release of steroids and intends its first product to be based on the delivery of hydrocortisone, in a manner which mimics the circadian rhythm.

The initial target patient group suffer from congenital adrenal hyperplasia, which is a defect in the production of cortisol from the adrenal gland, where the adrenal gland produces too much male hormone. Subsequent complications include ambiguous genitalia, precocious puberty, short stature, infertility and testicular tumours. Current steroid therapy for this condition does not mimic the natural circadian rhythm of the target steroid. Diurnal believes that it is, therefore, appropriate that a circadian rhythm of hydrocortisone, through a delayed and sustained-release hydrocortisone tablet, would be a more effective, and much needed, treatment.

Diurnal also intends to explore additional opportunities for new indications in areas in which cortisol levels may be implicated in other diseases (such as inflammatory conditions).

The company is a spin-out from the University of Sheffield, and is a Biofusion portfolio company in which Biofusion now has a fully diluted shareholding of 60%.

About Phoqus

Phoqus Pharmaceuticals Ltd. (www.phoqus.com) is a leading-edge drug delivery company dedicated to the development of innovative and patent-protected drug delivery systems. Phoqus has pioneered a unique technology based on the same electrostatic deposition principle used in photocopying for coating and loading of active drug compounds onto the surface of tablets for oral delivery. Phoqus holds multiple patents on its technology and provides clients with a comprehensive drug delivery service, from formulation, feasibility studies and development programs, through to clinical trials manufacture. The company is headquartered in West Malling, United Kingdom.