

# Devonian Health Group Announces Positive Topline Results from Phase 2 Clinical trial of Thykamine™ in Adult Patients with Mild-to-Moderate Atopic Dermatitis.

*-Thykamine™ monotherapy achieved positive results by reaching the study's primary endpoint with statistical significance, delivering significant improvement in skin clearance as determined by the Investigator Global Assessment (IGA)*

*-Trial demonstrated statistically significant results on secondary endpoint of Body Surface Area (BSA)*

*-Thykamine™ was well well-tolerated, safety profile consistent with prior studies*

*- Efficacy and safety profile support advancement into Phase 3 in Adult Patients with Mild-to-Moderate Atopic Dermatitis*

*- Efficacy and safety profile support advancement into a clinical trial in Pediatric population with Mild-to-Moderate Atopic Dermatitis*

QUEBEC CITY--(BUSINESS WIRE)--February 18, 2021--Devonian Health Group Inc. ("Devonian" or the "Corporation") (TSXv: GSD), a clinical stage botanical pharmaceutical corporation, focused on developing a unique portfolio of botanical pharmaceutical and cosmeceutical products, today announced that Thykamine™ met the primary endpoint in its Phase 2 Study for the treatment of mild-to-moderate atopic dermatitis (AD).

The Phase 2 trial was a double-blind, randomized, placebo-controlled trial designed to evaluate the efficacy and safety of Thykamine™ cream monotherapy (0.05%, 0.1% and 0.25%) compared to placebo in skin clearance as assessed by the Investigator Global Assessment (IGA) in adult patients with mild-to-moderate atopic dermatitis. Efficacy and safety were assessed every week over a four-week dosing treatment (twice-a-day). A total of 162 patients, spread over several sites in Canada, were recruited for this study.

Compared to placebo, Thykamine™ at 0.1% demonstrated significant improvement of the primary endpoint, i.e. skin clearance (IGA) at all measured timelines (week 1:  $p = 0.006$ ; week 2:  $p < 0.001$ ; week 3:  $p < 0.001$ ; Week 4:  $p=0.002$ ) resulting in demonstrating a fast onset of the therapeutic effect.

In addition, Thykamine™ achieved statistically significant differences, compared to placebo, in its key secondary efficacy endpoint, i.e. Body Surface Area (BSA). Thykamine™ at doses of 0.05% and 0.1% demonstrated statistically significant results of BSA after 2 weeks, ( $p=0.036$

and  $p=0.001$  respectively), 3 weeks ( $p=0.02$  and  $0.002$  respectively) and 4 weeks ( $p=0.04$  and  $p=0.004$  respectively) of therapy.

Thykamine™ was shown to be safe and well tolerated during the study with no Thykamine™-related adverse events (AEs) reported.

"We are very pleased with the results of this Phase 2 study, which underscores our belief in the potential for Thykamine™ to provide a better solution for patients with mild-to-moderate atopic dermatitis," said Dr André P. Boulet, President and CEO of Devonian. "These results bring into focus the exciting opportunity for Thykamine™, with the possibility of improving immuno-related skin diseases and serious immuno-inflammatory diseases, for which there remains a great unmet need for new treatment options. We have now results demonstrating the anti-inflammatory efficacy of Thykamine™ in two distinct disorders and two different modes of administration. Indeed, Thykamine™ efficacy and safety, as enema treatment, was demonstrated in patients with distal mild-to-moderate Ulcerative Colitis (UC) after only 14 days of treatment. The results of the Atopic Dermatitis trial showed a fast onset of action as seen in the Ulcerative Colitis trial." added Dr Boulet.

The full detailed analysis of the study data will be presented at a Dermatology Conference and subsequently published in a peer-reviewed medical journal.

