TopiVert Announces Publication of Data from its Positive Phase 2 Study with TOP1630 in Dry Eye Disease in Peer-reviewed Journal

Phase 2b/3 program in dry eye disease to start during 2019

London, UK, 12 February 2019: TopiVert Pharma Ltd ("TopiVert" or the "Company"), a clinical-stage biotechnology company developing non systemic kinase inhibitors (NSKIs) as novel, locally-acting medicines for the treatment of chronic inflammatory ocular diseases, today announces the publication of the paper "A Phase 2 randomised, double-masked, placebo-controlled study of novel nonsystemic kinase inhibitor TOP1630 for the treatment of dry eye disease" in Clinical Ophthalmology. Authors: Taylor et al; Clinical Ophthalmology 2019;13:1-15. URL: https://www.dovepress.com/articles.php?article_id=44028

In this notable study TOP1630 produced statistically significant improvements in multiple symptom and sign endpoints compared with vehicle in both environmental and Controlled Adverse Environment (CAE®; Ora, Inc.) challenge settings. Positive assessments consistently favoured TOP1630 across a broad range of symptom endpoints, including relief of ocular dryness, pain/ocular discomfort, foreign body discomfort, and grittiness. Consistent with the promising efficacy profile on symptoms, positive effects were seen for total, corneal, and conjunctival region staining scores. This finding is indicative of a benefit on the total ocular surface and this endpoint may represent the most relevant staining measure for dry eye compared with individual segmental scores. TOP1630 also demonstrated placebo-like safety and tolerability. The resultant TOP1630 benefit-risk profile for the treatment of dry eye disease is highly favourable. Top-line results from the study were presented at the Association for Research in Vision and Ophthalmology (ARVO) 2018 annual meeting.

Based on this successful Phase 2 study result and following discussion with the FDA, TopiVert is initiating a Phase 2b/3 program in dry eye disease in 2019. The first study in this program **THEIA-1** is anticipated to start recruiting subjects during Q1 2019. **THEIA-1** is a multicentre, randomised, double-masked, placebo-controlled efficacy and safety study of 0.1% TOP1630 ophthalmic solution in dry eye subjects. This study is scheduled for completion in 2019 and represents an important component of the registration program for TOP1630.

Ajay Duggal, TopiVert's Chief Medical Officer, said: "We are excited to publish, for the first time, results from our important clinical data demonstrating TOP1630's convincing efficacy in treating both the symptoms and signs of dry eye disease with placebo-like tolerability. These compelling clinical data support progression of TOP1630 to late-stage development for dry eye disease starting imminently with the **THEIA-1** study, and the exploration of the use of NSKIs as potential treatments for other ocular inflammatory disorders."

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About TopiVert

TopiVert is a clinical-stage biotechnology company developing non systemic kinase inhibitors (NSKI)s as novel, locally-acting medicines for the treatment of chronic inflammatory ocular and gastrointestinal (GI) diseases. The Company's lead ophthalmology programme, TOP1630 for dry eye syndrome, has reported compelling results in a Phase 1/2a POC study conducted in the US. The Company's lead GI programme, TOP1890 for the treatment of ulcerative colitis, is clinic-ready. Current therapies for these debilitating inflammatory diseases provide inadequate long-term control in a high proportion of patients and are associated with troublesome side effects such that considerable unmet medical need remains. The Company commenced operations in early 2012 and its investors include SV Health Investors, IP Group, NeoMed and Johnson & Johnson Innovation – JJDC, Inc.

About Non Systemic 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, thereby providing enhanced safety and tolerability. 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 Disease

Dry eye disease, also known as dry eye syndrome, keratoconjunctivitis sicca or keratitis sicca, is an inflammatory eye condition 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]. Dry eye disease becomes more common with age, with a third of elderly people suffering from this ailment.

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