



## **Sinclair Pharma Decapinol<sup>®</sup> recognised as medical device by FDA**

**Godalming UK, 28 April 2004:** Sinclair Pharma plc, the British pharmaceutical company developing novel patented products in niche markets, today announces that Decapinol<sup>®</sup>, an oral rinse for the treatment and prevention of gingivitis and periodontitis, has been designated as a medical device by the US Food and Drug Administration ("FDA"). The next step is to file for registration of the device so that it can be marketed in the USA.

Decapinol<sup>®</sup> is an oral rinse intended for the treatment and prevention of gingivitis and periodontitis. 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 60 per cent of the US adult population are estimated to have some degree of gum inflammation.

Decapinol<sup>®</sup> 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<sup>®</sup>. In addition the antibacterial effect of chlorhexidine may disrupt the natural balance of oral microorganisms. In contrast Decapinol<sup>®</sup> acts by interfering with bacterial adherence to the teeth and gums, facilitating plaque removal and an improvement in gum health. This mechanism does not disrupt the natural balance of oral bacteria.

Chlorhexidine currently achieves sales of more than \$100m in the US, Japan and major EU markets. Several other popular mouthwash brands contribute to a much



larger total market size. The Company believes there is substantial market potential for a new product with good efficacy and a novel mode of action.

Dr Michael Flynn, CEO of Sinclair Pharma, commented: "We have expended considerable effort evaluating Decapinol<sup>®</sup> and consulting with advisors concerning the most appropriate regulatory pathway. We are very pleased that the FDA has designated Decapinol<sup>®</sup> as a medical device. This is a significant step for us as it may reduce the timeframe for Decapinol<sup>®</sup> to become available for sale in the USA."

### **Enquiries:**

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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 the Group's products.

"Safe Harbor" Statement under the US Private Securities Litigation Reform Act of 1995: Some or all of the statements in this document that relate to future plans, expectations, events, performances and the like are forward-looking statements, as defined in the US Private Securities Litigation Reform Act of 1995. Actual results of events could differ materially from those described in the forward-looking statements due to a variety of factors."

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