



TopiVert completes preclinical development with TOP1630 for dry eye disease

- IND to be submitted in US in H2 2016
- Phase I/II study on track to commence in US in early 2017

London, UK, 16 May 2016: TopiVert Pharma Ltd (“TopiVert” or the “Company”), a clinical-stage biotechnology company developing Narrow Spectrum Kinase Inhibitors (NSKIs) as novel, locally-acting medicines for the treatment of chronic inflammatory diseases of the gastrointestinal tract and eye, announces that it has completed the preclinical development of TOP1630 for the treatment of dry eye disease. An investigational new drug (IND) application is being prepared for submission later in the year ahead of a planned Phase I/II study in the US which is on track to commence in early 2017.

TOP1630 is a potent, topical anti-inflammatory NSKI with minimal systemic uptake being developed for the treatment of dry eye disease, one of the most common ophthalmic diseases worldwide. In moderate to severe cases, sufferers commonly experience debilitating symptoms, including burning, irritation and blurred vision, which can have a considerable impact on quality of life. There is currently no adequate therapy available which effectively addresses both the signs and symptoms for dry eye disease sufferers.

Formulated as a simple eye drop solution for topical administration, TOP1630 has demonstrated excellent anti-inflammatory activity and shown to be at least as effective as topical steroids in preclinical models of disease. Steroids are established treatments for dry eye disease but their use is restricted, particularly in the long term, by significant safety issues. With excellent preclinical safety and minimal systemic uptake, TOP1630 promises to be a safe and effective topical treatment for dry eye disease. TopiVert is currently preparing to submit an IND to the US Food and Drug Administration (FDA) in the second half of 2016. Once approved, this would allow a planned Phase I-IIa study in dry eye disease patients to start in the US in early 2017, with results expected by mid-2017.

Steve Webber, CSO of TopiVert, commented: *“TOP1630 for dry eye disease is our lead ophthalmology programme and it has completed preclinical development with flying colours. Having already successfully progressed our first GI programme into the clinic, we are now delighted to be planning the start of our first ophthalmology study in early 2017. As a promising topical anti-inflammatory agent, TOP1630 aims to improve the signs and symptoms of dry eye disease, one of the most common eye diseases, where current therapy remains inadequate for all but the mildest of cases.”*

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About TopiVert

TopiVert is a clinical-stage biotechnology company developing narrow spectrum kinase inhibitors as novel, locally-acting medicines for the treatment of chronic inflammatory diseases of the gastrointestinal tract and eye. The Company's most advanced drug candidate, TOP1288 for the treatment of ulcerative colitis, has successfully completed Phase I development and a Phase IIa proof of concept study is planned to commence in mid 2016. TopiVert also expects to start the clinical development of TOP1630, its candidate for dry eye disease (DED), in early 2017. Current therapies for these debilitating diseases provide inadequate long-term control in a high proportion of patients and considerable unmet medical need remains. The Company commenced operations in early 2012 and its investors include Imperial Innovations, SV Life Sciences, NeoMed and Johnson & Johnson Innovation-JJDC, Inc.

About Narrow Spectrum Kinase Inhibitors (NSKIs)

NSKIs are novel small molecules characterised by relatively broad, potent anti-inflammatory activity and only minimal systemic exposure. Specifically, NSKIs are potent inhibitors of a select range of pivotal kinases involved in inflammatory cascades of both innate and adaptive immunity. Simultaneous targeting of multiple inflammatory components leads to a synergistic activity profile with broad anti-inflammatory effects. The NSKIs are designed to have low bioavailability to reduce their exposure to many of the body's healthy tissues, thereby enhancing their safety and tolerability profiles. Together, these attributes make NSKIs ideal treatment candidates for chronic inflammatory diseases where long term therapy demands a sustained effect accompanied by excellent safety and tolerability.

About Dry Eye Disease

Dry eye disease (DED) is an often-chronic ocular disease associated with inflammation. It is the most common eye disease worldwide, affecting an estimated 15-40 million people in the US alone, and its prevalence increases dramatically with age. DED is often associated with symptoms that reduce a sufferer's quality of life, impacting their ability to function normally at work and at home. It can also be a progressive disease and may eventually lead to damage to the surface of the eye. Currently available treatments have only limited efficacy or provide only symptomatic improvement and are associated with side effects that include burning and stinging. This makes DED an area of high unmet medical need and a major opportunity for TopiVert.

TopiVert's lead compound for DED, TOP1630, targets a select number of important kinases involved in the inflammatory cascade, synergistically inhibiting key pathways involved in innate and adaptive immunity. It has been specifically designed to have a localised action in the eye, with only minimal systemic absorption. Thus it has the potential to deliver enhanced efficacy, improving both signs and symptoms of dry eye disease, and an excellent safety profile to enable the long term treatment of this often debilitating disease.