**PROSPECTIVE PILOT EVALUATION OF THE EFFICACY AND SAFETY OF ADJUVANT TOPICAL INGENOL MEBUTATE GEL FOR LOCALIZED PATCH/PLAQUE STAGE MYCOSIS FUNGOIDES.**

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**Introduction:** Whether ingenol mebutate (IM) is effective as adjuvant topical treatment for mycosis fungoides (MF) remains undetermined.

**Materials and Methods:** Ten male patients with longstanding classic type MF (n=9) and follicular MF (n=1), T2bN0M0B0, stage Ib, receiving systemic methotrexate or acitretin therapies since at least 6 months, were included for this pilot study. In these patients 11 target lesions with an area ≤ 25 cm2 were selected for IM therapy (0,05%, 2 weekly applications). Primary endpoint was the improvement of the CAILS score after treatment, compared to control CAILS scores. Biopsies were performed before and after 2 months. Relapse rates were evaluated at 6 months. Treatment-related adverse effects were recorded.

**Results:** The mean CAILS score of target lesions was reduced by 59 %, compared to 5% for the control lesions. The mean erythema, scaling and plaque elevation scores were improved by 78%, 97% and 98%, respectively. Hyperpigmentation appeared in 8/11 (73%) of the target lesions. Lesion size remained unchanged. A complete or partial clearance of histological and immunohistochemical features of MF or FMF was observed in 6/10 (60%) and 4/10 (40%) of the target lesions, respectively. At baseline, monoclonal TCR rearrangement was positive in 7/7 (100%) cases and at 2 months post-treatment in 3/7 (43%) cases. The relapse rate at 6 months was 18%. All the patients experienced mild to moderate burning sensations, slight oozing and crusting for 3 to 5 days.

**Conclusion:** Topical IM gel may be considered as adjuvant treatment for localized patch/plaque stage MF and FMF.