

# Press release

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## MC2 Therapeutics Announces U.S. Food and Drug Administration Approval of Wyzora<sup>®</sup> Cream (calcipotriene and betamethasone dipropionate w/w 0.005%/0.064%) for Adults with Plaque Psoriasis

**Copenhagen, July 22<sup>nd</sup>, 2020** - MC2 Therapeutics, a commercial stage pharmaceutical company developing a new standard of topical therapies for chronic inflammatory conditions, announced today that the U.S. Food and Drug Administration (FDA) has approved Wyzora<sup>®</sup> Cream (calcipotriene and betamethasone dipropionate, w/w 0.005%/0.064%) for once-daily topical treatment of plaque psoriasis in adults 18 years of age or older.

The FDA approval is based on the results of the US Phase 3 clinical trial<sup>1</sup> against active comparator Taclonex<sup>®</sup> Topical Suspension (calcipotriene and betamethasone dipropionate, w/w 0.005%/0.064%). A total of 794 patients were randomized in this trial and the primary efficacy endpoint was the proportion of patients with PGA treatment success at week 8 defined as at least a 2-grade improvement from baseline in PGA to “clear” or “almost clear”. The difference in PGA treatment success to the active comparator was 14.6% (95% CI; 7.6%, 21.6%) in favor of Wyzora<sup>®</sup> Cream.

Reduction of itch as defined by at least a 4-point improvement in the 11-point peak pruritus numeric rating scale (NRS) from baseline to week 4 was assessed among patients who had at least a peak pruritus NRS score of 4 at baseline. A higher proportion of patients achieved at least a 4-point improvement in the peak pruritus NRS score at week 4 in the Wyzora<sup>®</sup> Cream group (60.3%) compared to vehicle (21.4%).

*“Wyzora<sup>®</sup> Cream is a novel topical treatment for plaque psoriasis which offers a unique combination of high efficacy, favorable safety and excellent treatment convenience in a single product,”* said Linda Stein Gold, MD, Director of Dermatology Clinical Research at Henry Ford Health System in Detroit, Michigan, and lead principal investigator in the study.

Studies show that more than half of psoriasis patients are dissatisfied with their treatment and that a large proportion of patients are not treated at all.<sup>2</sup>

*"The FDA approval marks an important milestone for patients with plaque psoriasis", stated Jesper J. Lange, CEO of MC2 Therapeutics and continued: "Our PAD™ Technology has uniquely enabled us to develop Wynzora® Cream with no compromises. It drives the compelling efficacy and safety data of Wynzora® Cream and transforms that data into impact for patients through a convenient formulation that allows patients to move on within minutes of a morning routine. It puts patients back in control of therapy and daily life."*

Founder and Executive Chairman of MC2 Therapeutics, Mads Clausen concurred: *"Wynzora® is a prime example of what we envision PAD™ Technology can do to help patients, physicians and payers release the full potential of topical therapies in real world settings."*

With the US approval, the [recent submission](#) of its marketing authorization application of Wynzora® Cream in EU, and its ongoing interactions with payers, physicians and patient organizations MC2 Therapeutics is well on track to launch Wynzora® Cream in major territories. In addition, MC2 Therapeutics continues development of its pipeline of new topical therapies within major chronic inflammatory indications such as atopic dermatitis, uremic pruritus, lichen sclerosus and dry eye.

### **About Plaque Psoriasis**

Psoriasis is a common, non-contagious, chronic skin disease, with no clear cause or cure. The negative impact of plaque psoriasis on people's lives can be immense as it affects the appearance of the skin with red, scaly plaques. According to the National Psoriasis Foundation, itch is present in between 70 and 90 percent of psoriasis patients, and together with flaking and scaling, itching is the most burdensome symptom to patients.<sup>3,4,5</sup> The appearance of flares of psoriasis can be unpredictable and affects people of all ages. With a reported prevalence of 2-4% of the population psoriasis constitutes a serious health problem with more than 100 million individuals affected worldwide. More than 90% of patients receiving treatment use topical drugs. Patients with psoriatic disease are at an elevated risk of developing other chronic and serious health conditions, including arthritis, cardiovascular diseases, metabolic syndrome, inflammatory bowel disease and depression.<sup>5</sup>

