Press Release

Spherium's Cyclatop© (SP14019), safe and efficacious for the treatment of atopic dermatitis in adults and infants

The clinical trial (NCT02865356) was designed to investigate the safety, tolerability, pharmacokinetics and efficacy of SP14019 (Cyclosporine A 5% topical spray) across all group ages for the treatment of mild to moderate atopic dermatitis.

Systemic Cyclosporine A is efficacious to treat moderate to severe atopic dermatitis, but its use is limited to short term because of the risk of adverse events, particularly nephrotoxicity. The topical formulation is expected to have the same efficacy with a much better safety profile since it reduces dramatically the systemic exposure.

Eight clinical sites in Spain participated in the study, including 44 patients (each patient being its own control) from ages 2 to 75.

The results confirmed the expected systemic low exposure to Cyclosporine A, with great tolerability and acceptability from patients and statistically significant (and clinically relevant) efficacy outcomes in all endpoints analyzed.

Barcelona, September 15th, 2018.- Spherium Biomed presented today the results of the Cyclatop pilot study to evaluate the safety and efficacy of its proprietary cutaneous spray of Cyclosporine A (SP14019) for the treatment of mild to moderate atopic dermatitis across all group ages, including pediatric population. Luis Ruiz-Avila, Spherium Biomed's CEO, shared that "SP14019 represents a unique opportunity to extend the well-established benefits of Cyclosporine A in the indication, both in time (allowing for longer treatments) and in the patient base (broadening the scope of treatment to milder cases and pediatric populations)."

The Cyclatop trial was carried out in 8 Spanish centers and included 44 patients with mild to moderate atopic dermatitis, aged between 2 and 75 years. It was double-blind, placebo-controlled and bilateral left-right (each patient received placebo on one side and Cyclatop on the other), with two daily administrations in the affected areas for 28 days. The treatment with Cyclatop did not generate any notable adverse effect and was very well accepted by the patients (more than 87% considered it to be quite acceptable or very acceptable), notably in pediatric patients. To determine the evolution of atopic dermatitis, three scales were used that measure different clinical aspects, such as redness, wounds, inflammation, itching, etc. (scales EASI, ADSI and IGA) and in all cases clinically relevant and statistically significant improvements were obtained with respect to placebo (for example, 62% of patients reduced the severity of their symptoms to levels that are considered practically normalization of the skin's condition). The effects were already apparent and significant at the first visit, that is, during the first week of the start of treatment. In addition to the improvement in global clinical symptoms, a very important reduction in itching was also observed, more than 50% also during the first week. Besides the clinical efficacy the study demonstrated that the amount of cyclosporine in the blood in the treated patients was one thousandth of that observed during conventional oral or intravenous treatment, anticipating an excellent safety profile. The full results were presented to the medical community today, at the Congress of the European Association of Dermatology and Venereology (EADV) in an oral session selected as "late breaking news" by the scientific organizing committee.

Atopic dermatitis (AD), also called atopic eczema, is a chronic and relapsing inflammatory skin disease affecting up to 20% of children and up to 3% of adults depending on the country. Its prevalence is still on the rise. The disease is characterized by itchy skin lesions and rashes. It is primarily managed in primary healthcare settings and often is considered a minor condition, but it has a significant impact in quality of life and in costs for the health-care systems and families. When its first manifestations appear early in life it may often precede other allergic diseases such as asthma or allergic rhinitis.

The global market is in the 6-billion-dollar range worldwide, with an estimated target population of 54 million people for the next decade. Its long-lasting nature and the multiple etiologies underlying the disease are the basis for the existence of many therapeutic options and, simultaneously, of an intense research activity focused in niche unmet needs in severe cases and in expanding the current therapeutic options, especially topical alternatives for infants.

Cyclatop, or SP14019, is based on a proprietary, high-load formulation of Cyclosporine A compatible with cutaneous spray administration. Spherium researchers have already shown that the formulation delivers appropriate amounts of Cyclosporine to the target layers in the skin, with efficacy correlates in preclinical models of atopic dermatitis. The key aspect of SP14019 development has been obtaining a high-load, skin penetrating, scalable, stable and regulatory compliant topical formulation of CsA.

Spherium Biomed is currently looking for partners to finalize the development of SP14019 as fast as possible to make the final product available to patients worldwide.

About Spherium (www.spheriumbiomed.com)

Spherium Biomed is a clinical-stage, biopharmaceutical portfolio company that sources its pipeline from academic research. The company acts as an advanced, hands-on venture builder with the ultimate goal of reaching a relevant value milestone in order 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 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 five projects in clinical stage, three of them ready to start phase IIb/III and complete development. The two remaining clinical stage projects will complete Phase II by 2020. The portfolio includes also several first-in-class preclinical projects with potential to complete IND-enabling work by 2020.

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