Sucampo Announces Positive Top-Line Results in Phase 1a Trials of Cobiprostone and SPI-3608

BETHESDA, Md., Aug. 7, 2013 (GLOBE NEWSWIRE) Sucampo Pharmaceuticals, Inc. (Nasdaq:SCMP) (Sucampo) today announced the positive top-line results of two recently completed clinical trials, a Phase 1a trial of cobiprostone and a Phase 1a trial of SPI-3608. The studies tested the tolerability and pharmacokinetic profiles versus placebo of the two compounds, both of which were demonstrated to be generally well-tolerated in the tested populations. Cobiprostone Cobiprostone is being investigated for the prevention and/or treatment of oral mucositis. The Phase 1a clinical trial for the investigational oral spray formulation of cobiprostone demonstrated that the drug is generally well-tolerated in healthy volunteers. A Phase 1b trial is expected to begin in the fourth quarter of 2013. "Oral mucositis is an extremely painful and often debilitating side effect of radiation therapy and chemotherapy in cancer patients, with limited prescription treatments available," said Ryuji Ueno, M.D., Ph.D., Ph.D., Chairman, Chief Executive Officer, and Chief Scientific Officer of Sucampo. "In oral mucositis, with the breakdown of the mucosal barrier function, ulcers form as surface cells die. Our pre-clinical data indicate that cobiprostone induces mucosal barrier repair and prevents mucosal barrier damage, and the fact that it was well-tolerated in this study is extremely encouraging. Even though we have not yet evaluated efficacy in patients, we are looking forward to advancing cobiprostone into Phase 1b later this year." The single-center, randomized, double-blind, placebo-controlled, dose-escalation study conducted in Japan was designed to assess tolerability and pharmacokinetics of a single dose of cobiprostone oral spray versus placebo in healthy adults aged 21-50 years. Approximately 48 individual subjects were analyzed, 36 of whom were treated with cobiprostone. The study consisted of six escalating-dose steps and one repeat-dose step. In total, six doses of cobiprostone were tested. No serious or severe adverse events (AEs) were reported and the most frequently observed AE was mild diarrhea. SPI-3608 Sucampo also announced the positive top-line results of SPI-3608 in a Phase 1a single-oral-dose study that demonstrated the drug to be generally well tolerated in healthy volunteers. SPI-3608 is being investigated for the treatment of mild to moderate lumbar spinal stenosis (LSS) and may be investigated for additional indications in the future. The next phase of development for SPI-3608 is expected to begin in the first quarter of 2014. "Spinal stenosis is a common degenerative disease, caused by the narrowing of and diminished blood flow to the spinal cord. There are an estimated 400,000 Americans suffering from the pain associated with this disease, which can include numbness and muscle weakness in the lower extremities," said Dr. Ueno. "Our pre-clinical data on SPI-3608 indicate that the compound is capable of the treatment of spinal stenosis by increasing spinal cord blood flow. This is an underserved market because there are currently limited options to treat lumbar spinal stenosis, and we are excited to continue investigating..."
SPI-3608 to address this unmet need." The clinical pharmacology study conducted in Japan assessed the tolerability and pharmacokinetics of SPI-3608 after a single oral administration in healthy men aged 20 to 37 years. Approximately 48 individuals were analyzed in this single-center, randomized, placebo-controlled, double-blind, dose-escalation study, 36 of which were treated with SPI-3608. In total, six doses of SPI-3608 were tested. No serious or severe AEs were observed and the most frequently observed AE was mild vomiting. These findings showed that SPI-3608 is generally well-tolerated at all doses tested in the study. About cobiprostone Cobiprostone is an investigational prostone compound under development by Sucampo as a potential treatment for oral mucositis. Sucampo holds worldwide, exclusive rights to cobiprostone. About SPI-3608 SPI-3608 is an investigational prostone compound under development by Sucampo as a potential oral treatment for mild to moderate lumbar spinal stenosis and may be investigated for additional indications in the future. Sucampo holds worldwide, exclusive rights to SPI-3608. Sucampo is also developing SPI-017, an IV formulation for the treatment of severe lumbar spinal stenosis, which is currently in Phase 2a clinical trials and is expected to conclude in Q4 2013. (www.pharmacychoice.com)

