**TopiVert receives IND approval for TOP1630 in the treatment of dry eye syndrome**

**London, UK, 28 November 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 (GI) tract and eye, announced today that its Investigational New Drug (IND) application for the evaluation of TOP1630 ophthalmic solution as a treatment of patients with dry eye syndrome (DES) has been approved by the US Food and Drug Administration (FDA).

NSKIs target several important kinases involved in the signalling cascade in inflammatory cells, leading to synergistic inhibition of key pathways involved in innate and adaptive immunities. TOP1630, the Company's lead NSKI for ophthalmology, has demonstrated an excellent activity profile in *in vitro* and *in vivo* pre-clinical inflammatory models where it was shown to be potent and have a fast onset of action. When administered as eye drops, TOP1630 is taken up and retained by target inflammatory cells in the cornea but has minimal systemic absorption, making it an ideal topical eye therapy.

TopiVert is initially developing TOP1630 in DES, a common inflammatory disorder of the "front of the eye". Currently available treatments for DES have only limited efficacy in treating both the signs and symptoms of the disease and they often display side-effects that include burning and stinging in the short term or lead to further complications in the long term. A major unmet medical need remains for a more effective and better tolerated therapy for this debilitating disorder.

TOP1630 has the potential to provide rapid symptomatic relief together with long-term efficacy in the treatment of the signs and symptoms of DES. Following this IND approval, TopiVert is on schedule to commence a Phase 1/2a proof-of-concept study in the US in January 2017 to assess the safety and efficacy of TOP1630 in DES patients.

**Steve Webber, TopiVert's Chief Scientific Officer, commented**: *"The FDA approval of this study, enabling us to advance our second NSKI into the clinic, is a significant step for TopiVert. TOP1630 is our lead NSKI compound in ophthalmology and which is being developed for the treatment of dry eye syndrome, one of the most common inflammatory eye diseases. We expect results from this proof of concept study in the second half of 2017, around the same time that we expect proof of concept data for TOP1288 in ulcerative colitis. This is an exciting time for TopiVert as it seeks clinical validation of its NSKI technology in two different inflammatory diseases."*

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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, is currently in a Phase 2a proof of concept study which is due to report in the second half of 2017. TopiVert also expects to start the clinical development of TOP1630, its candidate for dry eye syndrome (DES), 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 immunities. Simultaneous targeting of multiple inflammatory components leads to a synergistic activity profile with broad anti-inflammatory effects. NSKIs are designed to have low systemic bioavailabilities in order to reduce their exposure to many of the body's healthy tissues and thereby enhance 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 Syndrome**

Dry eye syndrome (DES), also known as dry eye disease, keratoconjunctivitis sicca (KCS) or keratitis sicca, is an inflammatory eye disease characterised by dryness on the surface of the eye. It is usually a chronic problem and it can be debilitating in severe cases. It is also one of the most common eye diseases, with almost 19 million sufferers in the US alone and over 300 million worldwide[1], and it becomes more common with age, with a third of elderly people suffering from DES.

[1] Market Scope®, 2013 Report on the Global Market for Dry Eye Products