



# Mucomel® from Spherium Biomed Reduces the Severity of Oral Mucositis in Head and Neck Cancer Patients

*Mucomel® oral melatonin gel formulation reduces the severity of oral mucositis in cisplatin-treated head and neck cancer patients*

BARCELONA, SPAIN, May 17, 2018 /EINPresswire.com/ -- • Spherium Biomed disclosed today the top line results of its Phase II clinical trial of Mucomel®, an oral gel for the prevention and treatment of oral mucositis in head and neck cancer patients undergoing chemo/bio-radiotherapy.

- The trial included 84 patients with advanced disease receiving high dose radiotherapy and concomitant treatment with cisplatin or cetuximab, enrolled from 11 hospitals in Spain.
- Treatment with Mucomel® reduced the incidence of severe oral mucositis (grade 3 and 4), and shortened the duration of oral mucositis (grade 2, 3 and 4) when the condition appeared. These benefits were driven by the subgroup of patients receiving cisplatin.

Barcelona, May 16th, 2018.- Spherium Biomed announced today the top line results of the Mucomel trial, a prospective, double blind and placebo-controlled trial to evaluate the safety and efficacy of its high dose melatonin gel, Mucomel®, for the prevention and treatment of oral mucositis (OM) in head and neck cancer patients receiving chemo/bio-radiotherapy (NCT02630004).

The 84 patients, enrolled from 11 sites in Spain, received high dose radiation (median 70 Gy) and concomitant cisplatin or cetuximab treatment for 7-8 weeks according to standard clinical practices for advanced grade head and neck cancer. Patients were instructed to take Mucomel® or placebo gels 5 times a day over the full course of the chemo/bio-radiotherapy treatment.

The trial was designed for the evaluation of safety and exploratory assessment of efficacy. Mucomel® was safe, significantly reduced the incidence of severe oral mucositis in the group of patients receiving cisplatin (up to 44%), and significantly shortened the duration of oral mucositis (up to three weeks) in some patient groups. The results of the trial will be presented as an oral abstract at the head and neck cancer track during the 2018 Annual Meeting of the American Society of Clinical Oncology (ASCO).

Dr. Ramon Bosser, Chief Operating Officer at Spherium, commented: “the results encourage us to continue our development efforts for making Mucomel® available to patients worldwide. We have shown that Mucomel® reduces the incidence of severe oral mucositis in cisplatin patients and shortens the duration of mucositis in those patients that develop it, even in cetuximab-treated patients. We are very satisfied with the outcome of the trial, since it provides solid grounds to design a robust phase III strategy. We would like to show our deep appreciation to all the physicians, nurses and patients that made the trial possible. It has been an enormous team effort from everybody”.

Mucositis is defined as inflammatory and/or ulcerative lesions of the oral and gastrointestinal tract

mucosa. Oral mucositis affects the oral mucosa causing erythematous and ulcerative lesions. Every year more than 550.000 cancer patients worldwide suffer from OM as a secondary effect of some cancer treatment regimens. It is particularly relevant in patients with cancer being treated with chemo- and radiation therapy, especially in high dose CT/RT in Head and Neck cancer patients.

Nearly 100% of these patients develop OM in any grade, and 70% to 85% of them develop severe OM (Grades 3 or 4: at grade 3 the patients are in excruciating pain and cannot swallow solids, at Grade 4 the patients cannot drink and require feeding-tubes). Besides head and neck cancer, 75% of patients receiving bone marrow transplantation for hematological cancer treatment are expected to develop OM. In other types of cancer, 20-40% of patients receiving standard chemotherapy will also develop OM. Severe oral mucositis leads to pain, reduces patients' ability to eat thus weakening them leading in some cases to uncomfortable, expensive or even threatening medical decisions like parenteral feeding, hospitalization and de-escalation of oncologic treatment. Mucositis is recognized as a relevant medical unmet need. The standard of care is based on pain medication and oral rinses or barrier devices to maintain mucosal integrity.

Mucomel® is a patented, high-load, mucoadhesive gel of melatonin, presented in individual 10mL sachets to facilitate administration on out-patient basis. It is being developed by Spherium under an exclusive license from the University of Granada (Spain), where Drs. Germaine Escames and Dario Acuña discovered the key protective role of cellular melatonin against external insults to the mucosa. Spherium aims to partner the program during 2018 to complete development and make the product available to patients worldwide as soon as possible.

About Spherium ([www.spheriumbiomed.com](http://www.spheriumbiomed.com))

Spherium Biomed is a clinical-stage, biopharmaceutical portfolio company that sources its pipeline from academic research. The company utilizes a lean, hands-on venture builder model to advance its portfolio up to a relevant value milestone to increase the chance of academic discoveries reaching the market. The company applies its broad experience in drug development (from discovery to clinical and commercial stages) to deeply analyze the commercial potential of technologies. After defining the relevant gaps with respect to an ideal target product profile, the company acquires development and commercialization rights for the asset and derives a creative and cost-effective work plan to bring the project forward, and implements the plan with its own resources and the proactive coordination of external providers.

Spherium is privately owned; its shareholders are its founders and key executives, and the Spanish pharmaceutical company Ferrer ([www.ferrer.com](http://www.ferrer.com)). Its current pipeline includes three phase II clinical stage projects and one phase I. The portfolio includes several first-in-class preclinical projects as well, two of them undergoing IND-enabling regulatory safety-toxicology and industrial scaling up. The company is constantly looking for new opportunities addressing unmet clinical needs.

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