**INTRODUCTION**

- Actinic keratosis (AK) are precancerous lesions that if untreated may lead to invasive squamous cell carcinoma (SCC) (Fernandez).
- Tirbanibulin (KX2-391, KX01) is a synthetic, highly selective, novel inhibitor of tubulin polymerization and Src kinase signaling developed as a first-in-class topical formulation for the treatment for AK (Smolinski).
- Previous Phase I and II studies demonstrated that tirbanibulin ointment 1% was active against AK lesions on the forearm and face or scalp, respectively. Local skin reactions (LSRs) were mostly transient and mild-to-moderate in severity, and tirbanibulin was well tolerated (DuBois phase I and phase II).
- Tirbanibulin ointment 1% once-daily for 5 days resulted in higher overall complete AK clearance rates at Day 57 than vehicle in two Phase III studies (KX01-AK-003: 44% vs 5%; KX01-AK-04: 54% vs 13%, respectively; p<0.0001) (Blauvelt).

**RESULTS**

![Figure 1a: Firm verrucous plaque at distal periungual tip of the left 4th digit before treatment with tirbanibulin 1% ointment](image1)

![Figure 1b: Complete resolution of squamous cell carcinoma after 5 days of topical tirbanibulin 1% ointment](image2)

- Human papillomavirus type 57 complete DNA
  - Sequence ID: X55965.1
  - Length: 7861
  - Number of Matches: 1
  - Range 1: 6732 to 6864

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- Query 1
  - Query 61
  - Sbjct 6732
  - Sbjct 6792
  - Query 121
  - Sbjct 6852

**CASE REPORT**

- 29-year-old non-smoking male had a biopsy-confirmed squamous cell carcinoma in situ at the distal periungual tip of the left fourth fingernail.
- Previous treatment with imiquimod and monthly liquid nitrogen for 6 months had failed.
- Tirbanibulin 1% ointment was applied for 5 days with complete resolution on the fifth day without reported erythema, edema, or irritation.

**METHODS**

- HPV typing by nested PCR was performed on paraffin-embedded block.

**RESULTS**

- HPV 57 was detected (Figure 2).

**DISCUSSION**

- Although HPV 57 is most commonly associated with common warts, HPV 57 has also been reported with oral papillomas, esophageal SCC, and cutaneous SCC.
- Even though it is FDA-approved in the U.S. for treatment of actinic keratosis, tirbanibulin ointment may have efficacy on SCC or directly on HPV-driven carcinogenesis.

**CONCLUSION**

- Further research on the mechanism of tirbanibulin effect on HPV as well as SCC are required to confirm these findings.

**REFERENCES**


**Figure 2:** NCBI-BLAST alignment of sequencing data obtained from the HPV-PCR product

The sequence data obtained from patient’s sample (query) showed 95% identities to the prototype HPV 57 DNA deposited into the NCBI GeneBank (sbjt).