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(54) **DEEP LUNG PULMONARY DELIVERY OF
TREPROSTINIL**

Related U.S. Application Data

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(57) **ABSTRACT**

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Administration of aerosolized Treprostinil formulations may
provide a more homogeneous lung deposition of treprostinil,
whereby making deep lung delivery possible.

Fig. 1

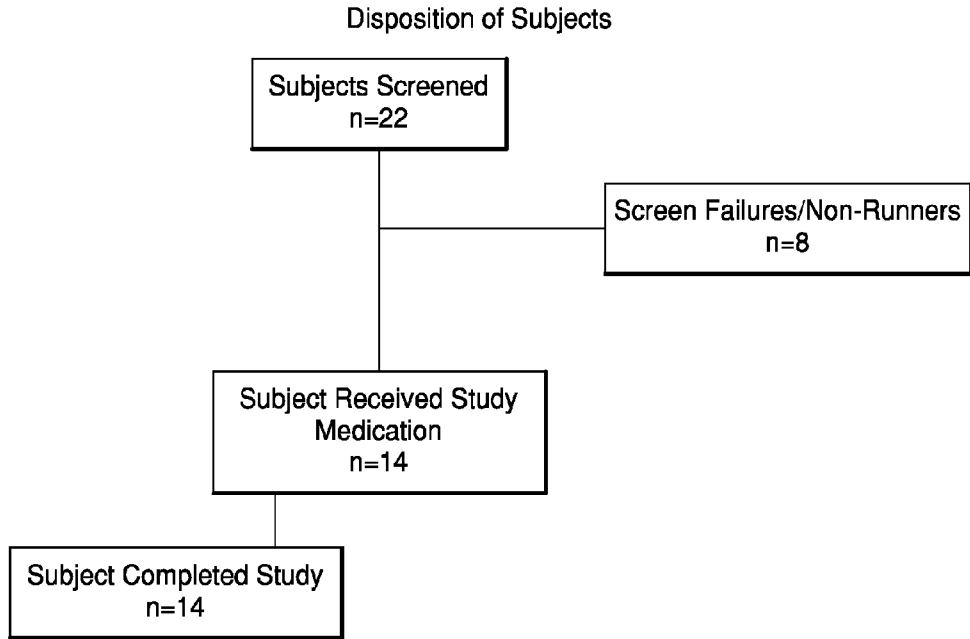


Fig. 2

Mean Plasma Treprostinil Concentrations (ng/mL) (Linear Plot) following Administration via AERx and Optineb (n=14)

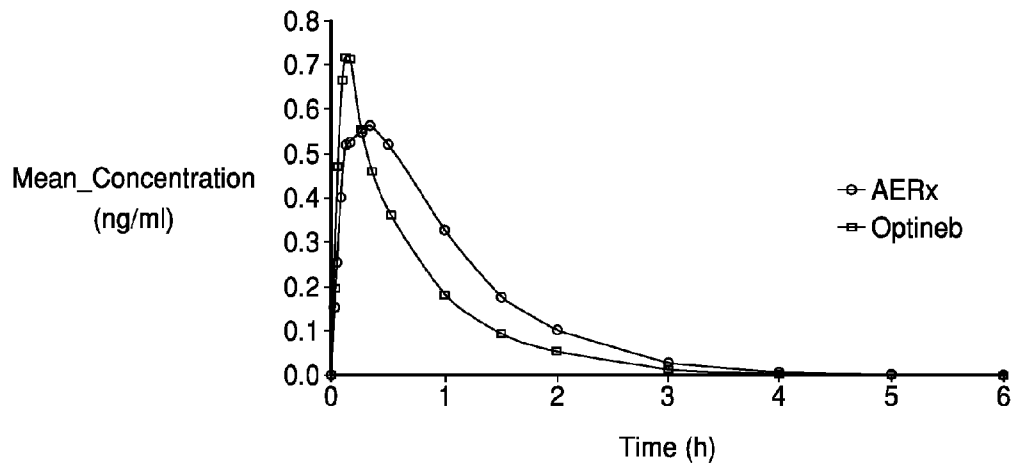


Fig. 3

Mean Plasma Treprostinil Concentrations (ng/mL) (Semi Log Plot) following Administration via AERx and Optineb (n=14)

