



**SINCLAIR PHARMA PLC**  
**ALOCLAIR® SPRAY RECEIVES FDA 510(k) APPROVAL**

**Godalming UK, 24<sup>th</sup> January, 2005:** Sinclair Pharma plc (“Sinclair” or the “Company”) (SPH.L), the specialty pharmaceutical company focused on the acquisition and development of patented pharmaceutical products, announces today that Aloclair® Spray, an OTC product for the treatment of mouth ulcers, has received approval from the FDA as a medical device.

Aloclair® now has three delivery systems – an oral rinse solution, an oral gel which is more suitable for children) and the oral spray. In the previous financial year the Aloclair® rinse and gel increased revenues by 150% to £1.8 million. The Aloclair® oral rinse is already approved in the US and Europe and is currently being marketed OTC by - Sunstar Butler, in the US and some major EU countries. Aloclair® gel also has EU and US regulatory approval and is being marketed by Sunstar Butler in various countries and by Recordati (Srl) in Italy.

Aloclair® spray was registered in 2004 in the EU and will be launched in this financial year in the first markets. Aloclair® spray provides a controlled application of the soothing formulation in a mobile, easy to use package designed for moments when rinsing with the Aloclair® solution is not an option.

The global mouth ulcers market is estimated to be worth more than \$1 billion per annum. TNS market research conducted for Sinclair indicates that 16% of the adult population get an oral ulcer over a 12 month period and 64% of that population seek pain relief with a medication. That research translates to a user base of over 100 million adults in the EU and US.

Dr Michael Flynn, CEO of Sinclair, commented: “Aloclair® is Sinclair’s biggest product at present and the addition of the spray formulation provides a range of delivery mechanisms which cover most situations for treatment of mouth ulcers. We are expanding the range of countries where Aloclair® can be sold in its various forms and are particularly pleased that this latest approval in the US will assist our partners to capture further market share and help us to establish a global brand for the treatment of this common condition.”

**Enquiries:**

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**Notes to editors:**

**Sinclair Pharma plc**

Sinclair Pharma plc based in Godalming in the UK, is quoted on the Alternative Investment Market (AIM) on the London Stock Exchange and has focused on the acquisition and development of niche patented pharmaceutical products in the fields of oral health, oncology support and dermatology, and bringing them to the international market place via out-licensing partners. 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 minimise 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 its products for distribution in over 40 countries around the world.

On 4<sup>th</sup> January 2005 Sinclair announced its first Decapinol® deal with Dompe SA for the Italian market in an agreement involving almost 1.5 million Euros in upfront and milestone payments and a supply agreement with minimum purchase obligations.

"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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