



TopiVert commences proof of concept study for TOP1630 in the treatment of dry eye syndrome

London, UK, 22 February 2017: 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 gastrointestinal (GI) and ocular diseases, today announces the successful dosing of the first patients in a Phase 1/2a proof of concept study in the US of TOP1630 ophthalmic solution for the treatment of dry eye syndrome (DES).

NSKIs target several important kinases 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 efficacy in *in vitro* and *in vivo* pre-clinical inflammatory models where it was potent and had a fast onset of action. When administered as eye drops, TOP1630 is absorbed and retained in target inflammatory cells in the cornea and with only minimal systemic exposure, 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. The current study is expected to report in the second half of this year.

Ajay Duggal, TopiVert’s Chief Medical Officer, commented: *“Advancing our second NSKI into the clinic is a major step forward for TopiVert. TOP1630, our lead NSKI in ophthalmology, 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 as 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 gastrointestinal (GI) and ocular diseases. The Company's lead GI programme, TOP1288 for the treatment of ulcerative colitis, is currently in a Phase 2a proof of concept study with a rectal formulation and an oral formulation is due to enter the clinic imminently. In parallel, its lead ophthalmology programme, TOP1630 for dry eye syndrome (DES), is currently being evaluated in Phase 1/2a proof of concept study in the US. All three clinical studies are due to report in the second half of 2017. Current therapies for these debilitating inflammatory 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 broad, potent anti-inflammatory activity and 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 bioavailability so that their exposure to the body's healthy tissues is reduced and thus their safety and tolerability enhanced. 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 worldwide¹, 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