Factor Therapeutics Results of Phase 2 Clinical Trial - Conference Call Details

Brisbane, Australia 14th November 2018: A conference call hosted by Factor CEO, Dr Ros Wilson, will be held at 11:00am AEST (Brisbane time) on Wednesday 14th November. Dr Wilson will reference the attached presentation during the call.

Participants can register for the conference call at the following link: https://services.choruscall.com.au/diamondpass/factortherapeutics-517845-invite.html

You will receive a calendar notification with dial-in details and a PIN for fast track access to the call. Alternatively, participants may dial in using the details below at the scheduled time:

Conference ID: 517845

Australia Toll Free:	1 800 558 698
Alternate Australia Toll Free:	1 800 809 971
Australia Local:	02 9007 3187
New Zealand Toll Free:	0800 453 055
China Wide:	4001 200 659
Belgium:	0800 72 111
Canada:	1855 8811 339
France:	0800 913 848
Germany:	0800 182 7617
Hong Kong:	800 966 806
India:	0008 0010 08443
Indonesia:	001 803 019 3275
Ireland:	1800 948 625
Italy:	800 793 500
Japan:	0053 116 1281
Malaysia:	1800 816 294
Norway:	800 69 950
Philippines:	1800 1110 1462
Singapore:	800 101 2785
Sweden:	020 791 959
South Africa:	0800 999 976
Switzerland:	0800 820 030
Taiwan:	008 0112 7397
Thailand:	001800 156 206 3275
UAE:	8000 3570 2705
United Kingdom:	0800 051 8245
United States:	(855) 881 1339
US Local (New York):	(914) 202 3258
US Local (Los Angeles):	(909) 235 4020
US Local (Chicago):	(815) 373 2080

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Patient Disposition

Study Populations (n)

	Placebo	Low Dose	High Dose
ITT	53	50	53
SAF	53	50	53
PP	44	43	44

Screen Failed n = 101 (39.3%)

Screened n = 257

Randomised n = 156

Placebo n = 53		
Healed n = 21 (39.6%)	Not Healed n = 25 (47.2%)	Discont. n = 7
Completed n = 49 (92%)	On Study n = 4 (8%)	

Reasons for Discontinuation:
Consent withdrawn x 2, SAE, lost to follow-up, non-compliance, incorrect inclusion, ulcer growth

VF001 Low Dose n = 50		
Healed n = 24 (48.0%)	Not Healed n = 24 (48.0%)	Discont. n = 2
Completed n = 44 (88%)	On Study n = 6 (12%)	

