Press Release

ProStrakan Acquires Breast Cancer Product for the US

Galashiels, UK - ProStrakan Group plc ("ProStrakan") announces today (1st October, 2012) that it has acquired exclusive US commercial rights to Fareston® (toremifene citrate) for the treatment of metastatic breast cancer in postmenopausal women.

Fareston is a selective oestrogen receptor modulator ("SERM") indicated for the treatment of metastatic breast cancer in postmenopausal women with oestrogen receptor-positive("ER+ve") or unknown tumours. Fareston is available in a once-daily 60mg oral tablet.

ProStrakan, which is a subsidiary of global specialty pharmaceutical company, Kyowa Hakko Kirin Co. Ltd. ("KHK"), has entered into an Asset Purchase Agreement with US-based biopharmaceutical company, GTx Inc. ("GTx"), to acquire GTx's rights to market, distribute and sell Fareston in the US. Orion Corporation ("Orion"), the Finnish corporation that developed toremifene will continue to manufacture and supply Fareston for the US market under an exclusive Licence and Supply Agreement executed between ProStrakan and Orion. ProStrakan has paid GTx a lump sum of US$21.7m to acquire the exclusive US rights to Fareston and related assets.

ProStrakan's acquisition of Fareston for the US market is in line with a strategic focus on the therapeutic areas of oncology, nephrology and immunology shared with its parent company, KHK. ProStrakan plans to commercialise Fareston through its existing US sales force, who already promote two other ProStrakan products to oncology specialists - Sancuso® (Granisetron Transdermal System), for the prevention of chemotherapy-induced nausea and vomiting, and Abstral® (fentanyl) sublingual tablets for the treatment of

breakthrough cancer pain in adults with cancer who are already routinely taking other opioid pain medicines around the clock for cancer pain.

There are nearly 230,000 new cases of breast cancer in the US annually.[1] Approximately 70% of those patients have ER+ve tumours and may receive a combination of surgery, chemotherapy, radiotherapy and hormonal therapy.[2] In the US, an estimated 30% of women initially diagnosed with earlier stages of breast cancer subsequently develop metastatic disease.[3] These patients routinely receive hormonal therapy if they have ER+ve tumours, the majority of which are treated with either a SERM or an aromatase inhibitor. Fareston is one of only two SERMs approved by the FDA for the treatment of metastatic breast cancer in postmenopausal women and recommended in the National Comprehensive Cancer Network guidelines.[3]

Dr Tom Stratford, Chief Executive of ProStrakan, said:

“Fareston fits our strategic oncology focus in the US and serves an important group of breast cancer patients and their oncologists who may be seeking an alternative option to their current hormonal therapy. Our US sales force is already calling on these oncology specialists with our anti-emetic patch, Sancuso, and Fareston will be an excellent complement to our promotional efforts.”

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Notes to Editors
About ProStrakan

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

ProStrakan is a subsidiary of Kyowa Hakko Kirin Co. Ltd., the Japan-based global specialty pharmaceutical company.

ProStrakan's head office is located in Galashiels in Scotland. The company's development capabilities are centred in Galashiels and Bridgewater, New Jersey, USA. Sales and marketing of ProStrakan's portfolio of products are handled by commercial subsidiaries in the UK, US, France, Germany, Spain, Italy and other EU countries.

You can learn more about the business at: www.prostrakan.com

About Orion Corporation

Orion is a globally operating Finnish company developing pharmaceuticals and diagnostic tests – a builder of well-being. Orion develops, manufactures and markets human and veterinary pharmaceuticals, active pharmaceutical ingredients and diagnostic tests. The company is continuously developing new drugs and treatment methods. Pharmaceutical R&D focuses on central nervous system drugs, oncology and critical care drugs, and Easyhaler® pulmonary drugs.

Orion's net sales in 2011 amounted to EUR 918 million and the company had about 3,400 employees. Orion's A and B shares are listed on NASDAQ OMX Helsinki.

You can learn more about the business at: www.orion.fi/en

FARESTON Important Safety Information[4-8]

FARESTON (toremifene citrate) Tablet has been shown to prolong the QTc interval in a dose and concentration-related manner. Prolongation of the QT interval can result in a type of ventricular tachycardia called Torsade de pointes, which may result in syncope, seizure, and/or death. Toremifene should not be prescribed to patients with congenital/acquired QT prolongation, uncorrected hypokalemia or uncorrected hypomagnesemia. Drugs known to prolong the QT interval and strong SYP3A4 inhibitors should be avoided.

