

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 the cervical intraepithelial neoplasia (CIN) assessment.

Secondary Endpoint: CIN Categorisation

Patients had colposcopy performed by the investigator at Visit 1 (baseline), Visit 4 (Week 8), Visit 5 (Week 16), Visit 6 (Week 24), Visit 7 (Month 9) and Visit 8 (Month 12). At baseline, 23 patients were CIN 2 and 10 patients were CIN 3. All 16 patients in Cohorts 1 and 2 were CIN 2 at baseline, 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 patient per cohort. The conizations affected the efficacy results in each cohort and the respective results are presented in separate columns in Table 1.

Table 1: CIN Categorisation by Visit (Efficacy Evaluable Population)

CIN Categorisation	VB10.16 Dose Cohort (3 mg/mL)					
	Cohort 1 (N=8)		Cohort 2 (N=8)		Expansion (N=17)	
Treatment	VB10.16	Conized	VB10.16	Conized	VB10.16	Conized
Baseline	N=8	N=0	N=8	N=0	N=17	N=0
CIN 2	8 (100.0%)	0	8 (100.0%)	0	7 (41.2%)	0
CIN 3	0	0	0	0	10 (58.8%)	0
Visit 4 (Week 8)	N=8	N=0	N=8	N=0	N=17	N=0
No CIN detected	0	0	0	0	3 (17.6%)	0
CIN 1	2 (25.0%)	0	1 (12.5%)	0	3 (17.6%)	0
CIN 2	6 (75.0%)	0	5 (62.5%)	0	9 (52.9%)	0
CIN 3	0	0	2 (25.0%)	0	2 (11.8%)	0
Visit 5 (Week 16)	N=8	N=0	N=8	N=0	N=17	N=0
No CIN detected	1 (12.5%)	0	0	0	4 (23.5%)	0
CIN 1	1 (12.5%)	0	1 (12.5%)	0	1 (5.9%)	0
CIN 2	5 (62.5%)	0	2 (25.0%)	0	8 (47.1%)	0
CIN 3	1 (12.5%)	0	5 (62.5%)	0	4 (23.5%)	0
Visit 6 (Week 24)	N=8	N=0	N=7	N=1	N=16	N=1
No CIN detected	1 (12.5%)	0	1 (14.3%)	0	6 (37.5%)	1 (100.0%)
CIN 1	3 (37.5%)	0	1 (14.3%)	0	2 (12.5%)	0
CIN 2	3 (37.5%)	0	1 (14.3%)	0	5 (31.3%)	0
CIN 3	1 (12.5%)	0	4 (57.1%)	0	3 (18.8%)	0
Not assessed	0	0	0	1 (100.0%)	0	0

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CIN Categorisation	VB10.16 Dose Cohort (3 mg/mL)					
	Cohort 1 (N=8)		Cohort 2 (N=8)		Expansion (N=17)	
Treatment	VB10.16	Conizedated	VB10.16	Conizedated	VB10.16	Conizedated
Visit 7 (Month 9)	N=6	N=2	N=6	N=2	N=16	N=1
No CIN detected	2 (33.3%)	2 (100.0%)	0	2 (100.0%)	6 (37.5%)	1 (100.0%)
CIN 1	1 (16.7%)	0	2 (33.3%)	0	3 (18.8%)	0
CIN 2	3 (50.0%)	0	0	0	3 (18.8%)	0
CIN 3	0	0	4 (66.7%)	0	4 (25.0%)	0
Visit 8 (Month 12)	N=6	N=2	N=6	N=2	N=15	N=2
No CIN detected	2 (33.3%)	2 (100.0%)	2 (33.3%)	2 (100.0%)	7 (46.7%)	2 (100.0%)
CIN 1	2 (33.3%)	0	1 (16.7%)	0	1 (6.7%)	0
CIN 2	2 (33.3%)	0	1 (16.7%)	0	3 (20.0%)	0
CIN 3	0	0	2 (33.3%)	0	3 (20.0%)	0
Not assessed	0	0	0	0	1 (6.7%)	0