Press Release

Benefits for psoriasis practices: New phase III data shows subcutaneous methotrexate's favorable long-term efficacy and safety profile

Wien / Wedel (30 September 2016). Extensive clinical and molecular results of the first phase III trial investigating the effects of subcutaneous methotrexate (SC MTX) versus placebo in patients suffering from moderate-to-severe psoriasis were presented during the Medac satellite symposium at the congress of the European Academy of Dermatology and Venereology (EADV) 2016 in Vienna.[1]

"In the past, methotrexate has been given mostly orally for the therapy of psoriasis", said the chair of the symposium, Bruce E. Strober, MD, PhD, Professor and Chair Department of Dermatology, University of Connecticut School of Medicine, Farmington, US, and adds: "But subcutaneous methotrexate is associated with fewer adverse events and higher absorption rates, accompanied by bioavailability that is both linear and predictable".

In the 52-week, double-blinded, randomized, phase III trial METOP (**MET**hotrexate **O**ptimized treatment schedule in patients with **P**soriasis) 120 patients were randomized (3:1) to either receive weekly injections of methotrexate or placebo. "Subcutaneous methotrexate deserves its place as a first-line systemic therapy in moderate-to-severe psoriasis," said Professor Ulrich Mrowietz, Principal Investigator of the trial and Head of Psoriasis-Center, Dept. of Dermatology, University Medical center Schleswig-Holstein, Campus Kiel, Germany. "More than 40% of patients showed an improvement of 75% (PASI75) by week 16. Approximately one of five patients showed improvement of 90% (PASI90) at this timepoint." Both response rates increased by week 52: PASI75 was achieved by 45% of SC MTX-treated patients, and approximately every third patient fulfilled the criteria of PASI90.[2]

The patients of the SC MTX arm received a starting dose of 17.5 mg of Metoject®/Metex® pre-filled syringe per week; this is above the dose of 5–15 mg/week cited in recently published guidelines.[3,4] If the patients failed to achieve PASI50 at week 8, the dose could be increased up to 22.5 mg per week. A physicians' global assessment (PGA) 0/1 of clear or almost skin was investigated as well, and 40%

of patients treated with SC MTX fulfilled this criteria. No methotrexate-related severe adverse effects were observed in the trial.

A sub-study examined the unknown molecular mode of action of SC MTX in psoriasis: Pairs of skin biopsies were obtained at the beginning of the trial and at week 16. These tissue samples were used to investigate selected inflammatory pathways of the disease. In PASI75 responder biopsies, the mRNA level of cutaneous pro-inflammatory cytokines were reduced: IL-17A mRNA levels dropped to 10%, and interferon γ mRNA levels decreased to 25% compared to baseline. In parallel, the infiltrating CD3-positive T cells and CD11c-positive dendritic cells were reduced.

"The study documents a stable clinical response", concludes Ulrich Mrowietz his symposium session. "Optimized dosing of methotrexate given subcutaneously showed a favorable efficacy in PASI75 over one year in patients with moderate-to-severe psoriasis".

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References

[1] Medac satellite symposium „METOP study – evaluation of subcutaneous methotrexate for psoriasis patients" at the congress of the „European Academy of Dermatology and Venereology, Vienna, 30 September 2016

[2] Warren RB et al., J Am Acad Dermatol. 2016;74(5 Suppl 1):AB239

[3] Warren RB et al. Br J Dermatol. 2016;175:23-44

[4] Nast A et al., J Dtsch Dermatol Ges. 2012;10(Suppl 2):S1-S95

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