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### **Diurnal Completes Successful Phase I Clinical Study on Chronocort**

Biofusion plc ("Biofusion" or the "Company") (AIM:BFN) announces that its subsidiary Diurnal Limited ("Diurnal"), in collaboration with Phoqus Group plc ("Phoqus") has successfully completed the Phase I clinical trials programme on Chronocort - the first Circadian endocrine treatment for adrenal insufficiency.

In line with the collaboration's current strategy, Phoqus plans to license the product, later in 2006, to a marketing partner to complete the development and launch the product. Chronocort already has orphan medicinal product designation in the EU and Phoqus directors believe a product could be launched on the market in the period 2008-2009.

Results from the study showed that Chronocort released drug and generated blood levels of hydrocortisone which closely mirrored natural levels of hormone seen in healthy individuals. This indicates that Chronocort may be a valuable therapeutic tool for the treatment of adrenal insufficiency where cortisol levels are abnormally low. Additionally, Chronocort showed a correlation between in-vitro hydrocortisone release and in-vivo blood levels observed in the subjects following oral administration. The study also showed that Chronocort was well tolerated, with no treatment-related adverse events being reported.

The Phase I trial involved healthy volunteers who had their natural cortisol hormone production suppressed and were then dosed with Chronocort. The objectives of the study were firstly to evaluate the ability of Chronocort to release hydrocortisone in the blood in a way that mimics natural circadian hormone release and secondly to demonstrate a correlation between in-vitro hydrocortisone release and in-vivo blood levels observed following oral administration.

The Diurnal collaboration with Phoqus was set up to develop Chronocort, a once-daily modified release hydrocortisone tablet for the treatment of adrenal insufficiency, a condition which causes Addison's disease, hypopituitarism and congenital adrenal hyperplasia. Current steroid therapies for these conditions do not mimic the natural circadian rhythm of the endogenous steroid hormone, creating an unmet need in the annual worldwide market worth in excess of £75 million. Phoqus believes that the Chronocort tablet would address this need effectively and provide a much needed treatment.

Under the terms of the Diurnal agreement, Phoqus is supplying the tablets for the drug, which has already obtained orphan medicinal product designation in the EU.

David Baynes, CEO of Biofusion, said:

*"This is excellent news for Diurnal. The company continues to meet its milestones for the development of this product and we look forward to working with Diurnal and Phoqus in progressing this product to the market as quickly as possible."*

Andy Jones, Chief Executive Officer of Phoqus, commented:

*"We are delighted that Chronocort has successfully completed this Phase I trial. The study has clearly demonstrated that our technology allows the modified release of the drug into the patient in a way that mimics natural hormone release. These results will form the basis of the next phase of development and allow us to seek a marketing partner for the product."*

Professor Richard Ross, Managing Director of Diurnal, said:

*"I am delighted with the results which confirm our belief that a delayed and sustained formulation of hydrocortisone can mimic the natural levels of this steroid in man. As a clinician, I find it very satisfying that patients who suffer from a lack of cortisol could have the potential to be treated more effectively for this rare but serious condition."*

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**Notes to editors**

**About Diurnal**

Founded in 2004 Diurnal is a spin-out company from the University of Sheffield and is backed by majority shareholder Biofusion, an AIM listed company founded in 2002 to commercialise university intellectual property. Diurnal seeks to develop means for the controlled and sustained release of steroids in a manner which mimics the 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 the product being developed in partnership with Phoqus will offer a potential much needed improvement in steroid treatment for patients with congenital adrenal hyperplasia, a form of adrenal insufficiency.

**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 celebrated its centenary last 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. Biofusion is listed on AIM under the symbol "BFN".

Further Information on Biofusion can be found at [www.biofusion.co.uk](http://www.biofusion.co.uk)

**About Phoqus**

Phoqus is a drug delivery company using proprietary electrostatic powder coating technology, LeQtratoat<sup>®</sup>, to provide an extensive range of innovative systems targeting the oral drug delivery market. Drug delivery technologies 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 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.

In addition, the Company has developed its coating technology to create novel images on drug tablets as a means of brand enhancement and protection against counterfeiting.

Phoqus is the only company using electrostatic powder coating technology for pharmaceutical applications and has over 120 granted patents.

To assist the delivery of its strategy, Phoqus has entered into a strategic partnership with Cardinal Health, the world's largest supplier of services to the healthcare industry, to provide commercial scale GMP manufacturing to collaboration partners. Cardinal Health also co-markets Phoqus' drug delivery and image enhancement systems in all major markets.

Phoqus, based in Kent, 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 raising £10m and is listed on AIM under the symbol "PQS".

Further background on the Company can be found at [www.phoqus.com](http://www.phoqus.com).