

Dermtreat Announces First Patient Dosed in Phase 2b Clinical Trial of Rivelin Clobetasol for Oral Lichen Planus

SAN DIEGO and COPENHAGEN, July 23, 2018 — Dermtreat, a clinical-stage biopharmaceutical company focused on mucosal diseases, today announced treatment of the first patient in a Phase 2b clinical trial of Rivelin® Clobetasol patch (Rivelin®-CLO) for oral lichen planus (OLP). Rivelin-CLO is the first biodegradable oral adhesive patch designed for local delivery of clobetasol to treat lesions and ulcers in the mouth caused by OLP.

OLP is a chronic, inflammatory disease characterized by symptomatic lesions and ulcers in the mouth. It's estimated to affect 1 percent of the population, or over 6 million patients in the U.S. and EU. There is no approved topical treatment for OLP.

“Oral lichen planus causes pain and disrupts actions that are essential to basic quality of life such as talking, eating, swallowing and maintaining good dental hygiene, yet it remains poorly served by off-label topical treatments,” said Nishan de Silva, M.D., chief executive officer of Dermtreat. “The Rivelin patch is the first of its kind designed to enable targeted delivery of clobetasol to lesions in the mouth, adhering to mucosal tissue for up to two hours, and acting as a barrier to irritation from food and other consumables. Based on the high unmet medical need and the interest we've seen from leading physicians and specialists in the field, we anticipate efficient study enrollment and expect results in the first half of 2019.”

The Phase 2b trial will enroll approximately 240 adult patients clinically diagnosed with OLP and who have at least one visible and measurable symptomatic ulcerative lesion. Conducted at up to 20 sites in Europe and North America, the study is a randomized, double-blind and placebo-controlled clinical trial with three active dose arms (Rivelin-CLO 1 µg/patch; Rivelin-CLO 5 µg/patch; Rivelin-CLO 20 µg/patch) and one placebo arm (Rivelin plain patch). Patients will be treated twice daily and evaluated on a weekly basis for 28 days of treatment. The primary objective of the trial is to demonstrate the efficacy of three different doses of Rivelin-CLO patches in treating OLP lesions over four weeks of treatment assessed by change in ulcer area. Secondary objectives will evaluate change in lesion area and symptom scores. More information is available at www.clinicaltrials.gov ([Identifier #NCT03592342](#)).

[Rivelin](#), is a muco-adhesive two layered patch that delivers a pharmaceutical product (such as clobetasol) directly to patients' mucosal surface of the oral cavity. Rivelin utilizes a unique patch technology that adheres to mucosal surfaces for extended periods, facilitating uni-directional delivery of a pharmaceutical agent to the target site of action impacting disease progression, while limiting delivery to surrounding areas. This should enable higher efficacy, lower dosing and less toxicity to non-affected parts of the oral cavity. Rivelin may significantly improve the treatment paradigm for oral lichen planus and other inflammatory oral diseases, which today are largely addressed with unapproved or inconvenient ointments, inhalers or mouthwashes. Preclinical studies of the Rivelin patch for oral mucosal diseases were [recently published](#) in the journal *Biomaterials*.

About Oral Lichen Planus

Oral lichen planus (OLP) is a chronic inflammatory condition that affects the mucous surfaces of the oral cavity. OLP may appear as lesions in the mouth that may cause burning, pain and other discomfort. OLP requires regular monitoring given patients have increased risk of developing pre-cancerous cell changes including the development of mouth cancer. No U.S. Food and Drug Administration (FDA) approved treatment exists, with today's off-label treatment ranging from topical corticosteroids to laser ablation.

About Rivelin® Patch Platform

Dermtreat has developed the Rivelin patch, a breakthrough therapy for the treatment of mucosal diseases. Rivelin is designed to deliver a pharmaceutical drug uni-directionally to a mucosal surface using an occlusive, bio-adhesive and bio-degradable patch, with a long adhesion time and a high flexibility, conforming to the mucosal surface. The first Rivelin patch product candidate seeks to treat the inflammatory disease oral lichen planus (OLP) through direct delivery of the drug clobetasol propionate.

About Dermtreat

Dermtreat is a private biopharmaceutical company focused on innovative approaches to treat mucosal diseases. Dermtreat's lead product candidate, Rivelin®-CLO patch, is currently in Phase 2b clinical development for the treatment of oral lichen planus (OLP) a chronic inflammatory disease that affects 1% of the population. The Rivelin patch technology is able to adhere to mucosal surfaces, such as the mouth, to provide continuous and targeted therapeutic delivery for diseases where topical and other treatment modalities have proven inadequate. Investors include Sofinnova Ventures, Lundbeckfonden Emerge, Novo Seeds and Welfare Tech Invest. For additional information, please visit www.dermtreat.com.

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