

# Press Release

## **F.D.A. Approves SANCUSO<sup>®</sup>, the First and Only Patch for Preventing Nausea and Vomiting in Cancer Patients Undergoing Chemotherapy**

Patch Provides Five Days of Continuous Control for Highly Feared Side Effect of Chemotherapy

Expert Urges "Zero Tolerance" to Avoid Missed Treatments

**BEDMINSTER, N.J., September 15, 2008** – ProStrakan Group plc (LSE: PSK) today announced the U.S. Food and Drug Administration (F.D.A) approval of SANCUSO<sup>®</sup> (Granisetron Transdermal System), the first and only patch to provide up to five consecutive days of control of nausea and vomiting for patients receiving a moderately and/or highly nausea-inducing chemotherapy regimen.

Chemotherapy-induced nausea and vomiting (CINV) are commonly cited by patients undergoing chemotherapy as highly feared side effects. In addition to its social and emotional effects, if left untreated, CINV can lead to dehydration, malnutrition, treatment delay, or even discontinuation of treatment.

"We've made significant progress in our understanding of chemotherapy and how to prevent its side effects, yet undergoing chemotherapy remains a challenging experience on many levels," said Barbara Rogers, CRNP, MN, AOCN, Adult Hematology-Oncology Nurse Practitioner, Fox Chase Cancer Center. "We should have zero tolerance for CINV. A patch that can be applied before treatment, releasing medication consistently into the bloodstream over a number of days, has the potential to impact patient comfort and quality of life."

Despite advances in treatment, CINV remains a significant issue. Some patients expect to endure unpleasant symptoms in order to continue chemotherapy and

may suffer at home while not under the supervision of a health-care professional. With one application of Sancuso, patients receive up to five consecutive days of CINV treatment.

“When my doctor told me I would need chemotherapy, my first reaction was to wonder how the treatment would affect my life,” said Melvin Hren, a participant in the Sancuso clinical trial, whose tumour originated from his thymus gland. “But the patch helped alleviate my fears of some of chemotherapy’s side effects. It didn’t interfere with my daily activities, and I was able to complete my cancer treatment without feeling nauseous and sick.”

### **Clinical Result: Continuous and Reliable CINV Control**

Sancuso is a transdermal system, or skin patch, that delivers granisetron, its active component and an established inhibitor of nausea and vomiting, through a thin layer of adhesive that attaches the patch to the skin. The medicine is then released slowly and continuously into the bloodstream for up to five consecutive days.

The F.D.A. approved Sancuso for the prevention of CINV based on the results of a multicenter Phase III randomized, double-blind, double-dummy controlled study comparing the efficacy, tolerability and safety of Sancuso with once-daily oral granisetron (2 mg). The trial enrolled 641 patients who received moderately or highly nausea-inducing multi-day chemotherapy, and met its primary endpoint of achieving complete control of CINV, working as well as oral granisetron. Complete control was defined as no vomiting and/or retching, no more than mild nausea and no rescue medication from first administration of Sancuso until 24 hours after the last day of chemotherapy.

Sancuso was generally well-tolerated by patients in clinical trials. Adverse reactions considered drug-related by investigators occurred in 8.7 percent of patients receiving Sancuso. The most common drug-related adverse reaction was constipation. Application site reactions were reported but were mild and did not lead to discontinuation of use. The incidence of skin reactions was comparable to placebo.

## **Product Approval Introduces ProStrakan Inc.**

F.D.A. approval of Sancuso marks the official introduction of ProStrakan Inc. in the U.S. The company is also working with regulatory authorities to bring Sancuso to market in Europe. An international pharmaceutical organization, ProStrakan has introduced a range of products in a number of EU territories.

“ProStrakan was founded on a commitment to developing innovative products to better meet the needs of patients,” said company CEO Wilson Totten, MD. “We believe that Sancuso, used within an individualized approach to therapy, can help lift the burden that CINV can have on both patients and health-care providers.”

As part of the company’s commitment to better meeting the needs of patients, ProStrakan has developed a patient assistance program to ensure that Sancuso is available to any qualified patients who would benefit from it.

In order to strengthen the U.S. portfolio of the company, ProStrakan has partnered with NovaQuest, the managed partnership group of Quintiles Transnational, to recruit a 67-person sales force to commercialize ProStrakan’s products in the U.S., including Sancuso.

## **Important Safety Information About SANCUSO<sup>®</sup>**

Sancuso is contraindicated in patients with known hypersensitivity to granisetron or to any of the components of the patch.

Granisetron may mask a progressive ileus and/or gastric distention caused by the underlying condition. Mild application site reactions have occurred; remove patch if severe reactions or a generalized skin reaction occur. Patients should avoid direct exposure of application site to natural or artificial sunlight by covering with clothing while wearing the patch and for 10 days after removing it.

The most common adverse reaction is constipation. No clinically relevant drug interactions have been reported in clinical studies with Sancuso.

## **About ProStrakan**

ProStrakan is one of Europe’s fastest growing pharmaceutical companies, with new U.S. headquarters in Bedminster, New Jersey. ProStrakan is committed to

developing innovative therapies to improve the lives of patients. Our current products range from cancer, women's health, men's health, anesthesiology, and cardiovascular disease. For more information on ProStrakan, please visit [www.ProStrakan-USA.com](http://www.ProStrakan-USA.com).

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