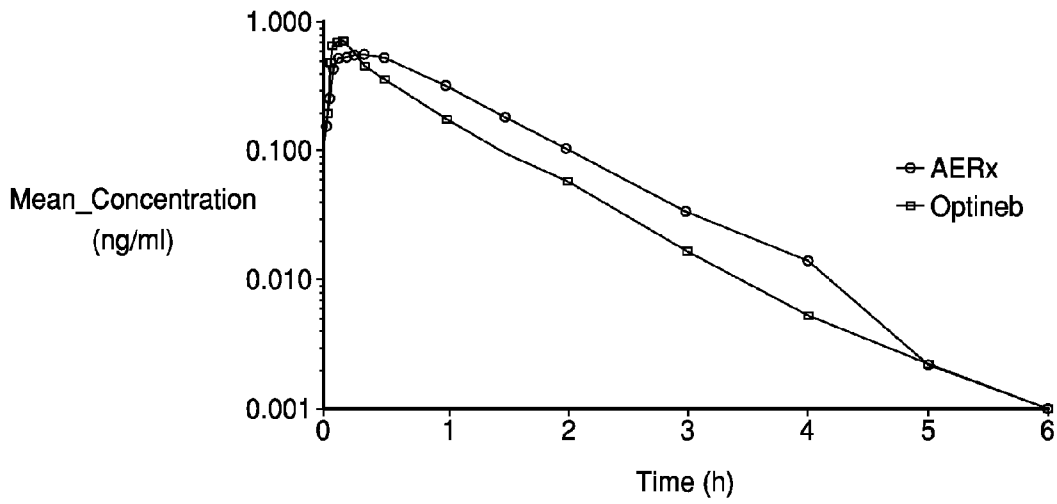


Fig. 4

Summary of Demographic Data

Age (yrs)	N	14
	Mean	38.0
	Std Dev	13.0
	Minimum	21
	Maximum	55
Height (cm)	N	14
	Mean	177.71
	Std Dev	7.85
	Minimum	166.00
	Maximum	190.00
Weight (kg)	N	14
	Mean	85.7
	Std Dev	13.1
	Minimum	63.9
	Maximum	108.0
BMI (kg/m ²)	N	14
	Mean	27.0
	Std Dev	2.6
	Minimum	22.1
	Maximum	30.6
Race	Caucasian	N 13 (92.9)
	Mixed	N 1 (7.1)

Fig. 5

Summary of Recovery (n=14) of Radiolabeled Treprostinil with sC/P and Mass Balance Following Administration via AERx

Subject Number	Date	Phase Number	DF Pre-Dose (CPM)	#AERx Post Dose (%LD)	*Mouth-piece (%LD)	*DF Post-Dose (%LD)	*Total dose retained (%LD)	Mouth-wash (%ED)	Mouth (%ED)	Oro-pharyngeal (%ED)	Stomach (%ED)	Total Oro-pharyngeal (%ED)	Total Lung (%ED)	sC/P	Mass balance (%)
S001	07-Apr-08	1	61050	50.10	0.72	21.92	72.74	0.44	0.52	0.70	1.83	3.49	96.51	1.28	96.91
S002	09-Apr-08	2	62097	27.12	3.35	20.52	51.00	0.18	0.34	1.27	9.32	11.11	88.89	1.76	104.53
S003	07-Apr-08	1	57850	32.67	2.26	21.30	56.23	0.35	0.96	0.43	1.96	3.70	96.30	1.33	104.22
S004	09-Apr-08	2	60344	43.88	2.80	22.93	69.61	1.00	10.86	3.16	16.23	31.24	68.76	1.85	96.94
S005	07-Apr-08	1	60772	24.76	4.41	22.65	51.81	0.43	1.41	0.49	2.71	5.04	94.96	1.12	99.63
S006	09-Apr-08	2	61525	25.91	2.43	21.59	49.94	0.12	0.08	1.70	1.25	3.14	96.86	1.31	99.71
S007	09-Apr-08	2	62529	26.22	1.52	20.72	48.46	1.02	0.17	1.52	2.45	5.17	94.83	1.96	96.59
S008	08-Apr-08	1	63614	34.91	1.71	19.71	56.34	0.15	0.20	0.46	2.19	3.00	97.00	1.26	98.17
S009	08-Apr-08	1	64948	24.64	1.90	19.21	45.76	0.13	0.72	2.48	3.18	6.51	93.49	1.52	98.55
S010	08-Apr-08	1	65065	27.95	3.02	17.98	48.95	0.18	0.06	0.19	1.23	1.66	98.34	1.47	102.36
S011	10-Apr-08	2	61110	25.53	2.95	20.97	49.45	0.10	0.22	0.69	9.52	10.53	89.47	1.22	105.91
S012	10-Apr-08	2	61359	26.48	1.98	20.53	48.99	0.09	0.17	0.79	6.59	7.64	92.36	1.17	104.70
S013	10-Apr-08	2	61564	24.94	1.93	20.87	47.74	0.21	0.52	1.86	15.70	18.29	81.71	1.20	96.48
S014	08-Apr-08	1	64778	25.39	1.88	21.24	48.51	0.66	3.15	0.86	1.83	6.51	93.49	1.00	91.99
Mean			62043	30.04	2.35	20.87	53.25	0.36	1.38	1.19	5.43	8.36	91.64	1.39	99.76
SD			2013	7.88	0.91	1.30	8.17	0.32	2.85	0.86	5.26	7.89	7.89	0.29	4.05
CV%			3.24	26.23	38.78	6.24	15.34	88.57	205.70	72.91	96.97	94.40	8.61	20.68	4.06
Min			57850	26.64	0.72	17.98	45.76	0.09	0.06	0.19	1.23	1.66	68.76	1.00	91.99
Max			65065	50.10	4.41	22.93	72.74	1.02	10.86	3.16	16.23	31.24	98.34	1.96	105.91

%ED - Percent of emitted dose (ex-mouthpiece)

CPM - counts per minute

DF - dosage forms

* % calculated from loaded dose (LD) in AERx Strips

AERx Post counts corrected for attenuation by AERx device

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