



***Phase II Study of KX2-391 Ointment  
1%, a Novel Field Treatment Based  
on Src/Tubulin Polymerization  
Inhibition, for Actinic Keratosis***

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## ***Study Design***

Open-label, uncontrolled, multicenter Phase II study of KX2-391 Ointment 1% in adults with Actinic Keratosis (AK) on the face or scalp in 16 US sites

**2 Cohorts:** Daily treatment for 5 or 3 consecutive days (N=84 per cohort)

**Treatment area:** 25 cm<sup>2</sup> with 4-8 AK lesions on face or scalp

**Endpoints:** 100% clearance of AK at Day 57 and Safety (local skin reactions, LSR) until Day 57

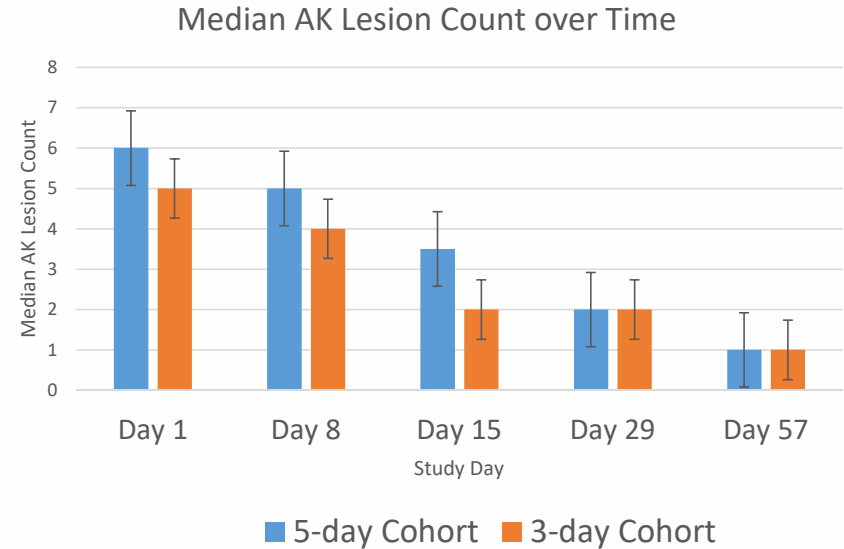
## ***Patient Characteristics***

- Primarily white males with mean age of 68 years, skin type I-III and median baseline AK lesions of 6 (5-day Cohort) and 5 (3-day Cohort)



# Efficacy of KX2-391 in Field Treatment of Actinic Keratosis

Cohort	Clearance of AK at Day 57	Responders/ Total Number (%)		
		Face	Scalp	Overall
5-Day	100%	23/44 (52%)	13/40 (33%)	<b>36/84 (43%)</b>
	≥75%	29/44 (66%)	18/40 (45%)	<b>47/84 (56%)</b>
3-Day	100%	20/66 (30%)	7/18 (39%)	<b>27/84 (32%)</b>
	≥75%	35/66 (53%)	9/18 (50%)	<b>44/84 (52%)</b>



## *KX2-391 was well tolerated and resulted in mostly mild local reactions*

Photos of the subject with score 4 for erythema and flaking/scaling



Day 1, Pre-treatment

Day 8

Day 57

## Incidence of Post-Baseline Maximal LSR

Score	Vesicles/ Pustules		Erosions/ Ulcers		Swelling		Crusting		Flaking/ Scaling		Erythema	
	5-Day	3-Day	5-Day	3-Day	5-Day	3-Day	5-Day	3-Day	5-Day	3-Day	5-Day	3-Day
0	80 (95%)	83 (99%)	71 (85%)	79 (94%)	66 (79%)	76 (90%)	51 (61%)	58 (69%)	33 (39%)	39 (46%)	15 (18%)	30 (36%)
1	4 (5%)	0	12 (14%)	5 (6%)	16 (19%)	8 (10%)	25 (30%)	16 (19%)	10 (12%)	18 (21%)	16 (19%)	22 (26%)
2	0	1 (1%)	1 (1%)	0	1 (1%)	0	8 (10%)	9 (11%)	24 (29%)	19 (23%)	35 (42%)	26 (31%)
3	0	0	0	0	1 (1%)	0	0	1 (1%)	16 (19%)	8 (10%)	17 (20%)	6 (7%)
4	0	0	0	0	0	0	0	0	1 (1%)	0	1 (1%)	0

0-4 LSR severity scale: 0=absent to 4=worst

### Conclusions:

- 3-Day and 5-Day of KX2-391 Ointment 1% were active against AK on face or scalp
- Application site reactions were few, mild and short-lived
- 2 Phase III studies on 5-Day regimen are ongoing

Median LSR Composite Scores Over Time

