



Sinclair Pharma Plc Announces First Ophthalmology Product Approval and Two Further Product Approvals

Godalming UK, 12 July 2006: Sinclair Pharma plc ("Sinclair" or the "Company") (SPH.L), the specialty pharmaceutical company focused on the acquisition and development of patented pharmaceutical products, today announces EU regulatory approval for a new ophthalmology product for dry eye syndrome and two new line extension products in their key therapeutic areas of oral health and dermatology.

The following products have been approved in the EU:

SPHP700 will address the prescription market for dry eye. It has been approved as a Medical Device Class I (sterile).

SPHP700 will offer a new approach to relieving the symptoms of dry eye, that are experienced by as many as 30% of the over 65s. It contains a specific polysaccharide that is able to bind large quantities of water and designed to deliver moisture to the eye surface for fast and prolonged symptom relief.

The current market leader in prescription dry eye products in the US achieves sales of \$100m. Sinclair's product will be commercialized through marketing partners in key territories; licensing discussions will start in the second half of the current financial year.

Decapinol[®] Spray is a new presentation of Sinclair's gingivitis product Decapinol[®] Rinse, which is already approved in the EU and USA. Decapinol[®] Spray is now approved in the EU as a Medical Device Class IIa. This new presentation offers a convenient alternative to the oral rinse. Two other Decapinol[®]-containing products, Decapinol[®] Gel and Decapinol[®] Toothpaste have already been approved in the EU and have been filed for approval in the USA. Further presentations of Decapinol[®] are in development.

Decapinol[®] Rinse is on sale in Italy and Spain. In the USA, Johnson & Johnson's oral health subsidiary, OraPharma Inc., will be launching Decapinol[®] Rinse as a prescription product following their recent appointment as US licensees. Launch is expected within the next twelve months.

Sinclair believes that Decapinol[®] is the first new product class to enter the gingivitis market for several decades. It is an award-winning, patented product with a new mode of action for the treatment of gingivitis (gum inflammation) and dental plaque, and for the prevention of periodontitis (a severe form of gum disease causing tooth loss).

With approximately 80 per cent of the adult population estimated to have some degree of gum inflammation, Decapinol[®] addresses a large and growing market, estimated at more than \$1.5bn¹.

Atopiclair[™] Fluid is a new presentation of Sinclair's dermatitis product Atopiclair[™]. It is designed for those with large areas of skin affected by dermatitis, with a lower viscosity for easier application. Atopiclair Fluid will complement Atopiclair[™] cream, an effective, steroid-free product that has been shown to relieve the signs and symptoms of atopic dermatitis (eczema) and irritant contact dermatitis. Atopiclair fluid is now approved in the EU as a Medical Device Class IIa.

¹ Piper Jaffray Analyst report



Atopiclair™ cream is already on the market in the US (Chester Valley Pharmaceuticals Inc.), Spain and Portugal, and is also sold in Italy by Sinclair's own sales force.

Atopic dermatitis is one of the most common dermatological complaints; it is estimated to affect 1-3% of adults and up to 20% of school aged children. The sector of the market in which Atopiclair™ competes is estimated at \$1.9bn in 2004, having grown at 11% since the year before.

Dr Michael Flynn, Chief Executive of Sinclair Pharma Plc, said today "We are pleased to have achieved our first approval in the area of ophthalmology, a therapeutic area that is important to us in the future. We believe that SPHP700 is well-differentiated from existing prescription dry eye products and are confident that it will be an important product for the company. The EU approval of Decapinol® spray and Atopiclair™ fluid will allow us to make further inroads into these two important markets."

-ends-

For further information please contact:

Sinclair Pharma plc

Dr Michael Flynn, CEO
John Barrington-Carver, Corp. PR
Mike Killeen, US

Tel: +44 (0) 148 342 6644
Tel: +44 (0) 207 351 3409
Tel: +1 972 478 4380

Financial Dynamics

Ben Atwell
John Gilbert

Tel +44 (0) 207 831 3113

Notes to Editors

About Dry Eye Syndrome.

Tears are nature's lubricant and also provide protection against some forms of infection and inflammation in the eye. Dry eye syndrome occurs when the quality or quantity of tears is impaired. This commonly is seen in older ages. Dry eye syndrome leading to a clinical diagnosis or severe symptoms is prevalent, affecting over 3.2 million American women middle-aged and older.² including 5.7% of the over 50s and 9.8% of the over 75s³

About Decapinol®

Gingivitis is an inflammation of the gum surrounding the teeth. Periodontitis is a more advanced and severe condition that may result in bone or tooth loss. Both conditions are associated with dental plaque bacteria.

Current treatment of gingivitis may involve the use of an oral rinse, alongside 'scaling and planing' (mechanical cleaning of the teeth by a dental professional).

Decapinol® has a new mechanism of action that offers an 'intelligent' way to treat gingivitis. It acts at the interface between dental plaque bacteria and the surface of the tooth/gum – the starting point for all gingivitis. Decapinol® prevents the bacteria that cause gingivitis from adhering to these surfaces and to one another. This adhesion is essential for the bacteria to cause the

² Schaumberg DA. Am J Ophthalmol 2003 Aug;136(2):318-26. Prevalence of dry eye syndrome among US women

³ Schein OD. Arch Intern Med 1999 Jun 28;159(12):1359-63. Dry eye and dry mouth in the elderly: a population-based assessment.



disease and if it is prevented it allows the desirable bacteria responsible for maintaining a healthy mouth to dominate again. This softens dental plaque, making it easier to remove, and prevents its re-formation. It therefore promotes better gum health and clinical studies have shown that Decapinol[®] significantly reduces gingivitis.

Decapinol[®] has advantages over existing products, which may cause semi-permanent tooth staining or have high alcohol content. While other leading products work by killing oral bacteria indiscriminately, Decapinol[®] specifically targets the 'bad' bacteria associated with gum disease. Decapinol[®] therefore promotes a healthy balance of oral bacteria.

In March 2006, Decapinol[®] Oral Rinse was awarded the 2006 Oral and Dental Care Product of the Year by Frost & Sullivan in the US.