



## **SpePharm announces the European launches of two new products: MuGard<sup>®</sup> and Xerotin<sup>®</sup>**

**Amsterdam, April 20 2009** - SpePharm, a pan-European specialty pharmaceutical company dedicated to the provision of high medical value medicines in supportive and critical care, today announced the European introduction of two new products; MuGard<sup>®</sup> & Xerotin<sup>®</sup>, aimed at relieving some of the most debilitating side effects experienced by cancer patients. The European roll-out of MuGard<sup>®</sup> and Xerotin<sup>®</sup> starting this month with Germany, Italy, UK, Nordic countries and Greece. The rest of Europe will follow over the coming 12 to 18 months.

**MuGard<sup>®</sup>** is a ready-to-use, muco-adhesive oral rinse indicated for the prevention and management of the lesions and symptoms of oral mucositis, a condition mainly caused or induced by radiation and/or chemotherapy. Treatment with MuGard<sup>®</sup> should be initiated at the beginning of radiation therapy or chemotherapy before the signs and symptoms of mucositis are evident.

In October 2008, MuGard<sup>®</sup> was granted CE Mark certification by the Dutch Notified Body (KEMA). SpePharm is responsible for manufacturing, regulatory approval and commercialization in the 27 countries of Europe under a license from Access Pharmaceuticals Inc, a US biopharmaceutical company developing proprietary products for the treatment and supportive care of cancer patients. MuGard<sup>®</sup> has also received a marketing allowance in the USA from the Food and Drug Administration under a 510(k) procedure.

**Xerotin<sup>®</sup>** is a ready-to-use mouth moisturizing spray indicated for the relief of xerostomia, the lack of, or reduced levels of, saliva, which is a common side-effect of some cancer treatments especially radiotherapy for head and neck cancer, Sjögren's syndrome, nerve damage and also a common side effect of chronic administration of many medications. SpePharm has obtained the exclusive rights to distribute Xerotin<sup>®</sup> throughout Europe from Difa-Cooper an Italian company which is the Manufacturer of Xerotin<sup>®</sup>.

Oral complications are common in patients receiving radiation and/or chemotherapy treatments, and especially in the head and neck area. Chemotherapy and radiation therapy can cause damage to the lining of the mouth and affect the production of saliva. These changes frequently lead to mouth sores, severe mucosal ulcerations (oral mucositis) and dry mouth, referred to as xerostomia. Depending on their severity, these debilitating side effects may significantly interfere with patients' medical management and alter their quality of life.

"These new treatment options will provide much needed respite for patients", commented Dr. Caroline Dumas, Vice President Medical Affairs of SpePharm. "International clinical practice guidelines for the prevention and management of mucositis include recommendations for *'the use of a preventive oral care regimen as*

*part of routine supportive care along with a therapeutic oral care regimen if mucositis develops.* The efficacy of MuGard® in delaying the onset of lesions of oral mucositis and in significantly reducing their severity has been demonstrated using validated scales for the assessment of oral mucositis."

"Following radiotherapy and/or chemotherapy, many patients also suffer from a dry mouth. The ability of Xerotin® to lubricate and moisturize the mouth will offer a new option for patients. Xerotin® mimics normal saliva composition (it contains the potassium, magnesium and calcium chlorides necessary to mimic the normal saliva effects), has a neutral pH aimed at fighting against acid corrosion and is not damaging to teeth", she continued.

Mr. J.-F. Labbé, CEO of SpePharm commented "We are pleased to announce the introduction of MuGard® and Xerotin® to meet clear unsatisfied medical needs and provide relief to thousands of patients, already confronted with severe diseases."

**About SpePharm Holding, BV**

SpePharm Holding, B.V. is a Dutch company with its registered office in Amsterdam, and its European operations based in Paris, France. SpePharm is an emerging pan-European specialty pharmaceutical company focused on acquiring, registering and marketing high medical value specialty medicines essentially for the hospital market. Particular areas of therapeutic interest are oncology, critical and supportive care. SpePharm has completed two pan-European license/distribution agreements in 2007 & 2008 for respectively MuGard® and Xerotin® and, acquired last year the full rights for Europe and other territories of dantrolene sodium (Dantrium® / Dantrolen® / Dantamacrin®) from Procter and Gamble Pharmaceuticals. SpePharm was founded in September 2006 by Jean-François Labbé together with leading life science investment firms TVM Capital and Signet Healthcare Partners (part of the Sanders Morris Harris Group). Paul Capital Healthcare, one of the largest dedicated healthcare investors globally, made an equity investment in SpePharm in August 2008, and provided additional non-dilutive financing for SpePharm to acquire the rights to Dantrium®. Jean-François Labbé is a former top executive of Hoechst Marion Roussel and Parke Davis with over 30 years of experience in international pharmaceutical management. To date SpePharm has an established commercial presence in the UK, Germany, Italy, Spain, Benelux and the Nordic area.

For more information about SpePharm, please visit the web site at [www.spepharm.com](http://www.spepharm.com)

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