



**TopiVert to present first in human data from its Phase I clinical study with TOP1288 at DDW 2016 in San Diego**

**London, UK, 9 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 will present posters on the Phase I study data results and pre-clinical pharmacology for TOP1288, its lead compound for the treatment of ulcerative colitis (UC), a form of inflammatory bowel disease (IBD), at the Digestive Disease Week (DDW) 2016 in San Diego, California, from 21-24 May.

Senior members of the management and R&D teams will be available at the conference to discuss the data with interested parties. The posters to be presented are:

- *A first-in-human randomized double-blind placebo-controlled clinical trial of a novel narrow spectrum kinase inhibitor.* Rowley et al.
- *TOP1210 NSKI Demonstrates Superior Activity and Improved Safety Profile Potential Compared to Corticosteroid and Immunomodulators in Preclinical Models of Colitis.* Walshe et al.
- *Inhibition of cytokine release from HT-29 cells and ulcerative colitis biopsies is potentiated by combination of selective kinase inhibitors and such effects are mimicked by TOP1210, a Narrow spectrum kinase inhibitor (NSKI).* Foster et al.
- *Effects of TOP1210, a narrow spectrum kinase inhibitor, and selective kinase inhibitors on the intestinal pro-inflammatory immune response in ulcerative colitis.* Foster et al.

The posters are all available at [www.topivert.com/our-science-publications](http://www.topivert.com/our-science-publications)

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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 the middle of this year. 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.

#### **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, as many as 40% of patients remain uncontrolled and around 20% require surgery to manage the disease.