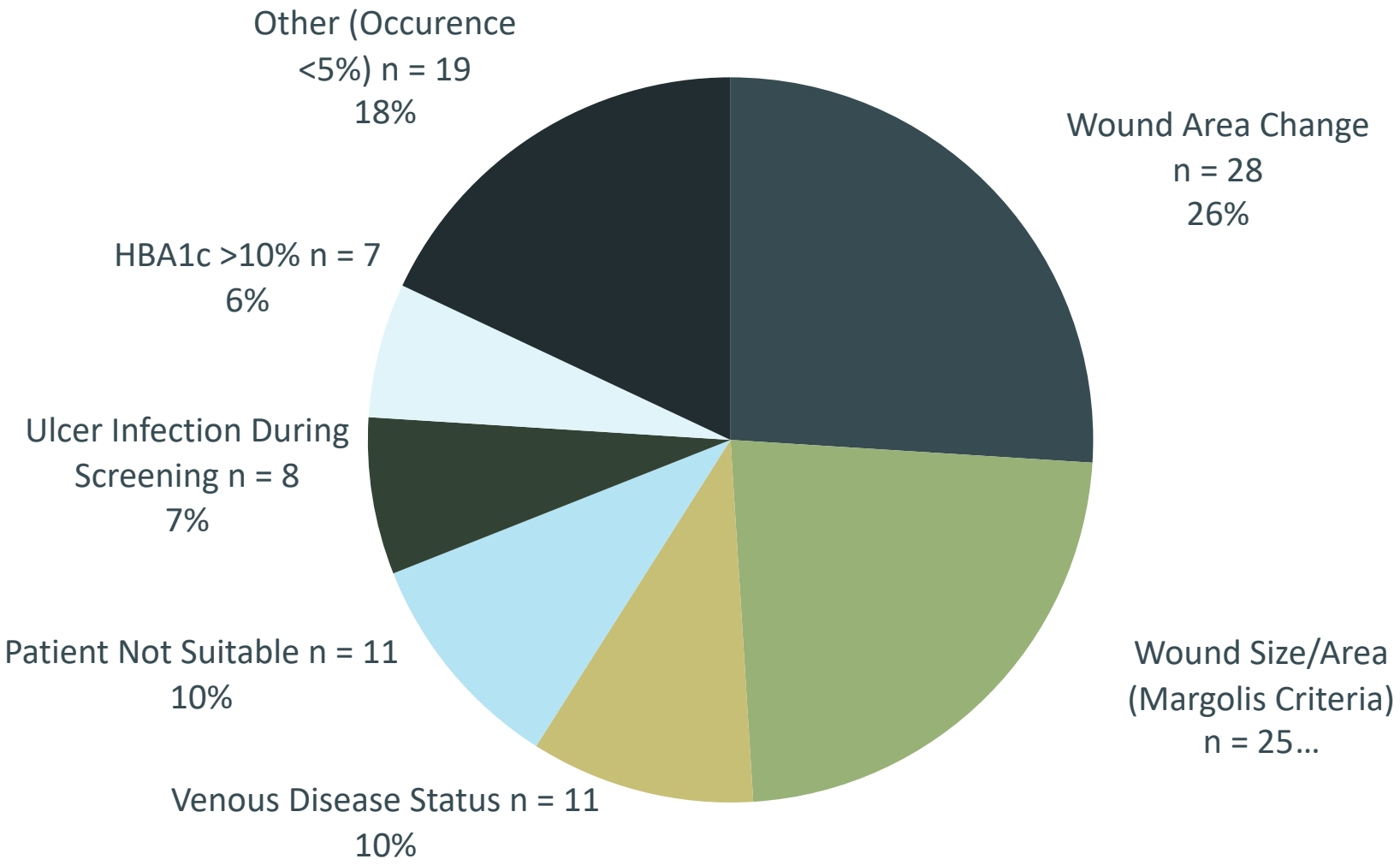
Reasons for Discontinuation:
Consent withdrawn, ulcer growth

VF001 High Dose n = 53		
Healed n = 22 (41.5%)	Not Healed n = 26 (49.1%)	Discont. n = 5
Completed n = 47 (89%)	On Study n = 6 (11%)	

