with Papilocare® (or extending it up to 12-months if needed) in 3 out of 4 patients. These findings need to be confirmed upon study completion.

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**Abstracts**

**288 EFFICACY OF A MULTI-INGREDIENT CORIOLUS VERSICOLOR-BASED VAGINAL GEL IN HIGH-RISK HPV+ PATIENTS: RESULTS OF DIFFERENT STUDIES**

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**Introduction/Background** To evaluate the consistency of the efficacy of a non-hormonal multi-ingredient Coriolus versicolor-based vaginal gel, Papilocare®, on HPV clearance in patients infected by high-risk HPV (HR-HPV) in several studies.

**Methodology** Results at 6 months from independent observational non-comparative studies carried out in three different public centers and in a one private center were compared to results from both a randomized, open, parallel and controlled clinical trial comparing the Papilocare® vs wait and see approach (The Paloma RCT) and a observational, multicenter, prospective, one-cohort study (Papilobs real-life study).

Two prospective (Vigo and Bari studies) and two retrospective studies (Coruña and Hospitalaet studies) have been performed.

Vigo study: HPV clearance of 25 patients infected by HPV 16 and/or 18 was evaluated as a secondary endpoint.

Bari study: HPV clearance of 98 HR-HPV patients was evaluated as primary endpoint.

Coruña study: 57 medical records of patients with HR-HPV were analyzed. HPV clearance was evaluated as primary endpoint.

Hospitalaet study: Data of 91 HR-HPV patients were evaluated. Primary endpoint: composite efficacy variable (percentage of patients with normal cytology and/or HPV clearance).

Papilobs study: Interim data of 148 HR-HPV patients is presented. HR-HPV clearance was evaluated as secondary endpoint.

Paloma RCT: 66 HR-HPV patients were evaluated. Percentage of patients with HR-HPV clearance was assessed as a secondary endpoint.

**Results** After the 6-month treatment period, 48% and 57% of patients cleared HPV 16–18 and HR-HPV in Vigo and Bari studies, respectively. A reduction of 58% was observed in number of HR-HPV patients (Coruña) and 72.5% of patients negativated cytology and/or cleared HR-HPV (Hospitalaet) (p≤0.0001 vs baseline for all results, Chi-square). In the Paloma RCT, HR-HPV clearance was observed in 63% of patients treated with Papilocare® vs 40% in the control group. Similar rate of 59% HPV clearance was observed in the interim analysis of the Papilobs study.

**Conclusion** Papilocare® has shown significant and consistent rates of HR-HPV clearance ranging from 50% to 70% in the 6 different studies. This high consistently rate of HR-HPV clearance should be further confirmed in ongoing studies.

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