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MC2 Therapeutics's wynzora cream gets FDA nod to treat Plaque Psoriasis

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The pivotal phase 3 trial demonstrated that Wynzora™ Cream treatment has a substantial and statistically significantly greater efficacy compared to Taclonex® Topical Suspension

MC2 Therapeutics, an emerging pharmaceutical company focused on novel PAD™ Technology-based topical therapies for chronic inflammatory conditions, has announced that the U.S. Food and Drug Administration (FDA) has accepted for review the New Drug Application (NDA) for Wynzora™ Cream. MC2 Therapeutics is seeking marketing approval for Wynzora™ Cream for the treatment of plaque psoriasis. The FDA has set July 20th, 2020 as the Prescription Drug User Fee Act (PDUFA) action date.

MC2 Therapeutics' NDA for Wynzora™ Cream is comprised of extensive quality, non-clinical and clinical data. Specifically, data from the pivotal phase 3 trial demonstrated that Wynzora™ Cream treatment has a substantial and statistically significantly greater efficacy compared to Taclonex® Topical Suspension ("Taclonex®") based on treatment success defined as a minimum two-point decrease in the Physician Global Assessment (PGA) score to clear or almost clear disease (40.1% versus 24.0%, $p < 0.0001$).

"We are very proud of the overall clinical profile of Wynzora™ Cream and look forward to continuing our interaction with the FDA during the NDA review", said Jesper J. Lange, President & CEO of MC2 Therapeutics and added "In parallel we will continue our efforts to ensure widespread patient access to Wynzora™ Cream pending approval".