EA DV CONGRESS
PARIS 17-20 SEPTEMBER 2025
EUROPEAN ACADEMY OF DERMATOLOGY & VENEREOLOGY

Abstract N°: 3747

A randomized phase 2 proof-of-concept study to evaluate the efficacy and safety of topical bimiralisib application in patients suffering from actinic keratosis on the face and/or scalp and/or back of hands over a 2 and 4-week treatment period

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Background:

Actinic keratosis (AK) is the most common precancerous skin condition, driven by multiple genetic and molecular alterations. Due to its chronic recurrent course, more effective targeted therapies are required for AK. Bimiralisib, a selective pan-PI3K/mTOR inhibitor, showed well tolerated efficacy in animal models of AK and cutaneous squamous cell carcinoma and high skin penetration indicating its clinical potential.

Methods:

In this multi-center trial, 46 adults (50 years or older) with AK (Olsen grade 1 or 2) on face, scalp, and/or back of hands were assigned in a 1:1 ratio to topical bimiralisib gel 2% once daily for either 2 weeks (Arm A) or 4 weeks (Arm B) as field-directed treatment. Primary outcome was percentage of patients with an Investigator's Global Assessment (IGA) score of 0 (completely cleared) or 1 (partially cleared) at the 4-week follow-up. Secondary outcomes included safety, tolerability, and percentage partial clearance of AK lesions. An optional 8-week treatment extension was offered if at least 50% improvement in lesion size was seen.

Results:

Enrollment is complete with 42 of 46 randomized patients treated with bimiralisib (21 patients per arm). All patients have reached the primary endpoint and received the initial treatment course without dose interruption except one patient who discontinued after 2 weeks due to constraints of the clinical trial setting. Bimiralisib gel 2% led to significant reductions in AK lesions. 52% (Arm A) and 71% (Arm B) of patients achieved an IGA score of 0-1, respectively, with all patients showing some degree of clearance after the initial treatment period. Clearance was seen in Olsen grade 1 and grade 2 AK lesions. Further efficacy sub-analyses are planned.

	No. Pts	Complete Clearance	Partial Clearance	Moderate Clearance	Minimal Clearance	No Change	Percent (complete + partial)
Arm A (2 week)	21	2	9	8	2	0	52.4%
Arm B (4 week)	21	6	9	6	0	0	71.4%

Related adverse events were generally local skin reactions with the vast majority being mild (only three grade 2 events) resolving without intervention. Related adverse events are listed below:

Original Terms (grouped)	Arm A (21 pts)			Arm B (21 pts)		
	Gr 1	Gr 2	Total AEs (pts)	Gr 1	Gr 2	Total (AEs (pts)
Erosion	6	2	8 (6)	4	-	4 (3)
Crusting	5	1	6 (6)	5	-	5 (5)
Erythema (of lesions)	5	-	5 (5)	5	-	5 (5)
Pruritus	2	-	2 (2)	3	-	3 (3)
Itching	-	-	-	1	-	1 (1)
Burning (sensation)	-	-	-	2	-	2 (2)
Flaking/ dryness	1	-	1 (1)	-	-	-
Local skin irritation	1	-	1 (1)	3	-	3 (3)
Scaling	1	-	1 (1)	1	-	1 (1)

A similar safety profile was seen for both 2- and 4-week treatment arms, with no increase in toxicity associated with prolonged treatment. 17 patients entered the optional 8-week extension treatment. Only 4 related adverse events were noted during the extension treatment, with 10 patients completing the extension to date. 6 patients discontinued extension treatment early (4 due to patient decision and 2 due to adverse events - grade 1 recurrent erosion and grade 2 inflammatory response of lesions). The extension treatment showed retreatment is feasible without any significant or new safety concerns. Further improvements of lesions were noted with additional cases of complete clearance.

Conclusions:

Bimiralisib gel 2% demonstrated substantial efficacy in the treatment of AK, both in Olsen grade 1 and grade 2, with a favorable safety profile supporting further clinical development and offering a new option for the treatment of AK. Detailed efficacy, safety (including the extension period), PK and imaging analyses will be presented at the meeting.