Sponsor:	VACCIBODY A.S.
Protocol Number:	VB C-01
EudraCT Number:	2014-005576-28
Date of Clinical Study Report:	07 June 2019

The following text and table have been summarised from the final VB C-01 Clinical Study Report (dated 07 June 2019) and present a summary of the results of HPV16 clearance as assessed by Cobas® HPV test.

Secondary Endpoint: The Percentage of Patients with HPV Clearance

HPV testing was performed using the Cobas® HPV test (Roche Molecular Diagnostics). All patients in the efficacy evaluable population were HPV16 positive at study entry, as per the inclusion criteria.

Six patients underwent a conization procedure during the study. The conizations are evenly distributed between the three cohorts, with two patients per cohort. The conizations affected the efficacy results in each cohort and the respective results are presented in separate columns within Table 1.

Table 1: HPV Clearance by Visit (Efficacy Evaluable Population)

HPV16 Clearance	**VB10.16 Dose Cohort (3 mg/mL)**					
	Cohort 1 (N=8)		**Cohort 2 (N=8)**		**Expansion (N=17)**	
Treatment	**VB10.16**	**Conizated**	**VB10.16**	**Conizated**	**VB10.16**	**Conizated**
Visit 4 (Week 8)	**N=8**	**N=0**	**N=8**	**N=0**	**N=17**	**N=0**
Clearance	1 (12.5%)	0	2 (25.0%)	0	1 (5.9%)	0
No clearance	7 (87.5%)	0	6 (75.0%)	0	14 (82.4%)	0
Not assessed	0	0	0	0	2 (11.8%)	0
Visit 5 (Week 16)	**N=8**	**N=0**	**N=8**	**N=0**	**N=17**	**N=0**
Clearance	1 (12.5%)	0	2 (25.0%)	0	2 (11.8%)	0
No clearance	7 (87.5%)	0	6 (75.0%)	0	15 (88.2%)	0
Visit 6 (Week 24)	**N=8**	**N=0**	**N=7**	**N=1**	**N=16**	**N=1**
Clearance	1 (12.5%)	0	2 (28.6%)	0	4 (25.0%)	1 (100.0%)
No clearance	7 (87.5%)	0	5 (71.4%)	0	12 (75.0%)	0
Not assessed	0	0	0	1 (100.0%)	0	0
Visit 7 (Month 9)	**N=6**	**N=2**	**N=6**	**N=2**	**N=16**	**N=1**
Clearance	1 (16.7%)	1 (50.0%)	2 (33.3%)	1 (50.0%)	5 (31.3%)	1 (100.0%)
No clearance	5 (83.3%)	1 (50.0%)	4 (66.7%)	0	11 (68.8%)	0
Not assessed	0	0	0	1 (50.0%)	0	0
Visit 8 (Month 12)	**N=6**	**N=2**	**N=6**	**N=2**	**N=15**	**N=2**
Clearance	2 (33.3%)	1 (50.0%)	2 (33.3%)	1 (50.0%)	6 (40.0%)	2 (100.0%)
No clearance	4 (66.7%)	1 (50.0%)	4 (66.7%)	0	8 (53.3%)	0
Not assessed	0	0	0	1 (50.0%)	1 (6.7%)	0