

# Press Release

## **ProStrakan Group plc**

### **Rapinyl Receives Swedish Marketing Authorisation**

Galashiels, Scotland, 7<sup>th</sup> March 2008 – ProStrakan Group plc (LSE: PSK), the international specialty pharmaceutical company, announces that it has received Marketing Authorisation in Sweden for Rapinyl (to be branded as Abstral in Sweden).

Rapinyl is a fast-dissolving tablet for sub-lingual administration of fentanyl intended for the treatment of breakthrough cancer pain for which ProStrakan has in-licensed exclusive rights in Europe from Orexo AB.

Sweden is the Reference Member State (RMS) for the wider EU Regulatory filing of Rapinyl and has taken the decision to issue a Marketing Authorisation for Sweden alone based on its Assessment Report made as RMS for the EU regulatory procedure.

ProStrakan expects that the wider EU regulatory procedure will complete during 2008. Meanwhile, the Company anticipates launching the product, branded as Abstral, in Sweden in Q3 2008. Abstral will be marketed there through ProStrakan's joint venture with Orexo AB, which operates in the Nordic countries.

Commenting on today's development, Dr Wilson Totten, Chief Executive of ProStrakan, said:

“The Swedish Regulatory Authority's decision to issue a Marketing Authorisation for Rapinyl (Abstral) while the EU regulatory procedure is still under way underlines their continued support for Europe-wide approval of this product.”

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Notes to Editors:

ProStrakan

ProStrakan Group plc is a rapidly growing international specialty pharmaceutical company engaged in the development and commercialisation of prescription medicines for the treatment of unmet therapeutic needs in major markets.

ProStrakan's head office and development facilities are situated in Galashiels in Scotland. EU-wide sales and marketing of ProStrakan's portfolio of products are handled by commercial subsidiaries in the UK, France, Germany, Spain and other EU countries. ProStrakan has recently announced plans to expand its operations into the US. [www.prostrakan.com](http://www.prostrakan.com)

Rapinyl

This product is a new formulation of fentanyl, a long-established opioid used for the management of episodes of severe breakthrough pain experienced by cancer patients who are already receiving opioid analgesics for their chronic pain.

This product has completed the EU Decentralised Procedure (DCP) where a consensus is required to achieve approval. Of the 25 Concerned Member States, 21 expressed a positive opinion and the application has therefore been referred for review by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA), where a majority decision is sufficient to gain approval. The Company expects that EU approval will be achieved in 2008.