



DERMTREAT SUCCESSFULLY COMPLETES PHASE 1B STUDY

Copenhagen, Denmark – December 1st, 2017: Danish-based Dermtreat today announced the successful completion of its Phase 1b study of the Rivelin® patch tested in patients suffering from Oral Lichen Planus.

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 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.

Dermtreat has over four months conducted a Phase 1b clinical study covering three clinical sites in Germany, with the purpose of testing the non-drug-loaded Rivelin® patch in patients suffering from OLP. The study was conducted by patients applying the Rivelin® patch twice daily for 4 weeks at a sensitive OLP lesion on the buccal mucosa, gingiva or tongue.

The primary objective of the Phase 1b study was to investigate the adhesion time of the Rivelin® patch at a sensitive ulcerative/erosive and/or atrophic/erythematous OLP lesion.

The primary objective was met with a significant margin, as the adhesion times were generally much longer than the pre-specified minimum length of 15 minutes. Adhesions times were actually measured to an average of 90 minutes.

Secondary objectives were to investigate the tolerability to wear the patch and feasibility to apply and remove the patch in the oral cavity – and furthermore to investigate the safety of the patch.

Data indicated that the patients found the Rivelin® patch easy to apply and remove, with pain scores at application and removal lower than the patients' general pain grading from the disease. The patches were also found acceptable to wear with very positive scores on the patch sensitivity questionnaire consisting of 12 questions.

Finally, there were no serious adverse events or casually related adverse events recorded during the study.

"The Rivelin® patch provides a new and targeted treatment strategy for patients with mucosal conditions, which are severely affecting their quality of life. We are excited to be part of this opportunity to address this unmet clinical need", says prof. Thomas Ruzicka lead investigator.

"We are very pleased, that the Phase 1b study has confirmed the feasibility for patients of the Rivelin® patch – and are looking forward to commencing our Phase 2b study in April 2018 with the clobetasol loaded Rivelin® patch targeting the treatment of Oral Lichen Planus patients", says Jens Hansen, co-founder and CEO of Dermtreat.

For additional information please contact:

Jens Hansen, PhD
Chief Executive Officer
Dermtreat ApS
Phone: (+45) 4050 5597
jh@rivelin.eu



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 www.rivelin.eu

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).*