### **About Atopic Dermatitis (AD)**

AD, also known as eczema, is a type of inflammation of the skin. It results in itchy, red, swollen, and cracked skin that may lead to secondary infection. The condition typically starts in childhood with changing severity over the years. Although the cause of AD is unknown, it is believed to involve genetics, a compromised immune system and can be triggered by environmental factors. AD is the most common skin disease<sup>1</sup> and its prevalence continues to increase worldwide. In the United States, the incidence has been reported to be 10-20% of children with new diagnoses at almost 11% per year<sup>2</sup>. The severity of AD can be categorized into three stages, mild, moderate and severe. The mild and moderate forms constitute approximately 67% and 26% respectively of the AD childhood patient population. A similar distribution has been reported in the adult patient population (71% and 26% respectively)<sup>3,4</sup>. There is currently an enormous unmet need for new, effective and well-tolerated treatment options in AD<sup>5</sup>.

### **About Thykamine™**

Thykamine™, the first pharmaceutical product issued from Devonian's SUPREX™ platform, is a highly innovative product for the prevention and treatment of health conditions related to inflammation and oxidative stress including ulcerative colitis, atopic dermatitis, psoriasis, rheumatoid arthritis, and other autoimmune disorders. The anti-inflammatory, anti-oxidative and immunomodulatory properties of Thykamine™ have been demonstrated by a considerable number of in vitro and in vivo studies as well as in a Phase IIa clinical study in patients with mild-to-moderate distal ulcerative colitis. Thykamine™ is currently under development as treatment for ulcerative colitis and atopic dermatitis. Both Thykamine™ and SUPREX™ platform are protected by several patents in North America, Europe and Asia.

## About Devonian

Devonian Health Group Inc. is a late-stage botanical pharmaceutical corporation with novel therapeutic approaches to targeting unmet medical needs. Devonian's core strategy is to develop prescription botanical drugs from plant materials and algae for the treatment of inflammatory-autoimmune diseases including but not limited to ulcerative colitis and atopic dermatitis. Based on a foundation of over 15 years of research, Devonian's focus is further supported by a US-FDA set of regulatory guidelines favouring a more efficient drug development pathway for prescription botanical drug products over those of traditional prescription medicines. Devonian is also involved in the development of high-value cosmeceutical products leveraging the same proprietary approach employed with their pharmaceutical offerings. Devonian Health Group Inc. was incorporated in 2015 and is headquartered in Québec, Canada where it owns a state-of-the-art extraction facility with full traceability 'from the seed to the pill'. Acquired in 2018, Altius Healthcare Inc., its commercialization partner, brings opportunities for further diversification and growth potential. Devonian is traded publicly on the TSXV Exchange (**TSXv:GSD**).

For more information, visit [www.groupedevonian.com](http://www.groupedevonian.com)

## References

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2. Eichenfield F, Ellis CN, Mancini AJ, Paller AS, Simpsom EL. Atopic Dermatitis: Epidemiology and Pathogeneses Update. *Semin Cutan Med Surg* 2012, Sep; 31 (3 Suppl): S3-5.
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4. Chaplin S. Guide to treatments used for atopic dermatitis in adults. *Prescriber* 2016; 27(10): 30-39.
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## Forward Looking Statements

This press release contains forward-looking statements about Devonian's objectives, strategies and businesses that involve risks and uncertainties. These statements are "forward-looking" because they are based on our current expectations about the markets we operate in and on various estimates and assumptions. Actual events or results may differ materially from those anticipated in these forward-looking statements if known or unknown risks affect our business, or if our estimates or assumptions turn out to be inaccurate. Such risks and assumptions include, but are not limited to, Devonian's ability to develop, manufacture, and successfully commercialize value-added pharmaceutical and cosmeceutical products, the availability of funds and resources to pursue R&D projects, the successful and timely completion of clinical studies, the ability of Devonian to take advantage of business opportunities in the pharmaceutical and cosmeceutical industries, uncertainties related to the regulatory process and general changes in economic conditions. You will find a more detailed assessment of the risks that could cause

actual events or results to materially differ from our current expectations in Devonian's prospectus dated April 21<sup>st</sup>, 2017 under the heading "Risk Factors" related to Devonian's business. As a result, we cannot guarantee that any forward-looking statement will materialize. We assume no obligation to update any forward-looking statement even if new information becomes available, as a result of future events or for any other reason, unless required by applicable securities laws and regulations.

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