Reasons for Discontinuation:
Consent withdrawn x 3, SAE, lost to follow-up

Note: Completed/on study as at 5 Nov 2018

Reasons for Screen Failure

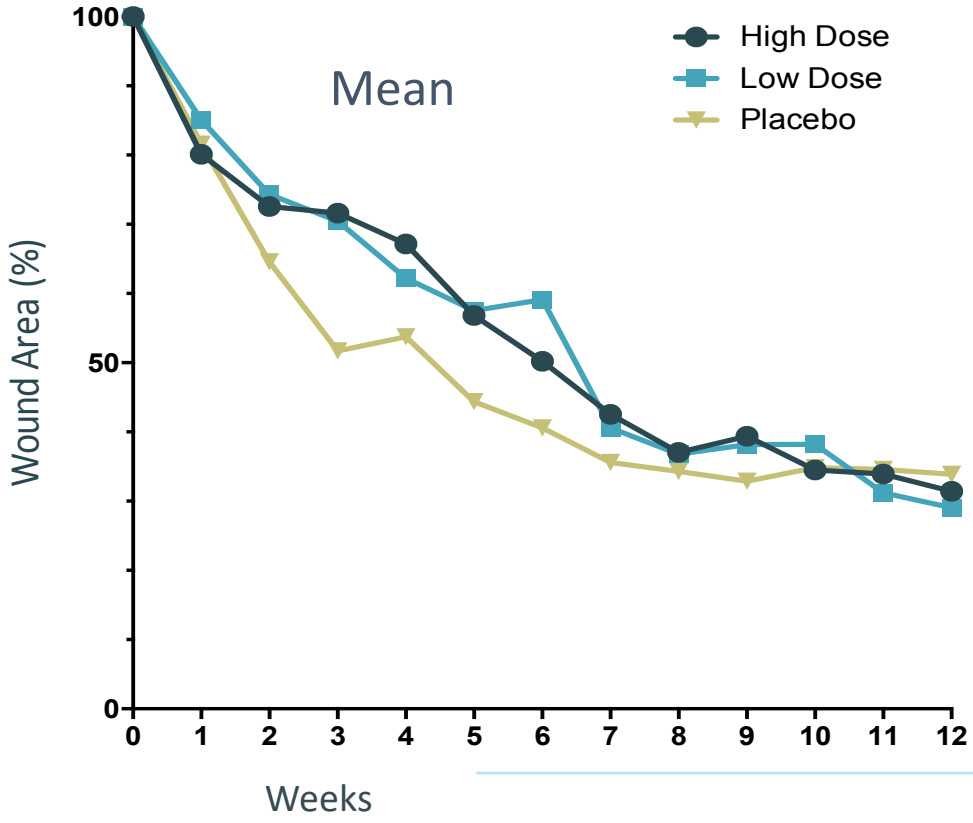


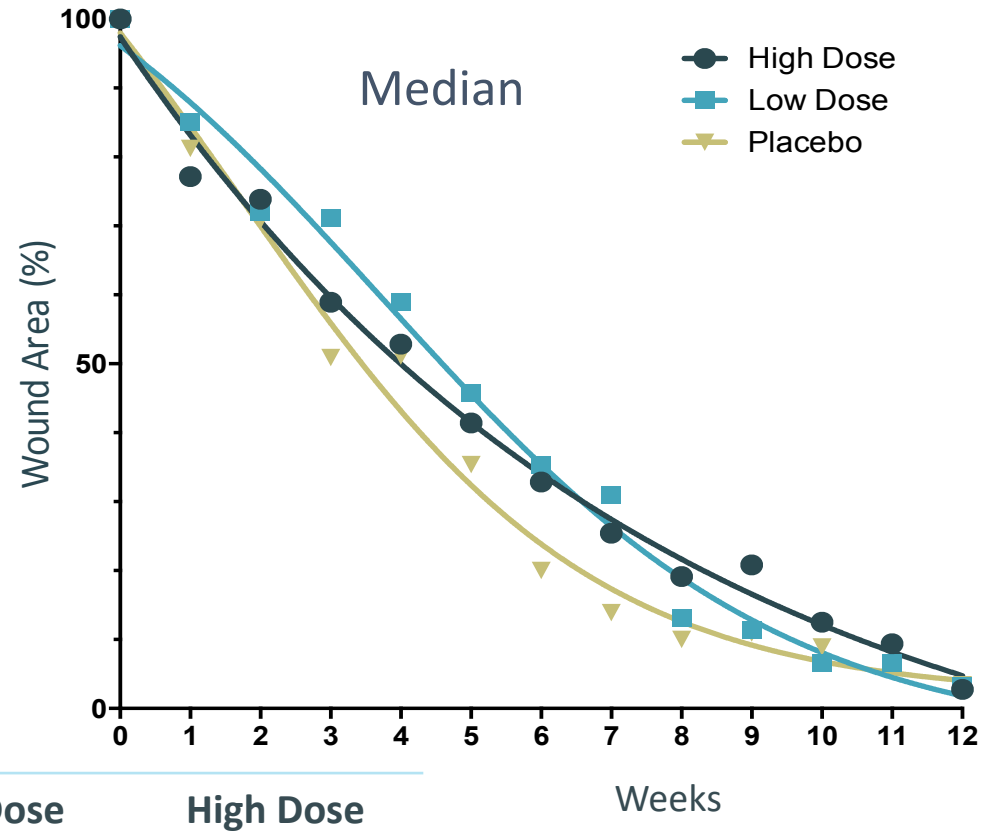
Groups Well Balanced and Representative of the Population of Patients with VLUs

