

Mucomel® Phase II Results Selected to be Presented at ASCO

Spherium Biomed announced today the completion of its Phase I/IIa clinical trial of Mucomel®, for the prevention and treatment of oral mucositis.



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/EINPresswire.com/ -- NEWS HIGHLIGHTS

Spherium Biomed announced today the completion of its Phase I/IIa clinical trial of Mucomel®, for the prevention and treatment of oral mucositis in head and neck cancer patients undergoing chemo-radiotherapy.

The trial was designed to include 84 patients with advanced disease receiving high dose radiotherapy and concomitant treatment with cisplatin or cetuximab enrolled from 11 hospitals in Spain.

The results will be presented by the leading investigator, Dr. Alicia Lozano, at the Head and Neck cancer oral abstract session of the ASCO meeting in Chicago on June 3rd.

MORE

Spherium Biomed has completed the analysis of the results of the Mucomel® trial, a phase I/IIb prospective, double blinded 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-radiotherapy (NCT02630004).

The trial aimed to include 84 patients from 11 sites in Spain. The patients were selected among those scheduled to receive high dose radiation (at least 66 Gy) and concomitant cisplatin or cetuximab treatment for 2 months according to standard clinical practices for advanced grade head and neck cancer in Spain. Patients were instructed to use Mucomel® or placebo gels 5 times a day over the full course of the treatment.

The trial's objectives were to evaluate safety and explore efficacy. The results will be fully disclosed at the oral abstract presentation of the Head & Neck Cancer track of the American Society of Clinical Oncology meeting in Chicago on June 3th according to the final program made public yesterday by the ASCO organizers (Abstract 6007, <https://iplanner.asco.org/am2018/#/>)

Mucositis is defined as inflammatory and/or ulcerative lesions of the gastrointestinal tract mucosa. Oral mucositis affects the oral mucosa causing erythematous and ulcerative lesions. It is particularly relevant in patients with cancer being treated with chemo- and/or radiation therapy, especially in high dose CT / RT in head and neck cancer patients. Severe oral mucositis leads to pain, changes in diet (including parenteral feeding), hospitalization and de-escalation of oncologic treatment.

There are more than 550.000 cases of Head and Neck cancer every year, and no drug is approved for the treatment or prevention of oral mucositis. The standard of care is based in pain medication and oral rinses or barrier devices to maintain mucosal integrity. Nearly 100% of patients receiving chemo and/or radio therapy will develop OM. 70% to 85% of patients receiving chemo-radio therapy will

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. In addition to head and neck cancer patients, 75% of patients receiving bone marrow transplantation for hematological cancer are expected to develop OM. In other types of cancer, 20-40% of patients receiving standard chemotherapy may also develop OM.

Mucomel® is based on a proprietary, patented high-load gel formulation of melatonin presented in individual 10ml sachets, to facilitate administration on out-patient basis. Spherium aims to partner the program during 2018 to complete development and reach patients worldwide as fast as possible.

ABOUT SPHERIUM (www.spheriumbiomed.com)

Spherium Biomed is a clinical-stage, biopharmaceutical portfolio company that sources its pipeline from academic research. The company applies 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 major shareholders are its founders and key executives, and the Spanish pharmaceutical company Ferrer (www.ferrer.com). Its current portfolio 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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