



Squarex Announces Publication of Clinical Results for SQX770 for the Prevention of Herpes Outbreaks in *Immunity, Inflammation and Disease*

Demonstrates Safety and Mechanism of Action in Patients with Frequent Cold Sores

St. Paul, MN – February 14, 2019 – Squarex, a clinical-stage pharmaceutical company developing a topical immunomodulator for the long-term prevention of recurrent cold sores, today announced the publication of clinical data from a clinical trial of SQX770 in patients with frequent, infrequent, or zero herpes labialis (cold sore) outbreaks per year. The study, titled, “*Immune characteristics correlating with HSV-1 immune control and effect of squaric acid dibutyl ester on immune characteristics of subjects with frequent herpes labialis episodes*,” by McTavish, Zerebiec, *et al.* has been published in the peer-reviewed journal *Immunity, Inflammation and Disease*.

The study characterized the immune-related gene expression levels in subjects with good versus poor control of HSV-1 infection (*i.e.*, those with zero or few cold sore outbreaks compared to those with greater than six outbreaks per year) and found that good immune control of HSV-1 correlated with a particular immune-related gene signature. Specifically, these patients exhibited higher expression of interferon-gamma (IFNG) and five other immune-related genes ($P < 0.05$ for each) and lower expression of interleukin 5 (IL5) and two other immune-related genes ($P < 0.05$ for each) in immune cells (peripheral blood mononuclear cells) stimulated with HSV-1 virus. Furthermore, it was found that a single topical application of squaric acid dibutyl ester (SADBE; Squarex’s lead product candidate SQX770) changed the gene signature in subjects with frequent cold sore outbreaks to be more in line with that of subjects with fewer outbreaks, signaling an improved immune response to HSV-1. It also found that patients with good control of HSV-1 infection had higher immune cell proliferation in response to an HSV-1 challenge, and that SADBE treatment improved immune cell proliferation in subjects with poor control of HSV-1.

Founder and President of Squarex, Hugh McTavish, Ph.D., said, “As a frequent cold sore sufferer, I was desperate to find something that would help prevent outbreaks from reoccurring. Currently, there is no FDA-cleared treatment for delaying or preventing cold sore outbreaks. These results, which highlight the positive effect of SQX770 on immune control of HSV-1, combined with our placebo-controlled Phase 1/2 study that showed SQX770 is safe and effective and tripled the time to next cold sore outbreak, are highly encouraging. We look forward to starting our pivotal trials and to sharing those results with the U.S. Food and Drug Administration.”

About Squarex

Squarex is a clinical-stage pharmaceutical company developing a topical formulation of the immunomodulator squaric acid dibutyl ester (SQX770) for the prevention of recurrent cold sores (herpes labialis) and other infections caused by Herpes Simplex Viruses. Its Phase 1/2 placebo-controlled clinical trial showed the drug was safe and effective in preventing cold sore outbreaks, tripling the time to next cold sore outbreak from 40 days

to more than 120. When FDA approved, SQX770 would be the first and only drug on the market to prevent cold sore outbreaks in the more than 2% of the U.S. population with greater than six outbreaks per year.

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