Baseline Characteristics (ITT)

	Placebo (n = 53)	Low Dose (n = 50)	High Dose (n = 53)
Mean Age, yrs (range)	60.3 (31 - 93)	63.2 (28 - 86)	65.6 (43 - 94)
Age < 65 / > 65 years, %	66 / 34	58 / 42	53 / 47
Gender M/F, %	64 / 36	54 / 46	55 / 45
Mean BMI (range)	34 (19 – 55)	36 (21 – 67)	34 (18 – 72)
Normal/Overweight/Obese, %	19 / 21 / 60	10 / 16 / 74	19 / 23 / 58
Mean ABI	1.056	1.076	1.022
Never Smokers, %	57	52	81
Hispanic / Latino, %	28	34	30

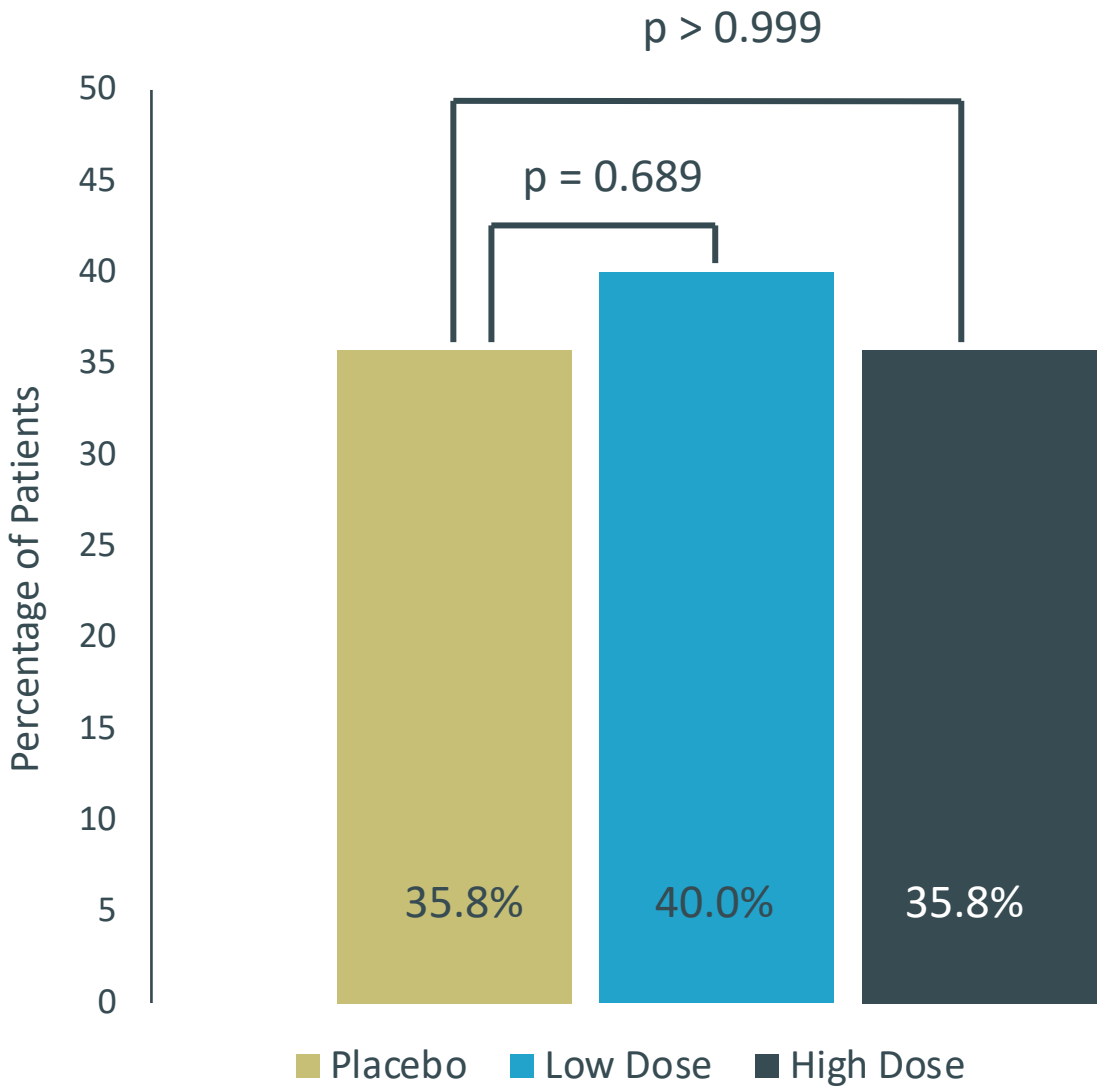
Primary Efficacy (LOCF ITT)
No Difference in Wound Area Reduction





