



SINCLAIR PHARMA FILES FOR DECAPINOL® 510(K) APPROVAL IN THE USA

Company also signs Marketing Agreements for SST™ and Aloclair™ Spray

Godalming UK, 16 June, 2004: Sinclair Pharma plc, the British pharmaceutical company developing novel patented products in niche markets, today announces that it has applied for 510(k)¹ approval for Decapinol®, its oral rinse for the treatment and prevention of gingivitis. Decapinol® was designated as a medical device by the US Food and Drug Administration ("FDA") in April 2004. Successful 510(k) approval, which can take from between 3 to 12 months, will allow the product to be marketed in the US. In addition, the Company also announces today that it has signed marketing agreements for SST and Aloclair Spray.

Filing for Decapinol® 510(K) approval in the USA

Gingivitis is an inflammation of the gums caused by an accumulation of bacteria within the dental plaque. Gingivitis may progress to periodontitis, where there is loss of attachment between the teeth and surrounding bone. Eventually teeth may be lost. Approximately 80² per cent of the US adult population are estimated to have some degree of gum inflammation which may lead to periodontitis resulting in gum recession and loss of teeth.

Decapinol® interferes with the adherence and aggregation of dental plaque to the gum. Clinical studies in more than 2,500 subjects have shown significant improvements in gingivitis, exceeding the level required by the American Dental Association for gingivitis control agents. Clinical studies also found an overall significant reduction in the amount of dental plaque.

Products for gingivitis control are frequently based on chlorhexidine which works by killing the oral bacteria. Chlorhexidine causes tooth staining that may need removal by a dentist; this effect is not seen with Decapinol®. In addition the antibacterial effect of chlorhexidine may disrupt the natural balance of beneficial oral microorganisms. In contrast Decapinol® acts as a barrier to bacterial adherence on the teeth and gums, and facilitates plaque removal and an improvement in gum health. This mechanism enhances the natural balance of oral bacteria.

In Europe, Sinclair have also submitted data on Decapinol® early this year to the Swedish Authorities in connection with its application for registration in Sweden.

Sinclair Chief Executive Dr Michael Flynn commented: "Since acquiring Biosurface AB in November 2002 and with it Decapinol®, Sinclair has applied for and received device designation for Decapinol® in the USA. This filing for 510(k) approval is the next step towards commercialisation of this new type of product. We believe Decapinol® will be the first new chemical entity for the treatment of gingivitis for 30 years and we believe it has much to offer in the management of oral diseases – in particular gingivitis and periodontitis."

¹ Medical device manufacturers are required to submit a pre-market notification or 510(k) to the FDA if they intend to introduce a device into commercial distribution in the US for the first time.

² Hugoson A, Laurell L, Lundgren D. Frequency distribution of individuals aged 20-70 years according to severity of periodontal disease experience in 1973 and 1983. J Clin Periodont 1992;19:227-232 Stephen J. *Gingivitis – a review article.*

At: <http://www.emedicine.com/emerg/topic217.htm>



Marketing agreements for SST and Aloclair Spray

Progressing its strategy of securing international licensing agreements for its products, Sinclair has signed a licensing agreement for the UK market with the German oncology specialist company Medac GmbH for the marketing of Sinclair's product SST™ for the treatment of xerostomia, (a dry mouth condition due to insufficient saliva production). Xerostomia may occur as a complication of radiotherapy for head and neck cancer, chemotherapy and a number of other mechanisms. Medac's UK affiliate Medac UK will carry out the marketing in the UK.

Sinclair has also signed its first agreement for its mouth ulcer line extension product Aloclair™ Spray with the Israeli company C.T.S. LTD for distribution in Israel. Sinclair has a strong commitment in oral health and is now in discussions for the international licensing of its line extension Aloclair™ Spray for mouth ulcers. The agreement with CTS for Israel is the first to be concluded with this new (line extension) product which the Company expects to have launched internationally over the coming 12 months.

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Notes to Editors

Sinclair Pharma plc is an international pharmaceutical company focused on the acquisition and development of niche patented products in the fields of oral health, oncology support and dermatology and brings them to the international market place. The Company combines product evaluation, product development, regulatory and business development expertise to add value to its acquired and in-house developed products. A key element of the Sinclair business model is to reduce risk and exposure by avoiding involvement in lengthy R&D programmes and rapidly achieving global distribution through a network of marketing partners. The Company has already licensed distribution in over 40 countries for some of its products

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