



DERMTREAT SUBMITS IND AND CTA FOR PHASE 2B STUDY

Copenhagen, Denmark, January 11th, 2018: Danish-based Dermatreat today announced the submission of the IND and CTA respectively for the clinical Phase 2b study of its novel Rivelin® patch to be tested in patients suffering from Oral Lichen Planus.

Dermatreat 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 product candidate of the Rivelin® patch is targeting the unmet need of treating the auto-immune, inflammatory disease Oral Lichen Planus (OLP) by incorporating the drug clobetasol propionate in the Rivelin® patch.

Following successful results from a Phase 1b clinical study of the non-drug-loaded Rivelin® patch in patients suffering from OLP, Dermatreat has finalized and submitted the IND and CTAs respectively to commence Phase 2b clinical study of the Clobetasol loaded Rivelin® patch.

The study will be a randomized, double-blind, placebo-controlled study enrolling 240 OLP patients over 19 clinical sites covering US, UK, Germany, Ireland and Denmark – with the first patient planned to be enrolled in April 2018.

As the first ever Phase 2b clinical study targeting an oral disease the preparatory work has been extensive, including also developing and testing the scales and methods for the clinician reported outcome measurement as well as for the patient reported outcome measurement.

The Rivelin® patch is manufactured by electrospinning, providing a significant contribution to the unique properties. Preparations have thus also included establishing what is believed to be the world's first GMP approved facility using electrospinning technology for the manufacturing of pharmaceutical products.

"Having a patch adhering for up to 2 hours directing delivery of clobetasol would be a huge advantage over current off-label treatment strategies; it would improve the efficacy of clobetasol significantly." says US lead investigator and oral medicine specialist, professor Mike Brennan of Carolina Healthcare System, Charlotte.

Europe lead investigator and dermatology specialist, professor Thomas Ruzicka of Ludwig Maximilian University of Munich adds, "Within dermatology, the Rivelin® patch is the most interesting invention over the last 10-20 years for the treatment of mucosal conditions such as lichen planus – with great potential also in other common diseases of the oral mucosa, such as oral ulcers. The Rivelin® patch provides a new and targeted treatment strategy for patients, who have their quality of life severely affected by such conditions. We are excited to be part of this opportunity to address this unmet clinical need".

The study is expected to last for 6-9 months with study results being available in 1H 2019.

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**About Dermtreat**

Dermtreat ApS is a Danish-based, private, biopharmaceutical company focused on innovative approaches to the treatment of mucosal diseases. Dermtreat's lead product candidate is using its novel Rivelin® patch for the treatment of Oral Lichen Planus (OLP), a chronic condition that affects 1-2% of the population. The Rivelin® patch incorporates clobetasol propionate to treat OLP and is planned to commence a clinical Phase 2b study in April 2018.

Shareholders include Sofinnova Ventures, Lundbeckfonden Emerge, Novo Seeds and Welfare Tech Invest.

For additional information, please visit <https://bioinicia.com/bioinicia-manufactures-a-new-dressing-that-will-revolutionize-the-treatment-of-oral-lesions/>

About Oral Lichen Planus

Oral Lichen Planus (OLP) is a chronic inflammatory condition that affects the mucous membranes of the mouth. OLP may appear as lesions in the mouth that may cause burning, pain and other discomfort. OLP is considered an autoimmune disorder and requires regular monitoring given patients may be at risk of developing mouth cancer in the affected areas. No approved treatment exists, with today's off-label treatment ranging from topical corticosteroids to laser ablation. It is estimated that OLP affects 1-2% of the population. (Sources: *Journal of Oral Maxillofacial Pathology* 2011 May – August; *Mayo Clinic*; *American Academy of Oral Medicine*).