

Press Release

Spherium Biomed starts efficacy trial Cyclatop for the treatment of atopic dermatitis in adults and infants

- **The clinical trial is a pilot study (the Cyclatop study) for the evaluation of SP14019—F-01 topical solution for the treatment of atopic dermatitis. It is designed to investigate the safety, tolerability, pharmacokinetics and efficacy of SP14019-F-01 across all group ages for the treatment of mild to moderate atopic dermatitis.**
- **SP14019-F-01 is a proprietary cutaneous spray microemulsion of Cyclosporine A. Systemic Cyclosporine A is efficacious to treat moderate to severe atopic dermatitis, and its use is limited to short term because of the risk of adverse events, in particular nephrotoxicity. The topical formulation is expected to have a much better safety profile since it reduces dramatically the systemic exposure.**
- **The Cyclatop trial initially involves eight clinical sites in Spain, including leading pediatric centers in Spain. It will include 36 patients with a left-right design (each patient will receive both placebo and treatment) from ages 2 to 75 segmented in three cohorts (pediatric, juveniles and adults). Top line results are expected by 4Q 2017.**

Barcelona, September 27th 2016.- Spherium Biomed announced today the initiation of the Cyclatop pilot study to evaluate the safety and efficacy of its proprietary cutaneous spray of Cyclosporine A 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-F-01 represents a unique opportunity to extend the well-established benefits of the drug in the indication, both in time (allowing for longer treatments) and in patient base (broadening the scope of treatment to milder cases and pediatric populations)."

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 4 billion dollar range worldwide, with an estimated target population of 54 million people for the next decade. The long lasting nature of AD 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 armamentarium, especially topical alternatives for infants.

SP14019-F-01 is a proprietary, high-load formulation of Cyclosporine A (CsA) compatible with cutaneous spray administration developed initially in collaboration with Bionanoplus (www.bionanoplus.com), a spin-off from the Navarra University. Spherium researchers have already shown that the formulation delivers appropriate amounts of Cyclosporine to the target layers in the skin, correlated with efficacy in preclinical models of atopic dermatitis. The key aspect



of SP14019-F-01 development has been solving the pharmaceutical challenge of obtaining a high-load, skin penetrating, scalable, stable and regulatory compliant formulation of CsA.

Spherium Biomed aims to complete the clinical trial and to deliver top line results by the end of 2017.

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 project incubator 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 three clinical stage projects expected to deliver efficacy results within the next year, and two more to be started by the end of 2017. The portfolio includes also several first-in-class preclinical projects expected to show proof of concept during 2017-2018. The company is constantly looking for new opportunities addressing unmet clinical needs.

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