TopiVert Announces First Patients Dosed in THEIA-1 Phase 2b/3 Clinical Study of TOP1630 as a treatment for Dry Eye Disease

The trial is the first of two pivotal studies that could support US registration of TOP1630, a novel, proprietary kinase inhibitor

THEIA-1 is scheduled to report top line data in H2 2019

London, UK, 27 February 2019: TopiVert Pharma Ltd ("TopiVert" or the "Company"), a clinical stage biotechnology company advancing innovative therapeutics to improve ocular health, today announces that the first patients have been dosed in the THEIA-1 phase 2b/3 clinical study evaluating TOP1630, a novel anti-inflammatory kinase inhibitor, as an ophthalmic solution for the treatment of dry eye disease.

THEIA-1 is a multi-centre, randomised, double-masked, placebo-controlled phase 2b/3 study that will enrol approximately 200 adult patients with moderate to severe dry eye disease. The objective of the study is to assess the efficacy of TOP1630 0.1% Ophthalmic Solution, compared to placebo at day 29 on primary endpoints of ocular grittiness and total ocular surface (all-regions) lissamine green staining. TopiVert expects top line data to be available from THEIA-1 during H2 2019. The study has been designed to serve as the first US registrational study for TOP1630 in dry eye disease.

The initiation of THEIA-1 follows the recent publication of results from the positive proof of concept phase 2 clinical study of TOP1630 in dry eye disease in the peer reviewed journal *Clinical Ophthalmology*[1].

Dry eye disease, also known as dry eye syndrome, keratoconjunctivitis sicca or keratitis sicca, is a chronic inflammatory eye condition. It is one of the most common ophthalmic diseases, with almost 19 million sufferers in the US alone and over 300 million worldwide[2]. While there are a limited number of drugs approved for the treatment of dry eye disease, there remains a significant unmet medical need for efficacious and well tolerated new therapies.

Ajay Duggal, TopiVert's Chief Medical Officer, said: "We are pleased to achieve this important milestone of dosing our first patients in the THEIA-1 phase 2b/3 clinical study. We hope the study will build on the results from our clinical proof of concept study, which demonstrated encouraging evidence of TOP1630's efficacy in treating both the symptoms and signs of dry eye disease along with placebo-like tolerability and a favourable adverse event profile. Importantly, this study is the first of two US pivotal trials that will potentially support US registration of TOP1630 as a treatment in this indication."

"Despite the availability of several treatments for dry eye disease, there remains a substantial unmet medical need based upon the limited efficacy and significant tolerability issues experienced by many patients prescribed currently available therapies. TopiVert is focused on leveraging its core expertise in inflammation to identify, develop and deliver novel therapeutics that bring meaningful benefits to patients with ocular disease."

Additional information about the THEIA-1 study, can be found at: https://clinicaltrials.gov (ClinicalTrials.gov Identifier: NCT03833388).

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About TopiVert

TopiVert is a clinical-stage biotechnology company advancing innovative therapeutics to improve ocular health. The Company's mission is to leverage its core expertise in inflammation to identify, develop and deliver novel therapeutics that bring meaningful benefits to patients with ocular disease. The Company's lead programme, TOP1630 for dry eye disease, has recently reported compelling results in a proof of concept study conducted in the US. The Company commenced operations in early 2012 and its investors include SV Health Investors, IP Group, NeoMed and Johnson & Johnson Innovation – JJDC, Inc.

About TopiVert's Kinase Inhibitors

TopiVert's proprietary kinase inhibitors are novel small molecules characterised by broad, potent anti-inflammatory activity with exceptional safety and tolerability. Specifically, TopiVert's kinase inhibitors target pivotal kinases that control pro-inflammatory cascades in both the innate and adaptive arms of the immune system. Simultaneous targeting of multiple inflammatory pathways leads to rapid down regulation of damaging inflammatory responses. TopiVert's kinase inhibitors are designed to have low systemic bioavailability so that exposure to the body's healthy tissues is reduced, thereby providing enhanced safety and tolerability. Together, these attributes position our candidates as ideal treatments for chronic inflammatory diseases where long term therapy requires sustained efficacy with no compromise on safety and tolerability.

About Dry Eye Disease

Dry eye disease, also known as dry eye syndrome, keratoconjunctivitis sicca or keratitis sicca, is a chronic inflammatory eye condition. It is also one of the most common ophthalmic diseases, with almost 19 million sufferers in the US alone and over 300 million worldwide[2]. Dry eye disease becomes more common with age, with a third of elderly people suffering from this ailment.

1 - Taylor et al; Clinical Ophthalmology 2019; 13: 261-275
2 - Market Scope®, 2013 Report on the Global Market for Dry Eye Products