



PRESS RELEASE

Squarex Announces Successful End of Phase 2 Meeting with FDA for its Cold Sore Prevention Asset

Saint Paul, Minnesota, USA, 19 January 2021 – Squarex Pharma (SQX), a St. Paul, Minnesota, USA-based company, announced updated results from its Phase 2 clinical study on humans with its novel asset SQX770 for prevention of cold sores also known as herpes labialis or oral herpes, an illness caused by herpes simplex virus, usually type 1 (HSV-1).

SQX770 is a unique, first in class topical immunomodulator. SQX770 is the only product shown to reduce the number of cold sore events or flareups as well as their severity.

About 50% of the Western population is infected with HSV-1. Herpes outbreaks give rise to cold sores, usually seen as painful sores or blisters around the lips of the patient. Currently there are no preventative treatments, only pills, creams, and ointments to be used once cold sores appear in order to shorten the outbreak. Current drugs do nothing to prevent reoccurrence of outbreaks or reduce the number of outbreaks.

SQX770 addresses a very substantial worldwide market—2.1% of the population has 6 or more outbreaks per year and 15% have 1 or more.

SQX770 is applied topically and has a systemic effect: one topical dose applied with a dermal patch to the upper arm prevents outbreaks for three months. An earlier Phase 1 study at Massachusetts General Hospital in Boston, USA, showed that SQX770 has significant efficacy versus placebo in reducing the recurrence of cold sores.

SQX770 is thought to work by stimulating the sufferer's immune system via the dendritic cell network in the skin and stimulation of T-cell activity. SQX770 is intended to be available by a doctor's prescription although ultimately it could be available over the counter in pharmacies.

The Phase 2 study with 139 patients using SQX770 at 5 sites confirmed this in showing reduced number of cold sore outbreaks and further showed reduction in severity of the (fewer) outbreaks that occurred.

Thus, efficacy and safety have been demonstrated in each of two double-blind placebo-controlled clinical trials. A third clinical trial showed significant improvement in cellular immune response to the HSV-1 virus after dosing with SQX770.

Patents covering SQX770 are issued in US, Europe, and Japan until at least 2036 and pending in China, Canada, India, and Australia

Squarex announces that it has completed an End-of-Phase 2 meeting with the U.S. FDA which has provided a clear and achievable path to a New Drug Application in the USA following ultimately a routine Phase 3 study. It will pursue a similar path for regulatory approval in Europe and the rest of the world.

Squarex seeks a global strategic partner with which it can collaborate to exploit its SQX770 drug and take it through final clinical development to market authorisation.

Hugh McTavish, CEO of Squarex, said “Results from patients recruited into our clinical study are very promising; we believe that our novel drug asset SQX770 addresses a large, global unmet clinical need for those people suffering from frequent cold sores due to herpes labialis. Our end of Phase 2 meeting with FDA has been very positive and helpful in pointing the way forward for marketing approval for SQX770. We estimate that the annual market for prevention of oral herpes in the USA is about \$600 million.”

For more information about Squarex and partnering opportunities for its Herpes Labialis preventative treatment, please contact:

Hugh McTavish
CEO, Squarex Pharma LLC
Tel: +1 [651 4920283](tel:6514920283)
hmctavish@squarex-pharma.com

About Squarex Pharma

Squarex is a clinical stage pharmaceutical company which has developed a topical formulation of the immunomodulator squaric acid dibutyl ester for the prevention of recurrent cold sores (herpes labialis) and other infections caused by Herpes Simplex Virus 1 or Herpes Simplex Virus 2.

More than 6 Million people in the U.S. alone suffer with 6 or more herpes labialis outbreaks every year with no existing medications indicated for the prevention of outbreaks.

Squarex’s drug SQX770 is unique. A single topical application to the arm, not the lip or face, has been shown in clinical trials to prevent cold sore outbreaks (oral herpes) in people with frequent outbreaks for 3 months.

Website: <https://squarex-pharma.com/>