

## Press release

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### Medac at the BAD meeting 2017

## **Update on the first-line agent Methotrexate in psoriasis treatment: Intensified dosing and subcutaneous administration recommended**

- **British Association of Dermatologists' guidelines reaffirms the importance of the well-established and inexpensive first-line systemic agent Methotrexate (MTX) for the treatment of patients with all types of psoriasis**
- **Recently in *The Lancet* published METOP trial meets the need of high-quality clinical trial with methotrexate in long-term therapy and shows lasting efficacy and safety of subcutaneous methotrexate over one year in an intensified dosing schedule**

*Liverpool, UK / Wedel, Germany (6 July 2017).* For more than half a century now, Methotrexate is globally used as an effective and safe first-line systemic treatment for plaque-type psoriasis. Recent treatment recommendations, like the updated British Association of Dermatologists' guidelines, still consider MTX a first-line and cost-effective therapeutic for the treatment of psoriasis.<sup>1,2</sup>

At the Medac symposium during the BAD meeting 2017<sup>3</sup> Dr Richard B. Warren, Manchester, being the lead author of the British guidelines on methotrexate use in psoriasis therapy, recommended the subcutaneous route of administration and an initial starting dose of 15 mg MTX once weekly, based on data up to October 2015. He underlined that the long-term data prove the safety and efficacy of

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<sup>1</sup> Warren RB et al. British Association of Dermatologists' guidelines for the safe and effective prescribing of methotrexate for skin disease 2016. *Br J Dermatol.* 2016;175:23-44.

<sup>2</sup> Nast A et al. European S3-Guidelines on the systemic treatment of psoriasis vulgaris – Update 2015 – Short version – EDF in cooperation with EADV and IPC. *J Eur Acad Dermatol Venereol* 2015;29:2277-94.

<sup>3</sup> Medac symposium: METOP Trial – Benefits of subcutaneous methotrexate therapy in daily practice. 5 July 2017 at the annual BAD meeting in Liverpool.

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Methotrexate for more than 50 years. These are the reasons for MTX still being the first-line agent in psoriasis therapy. Regarding the aspect of a folic acid substitution he emphasized its' importance with regard to the reduction of the mucosal and gastrointestinal side-effects of methotrexate and the possible protective effect against hepatotoxicity. Warren agreed with Reich upon a folic acid dosing of 5 mg after 24 hours of the MTX administration.<sup>4</sup>

The position of MTX as first-line agent in psoriasis therapy has currently been confirmed by the METOP trial results, published in The Lancet beginning of this year. Prof Kristian Reich, Hamburg, in his lecture presented the data of the Methotrexate Optimized treatment schedule in patients with Psoriasis (METOP) trial, a randomised, double-blind, placebo-controlled phase 3 trial, evaluating the efficacy and safety of self-administered subcutaneous methotrexate in patients with moderate to severe plaque-type psoriasis using an optimised dosing regimen.<sup>5,6</sup>

The results of the phase 3 METOP trial showed a Dermatology Quality of Life Index (DLQI)  $\leq 5$  in 59 % of patients treated with MTX and a DLQI score of 0-1 in 43 % of patients, versus 34 % and 10 % in the placebo group at 16 weeks. The data demonstrate that subcutaneous methotrexate has a rapid onset of action and is significantly better than placebo in improving the skin condition and quality of life of plaque-type psoriasis, with efficacy and safety sustained over one year. A subcutaneous injection of Metoject<sup>®</sup> 50 mg/ml using a dose of 17.5 up to 22.5 mg/week greatly reduces the severity of plaque-type psoriasis – in week 52 45% in the methotrexate group had a PASI 75. Furthermore skin biopsies demonstrated a correlation between the reduction in specific cytokines and inflammatory cells that suggests an inhibitory effect of methotrexate on the TH1/TH17 pathway in the skin.

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<sup>4</sup> Reich K et al. Methotrexate therapy in dermatology. J Dtsch Dermatol Ges. 2012;10:363-70.

<sup>5</sup> ClinicalTrials.gov: Trial in Patients With Psoriasis Treated With Methotrexate Using an Optimized Treatment Schedule (METOP). URL: <https://clinicaltrials.gov/ct2/show/NCT02902861> (06.07.2017)

<sup>6</sup> Warren RB et al. An intensified dosing schedule of subcutaneous methotrexate in patients with moderate to severe plaque-type psoriasis (METOP): a 52 week, multicentre, randomised, double-blind, placebo-controlled, phase 3 trial. Lancet. 2017;389:528-37.

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Warren and Reich stated a favourable 52 weeks risk-benefit profile of subcutaneous methotrexate in patients with psoriasis.

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