



DERMTREAT SECURES GMP MANUFACTURING

Copenhagen, Denmark – October 26th, 2017: Danish-based Dermtreat today announced the GMP (Good Manufacturing Practices) approval for the production of its novel 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-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 Rivelin® patch is manufactured by electrospinning, providing a significant contribution to these unique properties.

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 propionate in the Rivelin® patch.

Manufacturer of the Rivelin® patch is Dermtreat's Spanish partner Bioinicia S.L. – an engineering company dedicated to the development and manufacturing of nano- and micro-structured materials by electrospinning and electrospaying.

Based on a close cooperation with Dermtreat, Bioinicia has built an industrial scale electrospinning plant for the manufacturing of the Rivelin® patch. As a pharmaceutical product, the manufacturing must be audited and approved by the regulatory authorities to document meeting the required GMP standards – with the purpose of safeguarding the health of patients.

This GMP approval has just been awarded by the Spanish authorities – following shortly after an ISO 9001:2015 and ISO 13985:2016 certification of the manufacturing plant awarded in July.

"We are proud to be what we believe to be the world's first GMP approved facility using electrospinning technology for the manufacturing of pharmaceutical products", says Jose Manuel Valle, CEO of Bioinicia S.L. "We are very excited by the close cooperation with Dermtreat and the many possibilities with the Rivelin® patch, and are looking forward to developing the manufacturing processes for other applications of this strong drug delivery platform".

"We have been very impressed with the speed and dedication, with which Bioinicia has established an industrial scale, GMP approved manufacturing facility for our Rivelin® patch", says Jens Hansen, co-founder and CEO of Dermtreat ApS. "Bioinicia will now commence the production of the Rivelin® patch for our clinical Phase 2b study planned to launch in 1Q 2018".

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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 1Q 2018.

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

For additional information, please visit www.rivelin.eu.

About Bioinicia

Bioinicia S.L. is a Spanish-based materials science and engineering company dedicated to the development, industrial scale-up and manufacturing of nano- and microstructured materials by electro-hydro dynamic processes (i.e. electrospinning and electrospraying) for their clients, and providing premium quality equipment for laboratory to industrial-scale processing.

Using expertise in EHD process from laboratory research to industrial manufacture, Bioinicia can assist in developing products from concept to market. Bioinicia acts not just as a provider, but as a partner for product development, electrospinning-electrospraying technology and industrial manufacturing.

For additional information, please visit www.bioinicia.com.

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*).