Introduction/Background HPV clearance and resolution of cervical HPV-dependent lesions become difficult in peri and postmenopausal women. The objective of this analysis was to evaluate the effect of the Papilocare®, 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® 1 cannula/day for 1 month + 1 cannula/alternate days for 5 months; B) Papilocare® 1 cannula/day for 3 months + 1 cannula/alternate days for 3 months; C) Control group: watchful waiting approach. Papilobs study (ClinicalTrial.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® 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® 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 (73.3% at 6 months).

Conclusion After a 6 month treatment period, Papilocare® 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.