



## DERMTREAT LAUNCHES PHASE 1B STUDY

## Copenhagen, Denmark – June $1^{st}$ , 2017: Danish-based Dermtreat today announced the launch of its phase 1b study of the Rivelin® patch – a breakthrough therapy in treating mucosal diseases.

Dermtreat has developed the Rivelin® patch – a breakthrough therapy for the treatment of mucosal diseases. Rivelin® is designed to deliver a pharmaceutical drug uni-directional 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 by incorporating the drug clobetasol proprionate in the Rivelin® patch.

In preparation for the phase 2b study planned to commence in Q4 2017, Dermtreat is conducting a 30-patient phase 1b clinical study planned over four clinical sites in Germany, with the purpose of testing the non-drug-loaded Rivelin® patch in patients suffering from Oral Lichen Planus. The first patient was enrolled on May 30, and Dermtreat expect the study to be completed by Q3 2017.

"Dermtreat has the potential to make a significant difference for patients with mucosal conditions, which are severely affecting their quality of life with no efficacious treatment available", says Jens Hansen, co-founder and CEO of Dermtreat. "We are very encouraged by the strong interest and support we have been given from the community of dermatology and oral medicine experts, which includes a close cooperation with amongst others, University of Munich, University of Sheffield (UK), University of Copenhagen and Carolinas HealthCare System (North Carolina, US)."

The primary objective of the Phase 1b study is to investigate the adhesion time of Rivelin® plain patches at sensitive ulcerative/erosive and/or atrophic/erythematic OLP lesions.

Secondary objectives are to investigate (i) the tolerability and (ii) the safety of Rivelin® plain patches attached to sensitive ulcerative/erosive and/or atrophic/erythematic OLP lesions – and (iii) to evaluate the feasibility to apply Rivelin® plain patches in the oral cavity.

Furthermore exploratory objectives are (i) to explore the disease activity over time while using Rivelin® plain patches assessed by clinician observation; and (ii) to evaluate the effect on pain and functional limitation by applying Rivelin® plain patches to OLP lesions.

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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, a chronic condition that affect 1-2% of the population. The Rivelin® patch incorporates clobetasol proprionate to treat OLP and is currently in Phase 1b, with commencement of Phase 2b planned for 4Q 2017.

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

For additional information, please visit <u>www.rivelin.eu</u>.

## About Oral Lichen Planus

Oral Lichen Planus 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 topic 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*).