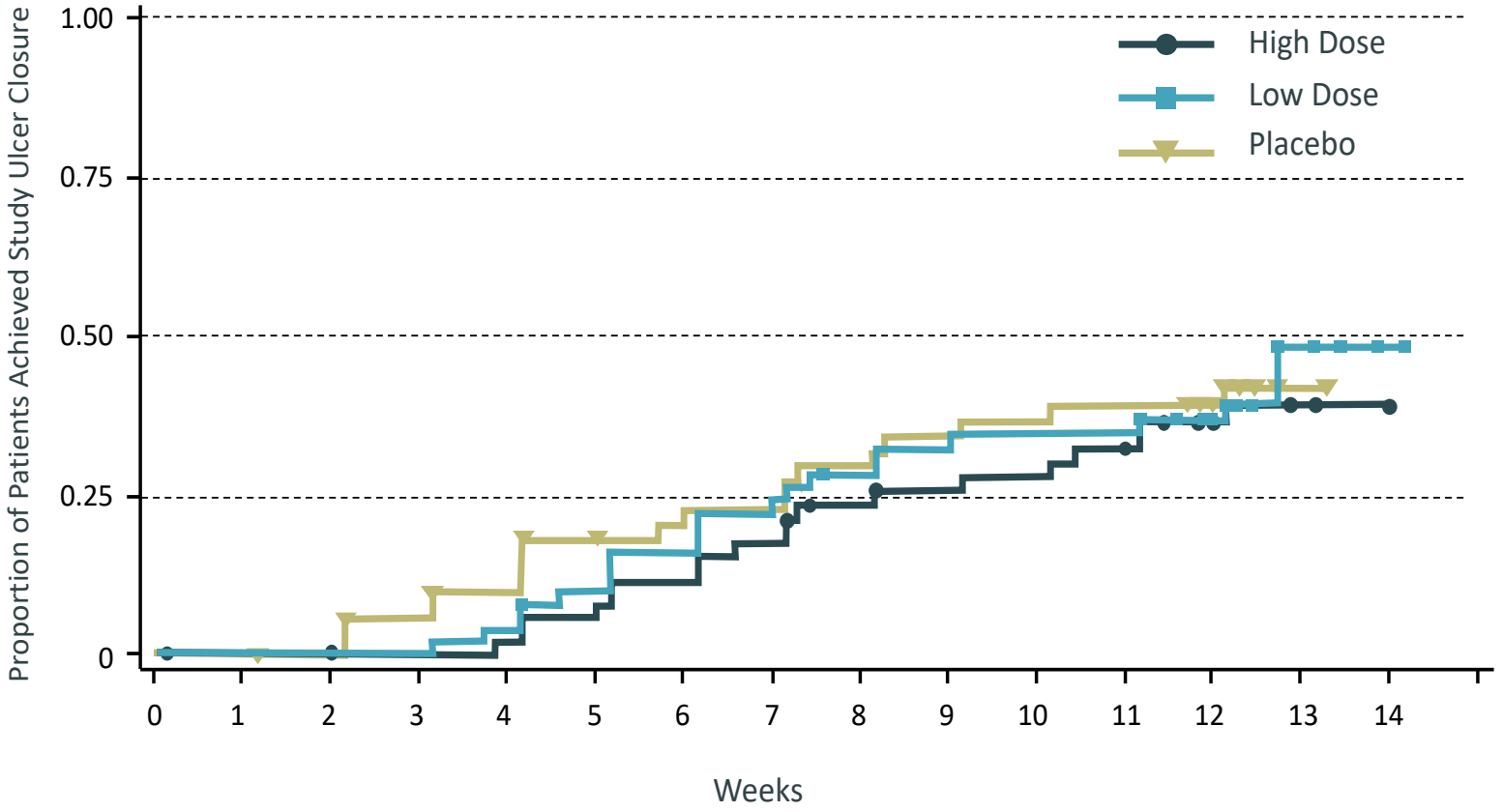
	Placebo	Low Dose	High Dose
Baseline, cm^2	5.1	5.2	5.6
Mean % change (SD)	55.7 (78.51)	61.0 (89.04)	57.4 (62.17)
Median % change	87.1	96.5	93.0
p value (median)	-	0.550	0.931

