



Topivert starts Phase I Clinical Trial with lead compound, TOP1288, in Ulcerative Colitis

London, UK, 14 May 2015: TopiVert Pharma Ltd (“TopiVert” or the “Company”), a clinical-stage biotech focused on the local treatment of serious inflammatory diseases, today announced the start of a Phase I study with its lead compound, TOP1288, in ulcerative colitis (UC).

TOP1288 is a Narrow Spectrum Kinase Inhibitor (NSKI). NSKIs are a novel class of small molecules with specific characteristics designed to deliver local effects in inflammatory cells whilst avoiding significant systemic exposure.

TOP1288 is being tested initially in a Phase I study, including volunteers and UC patients, to examine safety and tolerability of a rectal formulation as well as to explore predictive biomarkers for use in later studies. The trial, conducted at a specialist centre in London, is the first part of a programme to deliver a novel oral and rectal anti-inflammatory treatment for patients with UC. The trial will report in 2016.

UC is a relatively common inflammatory disease affecting the large bowel and around 40% of patients fail to respond fully to current drug therapy, which can also be linked to significant side effects. The disease can be serious enough to require surgery to remove the diseased colon in some patients.

Dr Steve Webber, Chief Scientific Officer of TopiVert, said *“We are pleased to reach the clinic so quickly with our lead compound which has significant potential to help patients with this debilitating condition.”*

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About TopiVert

TopiVert is a clinical-stage biotech focused on pioneering topical treatments for serious inflammatory diseases. TopiVert’s specifically designed small molecules, with a localised, non-systemic mode of action, exert a synergistic effect on key kinases which play a pivotal role in multiple inflammatory pathways, leading to broad efficacy in both innate and adaptive immunity.

TopiVert’s lead compound, TOP1288, is now in Phase I clinical development in both patients and healthy volunteers with data expected in H1 2016. The Company also has a candidate for ocular inflammatory conditions scheduled to start clinical trials in 2016 in addition to a range of early-stage molecules in development.

TopiVert commenced operations in early 2012 and its investors include Imperial Innovations, SV Life Sciences, NeoMed, and a strategic investment from Johnson and Johnson Development Corporation.

About Narrow Spectrum Kinase Inhibitors

Narrow Spectrum Kinase Inhibitors (NSKIs) are small molecules targeting key kinases which play pivotal roles as signalling molecules in multiple inflammatory pathways. Inhibition of this combination of kinases leads to potent and broad anti-inflammatory effects in both innate and adaptive immune responses. The compounds are specifically designed to prevent absorption into the circulation, thereby avoiding any propensity for systemic side effects

About Ulcerative Colitis

UC is a common disease occurring with a prevalence of 200/100,000 of the US population and approximately 150/100,000 of population in Western Europe. It is characterized by diffuse, superficial inflammation of the colonic mucosa associated with bloody diarrhoea, abdominal pain, faecal urgency, and incontinence.

Current treatments, which include systemically administered biologics, steroids and immune modulators, are associated with numerous serious side effects that limit their utility. In addition, failure of medical therapy leads to colectomy in 9% to 35% of UC patients within 5 years.

The limitations of current therapies for UC indicate that there is a significant need for safer and more effective therapies.

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