



TopiVert completes three clinical studies which will deliver proof of concept data for its two lead NSKI programmes in ulcerative colitis and dry eye syndrome

London, UK, 26 June 2017: TopiVert Pharma Ltd (“TopiVert” or the “Company”), a clinical-stage biotechnology company developing Narrow Spectrum Kinase Inhibitors (NSKI) as novel, locally-acting medicines for the treatment of chronic inflammatory gastrointestinal and ocular diseases, today announces the successful completion of three clinical studies TV02, TV03 and TV04, which are all on course to report later in the year.

TV02 is a Phase 2a study designed to demonstrate proof of concept (POC) for TOP1288 in the treatment of patients with moderate to severe UC when administered as an enema. This topical enema formulation has been developed to ensure the drug is presented directly to the site of the disease in the colon to demonstrate POC. The primary efficacy endpoint is endoscopic remission. TV03 is a Phase 1 study assessing the safety, pharmacokinetics and pharmacodynamics of TOP1288 delivered orally in healthy volunteers. The results from these studies will help guide the forward development of an oral formulation of TOP1288 as the intended commercial presentation in the treatment of inflammatory bowel disease (UC and Crohn’s disease).

TV04 is a Phase 1/2a proof of concept study of TOP1630 ophthalmic solution (eye drops) conducted in patients with dry eye syndrome (DES). The study is evaluating the safety and tolerability of the formulation along with multiple assessments of efficacy for both signs and symptoms of the disease. Results from this study are also expected later this year.

Ajay Duggal, TopiVert’s Chief Medical Officer, commented: *“We are delighted with the progress made in delivering all three clinical studies for TOP1288 and TOP1630, our lead NSKI programmes in IBD and ophthalmology respectively. These studies will report later this year and the results will guide the further development of these exciting NSKI programmes as potent topical, anti-inflammatory treatments. This is an exciting time for TopiVert as it seeks clinical validation of its NSKI technology in two different indications both with high unmet medical needs.”*

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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, has recently completed two clinical studies: a Phase 2a proof of concept study with a rectal formulation, and a Phase 1 study with an oral formulation of TOP1288. In parallel, its lead ophthalmology programme, TOP1630 for dry eye syndrome (DES), has recently completed a 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 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 SV Health Investors, Touchstone Innovations 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. The 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 IBD and ulcerative colitis

Inflammatory bowel disease (IBD) is a term used to describe several diseases that involve inflammation of the gastrointestinal tract. The two most common forms of IBD, Crohn's disease and ulcerative colitis, together affect over 4 million people worldwide. They are both chronic relapsing conditions that cause bloody diarrhoea, abdominal pain and significant reductions in a patient's quality of life. While their causes are not fully understood, these diseases are characterised by an abnormal inflammatory reaction that leads to damage of the intestinal wall.

Current treatments for ulcerative colitis involve administration of oral, rectal or intravenous/subcutaneous anti-inflammatory and immunomodulatory therapies, including biologics. Despite these products being effective in treating active disease in some patients, their long term use is often hampered by safety and tolerability issues. Furthermore, at least 40% of patients have poorly controlled disease and around 20% require surgery to manage the disease.

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