FARESTON is contraindicated in patients with known hypersensitivity to the drug. Patients with a history of thromboembolic diseases should generally not be treated with FARESTON. As with other antioestrogens, tumour flare, hypercalcemia, and endometrial hyperplasia have been reported in some breast cancer patients being treated with FARESTON. In general, patients with pre-existing endometrial hyperplasia should not be given long-term FARESTON treatment. During clinical trials involving 1157 patients treated with FARESTON or tamoxifen, the incidence of serious side effects were as follows: cardiac events (2.03% vs 2.42%), ocular events (10.30% vs 9.38%), thromboembolic events (3.21% vs. 3.28%), and elevated liver tests (26.2% and 23.7%), respectively.

SANCUSO Important Safety Information[9]

SANCUSO® (Granisteron Transdermal System) is indicated for the prevention of nausea and vomiting in patients receiving moderately and/or highly emetogenic chemotherapy regimens of up to five consecutive days' duration.

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 the patch if severe reaction or a generalised skin reaction occurs. 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 in patients receiving SANCUSO is constipation (5.4%). SANCUSO contains granisetron. Healthcare professionals should avoid prescribing any additional products that contain granisetron. No clinically relevant drug interactions have been reported in clinical studies with SANCUSO.

ABSTRAL Important Safety Information[10]

WARNINGS: POTENTIAL FOR ABUSE and IMPORTANCE OF PROPER PATIENT SELECTION

ABSTRAL contains fentanyl, an opioid agonist and a Schedule II controlled substance, with an abuse liability similar to other opioid analgesics. ABSTRAL can be abused in a manner similar to other opioid agonists, legal or illicit. Consider the potential for abuse when prescribing or dispensing ABSTRAL in situations where the physician or pharmacist is concerned about an increased risk of misuse, abuse or diversion. Schedule II opioid substances which include morphine, oxycodone, hydromorphone, oxymorphone, and methadone have the highest potential for abuse and risk of fatal overdose due to respiratory depression.

Serious adverse events, including deaths, in patients treated with other oral transmucosal fentanyl products have been reported. Deaths occurred as a result of improper patient selection (e.g., use in opioid non-tolerant patients) and/or improper dosing. The substitution of ABSTRAL for any other fentanyl product may result in fatal overdose.

ABSTRAL is indicated only for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain. Patients considered opioid tolerant are those who are taking at least 60 mg of oral morphine/daily, or at least 25 mcg transdermal fentanyl/hour, or at least 30 mg of oral oxycodone daily, or at least 8 mg oral hydromorphone daily, at least 25 mg oral oxymorphone daily or an equianalgesic dose of another opioid for a week or longer.

ABSTRAL is contraindicated in opioid non-tolerant patients and is contraindicated in the management of acute or postoperative pain, including headache/migraine, dental pain, or use in the emergency room. Life-threatening respiratory depression could occur at any dose in opioid non-tolerant patients. Deaths have occurred in opioid non-tolerant patients treated with other fentanyl products.

When prescribing, do not convert patients on a mcg per mcg basis from another fentanyl product to ABSTRAL. Patients beginning treatment with ABSTRAL must begin with titration from the 100 mcg dose [See *Dosage and Administration* (2.1)].

When dispensing, do not substitute an ABSTRAL prescription for other fentanyl products. Differences exist in the pharmacokinetics of ABSTRAL compared to other fentanyl

products that could result in clinically important differences in the amount of fentanyl absorbed and could result in fatal overdose.
Special care must be used when dosing ABSTRAL. If the breakthrough pain episode is not relieved patients must wait at least 2 hours before treating another episode of breakthrough pain with ABSTRAL [See *Dosage and Administration* (2.1)].
ABSTRAL is intended to be used only in the care of opioid tolerant cancer patients and only by healthcare professionals who are knowledgeable of, and skilled in, the use of Schedule II opioids to treat cancer pain.
Patients and their caregivers must be instructed that ABSTRAL contains a medicine in an amount which can be fatal in children, in individuals for whom it is not prescribed, and in those who are not opioid tolerant. All packs must be kept out of the reach of children [see *Patient Counseling Information* (17.1), *Contraindications* (4) and *How Supplied/Storage and Handling* (16.3)].
The concomitant use of ABSTRAL with cytochrome P450 3A4 inhibitors may result in an increase in fentanyl plasma concentrations, and may cause potentially fatal respiratory depression [see *Drug Interactions* (7)].
Because of the risk for misuse, abuse, addiction, and overdose, ABSTRAL is available only through a restricted program, required by the Food and Drug Administration, called the ABSTRAL REMS (**R**isk **E**valuation and **M**itigation **S**trategy). Under the ABSTRAL REMS, healthcare professionals who prescribe to outpatients, outpatients, pharmacies and distributors must enroll in the program to prescribe, receive, dispense, and distribute ABSTRAL, respectively [see *Warnings and Precautions* (5.10)]. Further information is available at www.abstralrems.com or by calling +1-888-227-8725.

References

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