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**EFFICACY OF A MULTI-INGREDIENT CORIOLUS VERSICOLOR-BASED VAGINAL GEL IN HIGH-RISK HPV WOMEN OVER 40: SUB-ANALYSIS OF THE PALOMA CLINICAL TRIAL & PAPILOBS REAL-LIFE STUDY**

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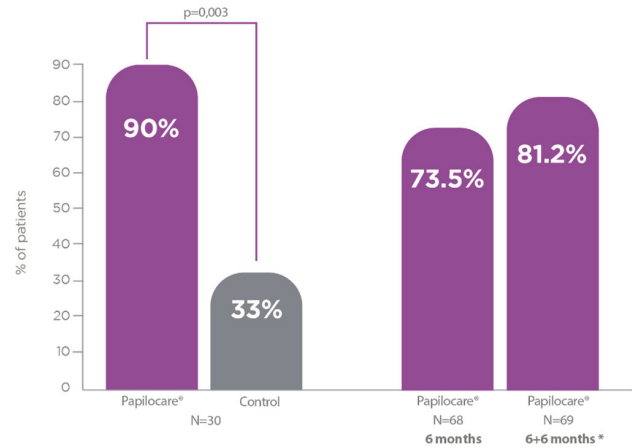
**Introduction/Background** HPV clearance and resolution of cervical HPV-dependent lesions become difficult in peri and post-menopausal women. The objective of this analysis was to evaluate the effect of the Papilocare<sup>®</sup>, a multi-ingredient Coriolus versicolor-based vaginal gel in repairing the high-risk (HR) HPV-dependent low-grade cervical lesions in women over 40 years

**Methodology** Paloma study (ClinicalTrials.gov NCT04002154) was a multicenter, randomized, open-label, parallel-group, watchful waiting approach-controlled clinical trial. Unvaccinated HPV positive women aged between 30–65 with cytology of ASCUS or LSIL and concordant colposcopy image were randomized into 3 groups: A) Papilocare<sup>®</sup> 1 cannula/day for 1 month + 1 cannula/alternate days for 5 months; B) Papilocare<sup>®</sup> 1 cannula/day for 3 months + 1 cannula/alternate days for 3 months; C) Control group: watchful waiting approach. Papilobs study (ClinicalTrials.gov: NCT04199260) was an observational, multicenter, prospective, one-cohort study. Vaccinated or not HPV-positive women aged > 25 y with cytology of ASCUS or LSIL and concordant colposcopy were included. Patients were treated with Papilocare<sup>®</sup> 1 cannula/day for 21 days during first month + 1 cannula/alternate days for 5 or 11 months. Percentages of patients with normal cytology and concordant colposcopy are presented.

**Results** A total of 30 and 68 HR-HPV patients above 40yo were evaluated in Paloma and Papilobs studies, respectively. In the Paloma trial, normal cytology and concordant colposcopy was observed in 90% vs 33% patients in A+B Papilocare<sup>®</sup> and control groups, respectively, (p=0.003, Fisher test). Overall, throughout the Papilobs study normal cytology and concordant colposcopy was achieved in 81.2% patients (73.5% at 6 months).

CLINICAL TRIAL  
PALOMA  
ClinicalTrials.gov NCT04002154

PAPILOBS  
NCT04002154



Abstract 2022-RA-1191-ESGO Figure 1

**Conclusion** After a 6 month treatment period, Papilocare<sup>®</sup> showed a clinically robust and statistically significant efficacy in repairing cervical HR-HPV lesions in women over 40 years vs watchful waiting approach. This efficacy was corroborated in the real-life study in more than 2/3 of the HR-HPV patients above 40.

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**EVALUATION OF MANAGING CIN 3 PLUS DIAGNOSED PREGNANT WOMEN BY METHYLATION ASSESSMENT USING FAM19A4/MIR124 METHYLATION TEST**

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**Introduction/Background** Pregnant women diagnosed with CIN3 (cervical intraepithelial neoplasia) have high regression rates after delivery. Biomarkers are needed to only identify pregnant women with progressive CIN requiring treatment to reduce over referral and overtreatment.

**Methodology** In this study we evaluated the performance of the FAM19A4/miR124–2 methylation test for molecular triage on formalin fixed samples of CIN3+–diagnosed pregnant women with known clinical course over time as well in a cross-sectional setting. In this German multicenter retrospective study biopsy material was collected from pregnant women diagnosed with cervical cancer (n=16), with CIN3 that progressed to cancer during pregnancy (n=7), with CIN3 that