Secondary Efficacy (ITT)
Similar Proportion of Patients Achieved Full Healing



	Placebo (n = 53)	Low Dose (n = 50)	High Dose (n = 53)
Complete Closure, %	35.8	40.0	35.8
Difference from placebo, % (95% CI)	-	4.2 (-14.6, 22.9)	0 (-18.3, 18.3)
p-value	-	0.689	> 0.999

Secondary Efficacy (ITT)
No Difference in Time to Achieve Full Healing



	Low Dose	High Dose
Hazard Ratio	0.79	0.75
95% CI	0.40, 1.43	0.42, 1.49
p value	0.386	0.462

Secondary Efficacy (ITT)
Similar Improvements in Pain

Time to First Instance of No Study Ulcer Pain

	Placebo (n = 53)	Low Dose (n = 50)	High Dose (n = 53)
Q1, weeks (95% CI)	3.14 (1.14, 4.14)	2.86 (1.14, 4.14)	2.57 (1.14, 4.14)
Median, weeks (95% CI)	8.86 (4.14, 12.14)	8.14 (4.14, NC)	8.14 (4.14, 12.14)
Q3, weeks (95% CI)	NC (11.14, NC)	NC (12.43, NC)	NC (12.14, NC)
p value	-	0.856	0.879

Time to Clinically Meaningful Study Ulcer Pain Reduction

	Placebo (n = 53)	Low Dose (n = 50)	High Dose (n = 53)
Q1, weeks (95% CI)	1.29 (1.14, 2.29)	2.14 (1.14, 3.14)	2.14 (1.14, 3.00)
Median, weeks (95% CI)	6.14 (2.29, 9.57)	7.14 (3.14, 12.71)	4.00 (3.00, 7.14)
Q3, weeks (95% CI)	NC (9.14, NC)	13.86 (11.14, NC)	NC (7.14, NC)
p value	-	0.410	0.922

Safety: Treatment-Emergent Adverse Events*

	Placebo (n = 53)	Low Dose (n = 50)	High Dose (n = 53)
Number of patients with at least one TEAE	17 (32.1%)	15 (30.0%)	14 (26.4%)
TEAE occurring > 5% in any group			
Infections	8	9	11
Tissue disorders	7	7	6
Injury	2	1	4
Gastrointestinal	0	2	3
Metabolism	1	3	1
Renal	0	3	2
Respiratory, thoracic	0	4	0

*Adverse events that either start or worsen in severity on or after the date/time of first dose of study treatment

Safety: Serious Adverse Events

	Placebo (n = 53)	Low Dose (n = 50)	High Dose (n = 53)
Number of patients with at least one TESAE	3 (5.7%)	3 (6.0%)	5 (9.4%)
TESAE			
Cellulitis/infected ulcer	1	1	3
Death	1		
Fever			1
Respiratory/COPD		2	
Cardiac/acute cardiac failure			1
GI/peptic ulcer disease		1	
Injury/fall			1
Congenital	1		
Skin			1

Summary

- Results are clear: no justification to continue further development of VF001
- Ongoing development of VF001, in all indications, halted
- Factor Therapeutics to limit further activity to maintaining intellectual property portfolio