GLAXO SMITHKLINE  
07/08/2013  
Regulatory update GSK announces EU submission for Cervarix two dose schedule

Wednesday 7 August 2013, London UK GlaxoSmithKline (GSK) plc today announced the submission of a regulatory application in the European Union for a two dosing schedule in 9-14 year old girls for its cervical cancer vaccine, Cervarix ® [Human papillomavirus bivalent (types 16 and 18) vaccine, recombinant]. A Marketing Authorisation Application (MAA) has been submitted to the European Medicines Agency (EMA) for the vaccine to allow for administration according to a two-dose schedule (0,6 months) in girls aged 9-14 years old for the prevention of premalignant genital (cervical, vulvar and vaginal) lesions and cervical cancer causally related to certain oncogenic Human Papillomavirus (HPV) types. The vaccine is currently approved in the EU for use in females from the age of 9 years, administered according to a three dose schedule (vaccination at months 0,1 and 6) for the prevention of premalignant genital (cervical, vulvar and vaginal) lesions and cervical cancer causally related to certain oncogenic Human Papillomavirus (HPV) types. The two-dose schedule in 9-14 year old girls is intended to be an alternative dosing schedule and not intended to replace the three-dose schedule. The use of Cervarix in a two dose schedule (vaccination at months 0 and 6) in girls aged 9-14 years old is investigational and not approved anywhere in the world. Cervarix is also approved in the US. For the full US Prescribing Information and EU Patient Information Leaflet, which includes information on the approved use of Cervarix, please visit http://www.gsk.com/products.html

TEVA  
08/08/2013  
Teva Receives European Marketing Authorization for Lonquex
JERUSALEM--(BUSINESS WIRE)--Aug. 8, 2013--Teva Pharmaceutical Industries Ltd (NYSE: TEVA) announced today that the European Commission has granted marketing authorization for Lonquex® (lipegfilgrastim). This approval provides the regulatory framework for the commercialization of Lonquex® in all twenty eight countries of the European Union plus Norway, Iceland and Liechtenstein. Lonquex is a long-acting recombinant granulocyte colony-stimulating factor (G-CSF) with the active ingredient lipegfilgrastim – a novel glycoPEGylated (PEG; polyethylene glycol) filgrastim molecule. Lonquex® (lipegfilgrastim) is indicated for the reduction of the duration of neutropenia and the incidence of febrile neutropenia in adult patients treated with cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukemia and myelodysplastic syndromes). Lonquex® is intended as a once-per-cycle fixed dose, subcutaneous injection for neutrophil support in cancer patients receiving myelosuppressive chemotherapy (with the exception of chronic myeloid leukemia and myelodysplastic syndromes).1 "This is an important milestone for Teva Specialty Medicines in Europe and demonstrates our commitment to making a difference to the lives of those with cancer" said Dr. Rob Koremans, President and CEO of Teva Specialty Medicines. "Lonquex® is an alternative G-CSF treatment for helping manage neutropenia during myelosuppressive chemotherapy. The European approval comes earlier than expected, just 8 weeks after the positive CHMP opinion. We look forward to providing this oncology supportive care treatment option in all European Union member states." Lonquex® has undergone a full clinical development program, including pre-clinical to clinical in vivo studies, as part of the efficacy and tolerability assessment for use with chemotherapy patients. Dr. Michael Hayden, Teva's President of Global R&D and Chief Scientific Officer, commented: "Effective prevention and treatment of febrile neutropenia is an important consideration for clinicians managing cancer patients who are undergoing cytotoxic chemotherapy. As well as targeting cancer cells, chemotherapy affects rapidly-dividing bone marrow cells, thereby dramatically reducing a patient's ability to fight off infection, with potentially serious consequences. This approval is testament to Teva's commitment to bringing new and alternative treatments to market to support clinicians in caring for patients."