MC2 Therapeutics Announces Submission of Marketing Authorization Application in EU for Wynzora® Cream (50 µg/g calcipotriol and 0.5 mg/g betamethasone (as dipropionate))

Copenhagen, July 16th, 2020 - MC2 Therapeutics, a commercial stage pharmaceutical company focused on topical therapies for chronic inflammatory conditions, today announced the submission of its Marketing Authorization Application (MAA) in EU for Wynzora® Cream (50 µg/g calcipotriol and 0.5 mg/g betamethasone (as dipropionate)) for the treatment of plaque psoriasis. The European filing follows the submission of a New Drug Application on Wynzora® Cream to the U.S. Food and Drug Administration (FDA) in September 2019.

The MAA is supported by two comprehensive Phase 3 trials including a trial conducted in EU evaluating the efficacy and safety of Wynzora® Cream compared to vehicle and active comparator Dovobet/Daivobet® Gel in patients with psoriasis vulgaris. The trial enrolled 490 patients at 32 clinical centers. Patients applied trial medication topically once daily for eight weeks. Dovobet/Daivobet® Gel is marketed as Taclonex® Topical Suspension in the US.

In this EU Phase 3 trial Wynzora® Cream demonstrated significantly greater treatment success compared to Dovobet/Daivobet® Gel, assessed by the proportion of subjects obtaining minimum two-points improvement in the Physician Global Assessment (PGA). Wynzora® Cream reached 51% PGA treatment success and a reduction from baseline in mPASI of 68%. In addition, the patient reported acceptability of treatment and the dermatology life quality index (DLQI) were rated significantly better for Wynzora® Cream than for Dovobet/Daivobet® Gel.

The pooled safety data from the two Phase 3 trials shows a favorable safety profile with no drug-related dermal adverse reactions exceeding 1%.

"With this submission we stay on track in our global development of Wynzora® Cream," said Jesper J. Lange, CEO of MC2 Therapeutics and added: "Enabled by our PAD™
Technology, Wynzora® Cream is uniquely designed to address the three essentials of topical drugs - high efficacy, a favorable safety profile and a formulation that allows patients to quickly move on in daily routines within minutes of a toothbrushing. We want to use PAD™ Technology to set a new standard and release the full potential of novel topical drugs for the benefit of patients, physicians, payers and societies. Wynzora® Cream represents all of that - no compromises".

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 and itching. Psoriasis affects people of all ages, and in all countries. The reported prevalence of psoriasis is 2-4% of the population making psoriasis a serious global problem with more than 100 million individuals affected worldwide. The flares of psoriasis can be unpredictable and significant comorbidities are common, including arthritis, cardiovascular diseases, metabolic syndrome, inflammatory bowel disease and depression.²

"More than 90% of psoriasis patients use topical drugs. However, there is a need for a significant upgrade of topicals to address the problem of treatment discontinuation and low adherence in topical therapies," said Prof. Dr. Med. Matthias Augustin, Director Institute of Health Care Research in Dermatology and Nursing, University of Hamburg and lead principal investigator in the EU Phase 3 trial and continues: "Of course the efficacy and safety profile of a topical drug has to be compelling, but ease of use in daily routines is a third key element that can motivate patients to be adherent to topical treatment and thereby obtain satisfactory treatment outcomes and improved quality of life in the real-world setting. From a health economics point of view, optimizing real-world topical treatment satisfaction can be an important element in controlling the cost for our societies. As I see it, the clinical profile of Wynzora® Cream is a prime example of a treatment of plaque psoriasis that can address these challenges."

About Wynzora® Cream

Wynzora® Cream is a cream-based fixed dose combination of calcipotriol and betamethasone dipropionate for topical treatment of plaque psoriasis. Wynzora® Cream is based on PAD™ Technology, which uniquely enables stability of both calcipotriol 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 significantly greater efficacy compared to Taclonex® Topical Suspension and Dovobet/Daivobet® gel. The unique combination of significant clinical efficacy, a favorable safety profile and high convenience of Wynzora® Cream holds promise to less treatment discontinuation and overall better patient satisfaction in topical treatment of plaque psoriasis in the real-world setting.
About MC2 Therapeutics
MC2 Therapeutics is a privately held commercial stage pharmaceutical company focused on novel 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 sclerosus and dry eye.

For additional information on MC2 Therapeutics, please visit www.mc2therapeutics.com

Contact information:

MC2 Therapeutics
Investors: Lonni Goltermann, +45 2018 1111 or log@mc2therapeutics.com

Media:
EU: Molecule A/S: Mette Thorn Sorensen, +45 4138 4300 or mts@moleculeconsultancy.com
US: Amy Phillips, +1 412.327.9499 or amyphillipspr@gmail.com

References:
1EudraCT no: 2018-001970-66 / NCT03802344 (EU Phase 3 trial); NCT03308799 (US Phase 3 trial)
2WHO Global report on Psoriasis 2016