

## Supplementary Data

SUPPLEMENTARY TABLE S1. CHANGE IN PERCENTAGE OF SUPERFICIAL CELLS FROM BASELINE TO WEEKS 2 AND 12

	Time point (week)	Placebo (N=187)		TX-004HR 4 µg (N=186)			TX-004HR 10 µg (N=188)			TX-004HR 25 µg (N=186)		
		LS		LS		p	LS		p	LS		p
		n	mean ± SE	n	mean ± SE		n	mean ± SE		n	mean ± SE	
Age, years												
≤56	2	61	8.72 ± 2.64	57	34.60 ± 2.74	<0.0001	72	33.02 ± 2.44	<0.0001	72	39.67 ± 2.43	<0.0001
	12	56	7.31 ± 2.73	51	17.23 ± 2.85	0.0122	67	14.93 ± 2.50	0.0403	70	22.45 ± 2.45	<0.0001
57–61	2	59	3.69 ± 2.68	60	29.43 ± 2.66	<0.0001	59	31.42 ± 2.67	<0.0001	51	38.03 ± 2.87	<0.0001
	12	56	5.22 ± 2.72	57	18.74 ± 2.70	0.0005	54	19.62 ± 2.76	0.0002	47	28.18 ± 2.94	<0.0001
≥62	2	65	5.36 ± 2.41	69	30.48 ± 2.34	<0.0001	57	31.15 ± 2.58	<0.0001	61	38.52 ± 2.49	<0.0001
	12	60	4.05 ± 2.49	62	16.75 ± 2.44	0.0003	50	16.18 ± 2.71	0.0010	57	19.96 ± 2.56	<0.0001
BMI, kg/m <sup>2</sup>												
≤24	2	68	6.40 ± 2.43	71	34.09 ± 2.38	<0.0001	67	35.23 ± 2.45	<0.0001	60	43.65 ± 2.58	<0.0001
	12	61	3.49 ± 2.53	67	18.78 ± 2.43	<0.0001	63	18.33 ± 2.52	<0.0001	56	24.75 ± 2.65	<0.0001
25–28	2	62	4.47 ± 2.57	52	31.62 ± 2.82	<0.0001	62	29.61 ± 2.58	<0.0001	66	38.21 ± 2.50	<0.0001
	12	58	7.04 ± 2.63	47	15.91 ± 2.91	0.0243	56	19.04 ± 2.67	0.0014	63	23.43 ± 2.54	<0.0001
≥29	2	55	7.13 ± 2.72	63	28.32 ± 2.55	<0.0001	59	30.95 ± 2.63	<0.0001	58	34.18 ± 2.64	<0.0001
	12	53	6.35 ± 2.76	56	17.73 ± 2.66	0.0031	52	12.85 ± 2.75	0.0962	55	21.04 ± 2.69	0.0002
Uterine status												
Intact	2	114	4.80 ± 1.88	99	31.60 ± 2.01	<0.0001	102	29.97 ± 1.98	<0.0001	99	39.01 ± 2.01	<0.0001
	12	107	4.60 ± 1.92	92	18.93 ± 2.06	<0.0001	95	18.76 ± 2.03	<0.0001	94	23.04 ± 2.04	<0.0001
Nonintact	2	71	7.94 ± 2.46	87	31.14 ± 2.23	<0.0001	86	34.29 ± 2.24	<0.0001	85	38.66 ± 2.25	<0.0001
	12	65	7.15 ± 2.54	78	15.89 ± 2.32	0.0111	76	14.12 ± 2.35	0.0442	80	23.37 ± 2.30	<0.0001
Pregnancy status												
n=0	2	21	4.87 ± 3.91	23	29.69 ± 3.72	<0.0001	22	35.02 ± 3.84	<0.0001	16	44.08 ± 4.54	<0.0001
	12	19	3.60 ± 4.06	21	22.38 ± 3.86	0.0009	22	14.43 ± 3.84	0.0546	16	22.39 ± 4.54	0.0024
n≥1	2	164	6.29 ± 1.61	163	31.65 ± 1.62	<0.0001	166	31.49 ± 1.60	<0.0001	168	38.19 ± 1.59	<0.0001
	12	153	5.99 ± 1.65	149	16.87 ± 1.67	<0.0001	149	17.02 ± 1.66	<0.0001	158	23.11 ± 1.62	<0.0001
Vaginal birth												
n=0	2	34	5.71 ± 3.51	26	41.58 ± 4.01	<0.0001	39	25.87 ± 3.28	<0.0001	36	45.94 ± 3.40	<0.0001
	12	30	8.31 ± 3.69	24	20.01 ± 4.13	0.0351	33	20.65 ± 3.49	0.0155	33	28.94 ± 3.51	0.0001
n≥1	2	130	6.40 ± 1.80	137	29.76 ± 1.75	<0.0001	127	33.28 ± 1.82	<0.0001	132	36.05 ± 1.78	<0.0001
	12	123	5.41 ± 1.83	125	16.28 ± 1.81	<0.0001	116	16.07 ± 1.88	0.0001	125	21.50 ± 1.82	<0.0001

BMI, body mass index; LS, least square; SE, standard error.