### **About Wynzora® Cream**

Wynzora® Cream is a cream-based fixed dose combination of calcipotriene and betamethasone dipropionate for topical treatment of plaque psoriasis. Wynzora® Cream is based on PAD™ Technology, which uniquely enables stability of both calcipotriene and betamethasone dipropionate in a convenient-to-use aqueous formulation. In the phase 3 trials conducted at multiple sites in the US and the EU, Wynzora® Cream has

demonstrated a unique combination of compelling clinical efficacy, a favorable safety profile and high convenience. These features of Wyzora<sup>®</sup> Cream hold promise to lead to less treatment discontinuation and overall better patient satisfaction in topical treatment of plaque psoriasis in the real-world setting.

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

### **Indication and Usage**

Wyzora<sup>®</sup> (calcipotriene and betamethasone dipropionate) Cream is a prescription medicine indicated for the topical treatment of plaque psoriasis in patients 18 years of age and older.

Apply Wyzora<sup>®</sup> Cream to affected areas once daily for up to 8 weeks and not more than 100 grams per week. Patients should stop treatment when the plaque psoriasis is under control unless a healthcare provider gives other instructions.

Wyzora<sup>®</sup> Cream is for use on skin only (topical). Do not get Wyzora<sup>®</sup> Cream near or in your mouth, eyes, or vagina. Avoid using Wyzora<sup>®</sup> Cream on your face, groin, or armpits, or if you have thinning of your skin (atrophy) at the treatment site.

It is not known if Wyzora<sup>®</sup> Cream is safe and effective in children.

### **Important Safety Information**

Tell your healthcare provider about all your medical conditions and all the medicines you take, including any corticosteroid medicines and any other products containing calcipotriene.

Do not use other products containing calcipotriene or a corticosteroid medicine without talking to your healthcare provider first.

Wyzora<sup>®</sup> Cream may cause side effects, including:

- Too much calcium in your blood or urine and/or adrenal gland problems
- Cushing's syndrome, a condition that happens when your body is exposed to large amounts of the hormone cortisol
- High blood sugar and sugar in your urine
- Vision problems, including an increased risk of developing cataracts and glaucoma.

The most common side effects include upper respiratory infection, headache, and application site irritation. These are not all the possible side effects. Call your healthcare provider for medical advice about side effects.

This summary is not comprehensive. Visit [www.wynzora.com](http://www.wynzora.com) to obtain the FDA-approved Full Prescribing Information.

### **About PAD™ Technology**

PAD™ Technology formulations are tailor-made to meet the target product profile for a selected product candidate. PAD™ Technology enables the mixing of oil and water into a cream using just a fraction of the emulsifier required in conventional creams and lotions. Key features of PAD™ Technology formulations are high penetration of active ingredients to the target tissue, improved solubility and stability of active ingredients, high tolerability and excellent treatment convenience.

### **About MC2 Therapeutics**

MC2 Therapeutics is a privately held commercial stage pharmaceutical company developing a new standard of topical therapies for chronic inflammatory conditions. Using its PAD™ Technology it aims to set a new standard of treatment experience for patients and to release the full potential of novel topical drugs for the benefit of patients, physicians, payers and societies. PAD™ Technology is the basis for its innovative pipeline of drug candidates within atopic dermatitis, uremic pruritus, lichen sclerosis, and dry eye.

**For additional information on MC2 Therapeutics, please visit**  
[www.mc2therapeutics.com](http://www.mc2therapeutics.com)

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#### **References:**

<sup>1</sup>Clinical trial ID: NCT03308799

<sup>2</sup>Armstrong et al. JAMA Dermatol. 2013;149(10):1180-1185

<sup>3</sup>[www.psoriasis.org/life-with-psoriasis/managing-itch](http://www.psoriasis.org/life-with-psoriasis/managing-itch) (accessed July 13<sup>th</sup>, 2020)

<sup>4</sup>The Voice of the Patient, Psoriasis. FDA Public Meeting Report, 2016

<sup>5</sup>WHO Global report on Psoriasis 2016