

## Klisyri<sup>®</sup> (tirbanibulin) – New drug approval

- On December 15, 2020, [Athenex announced](#) the FDA approval of [Klisyri \(tirbanibulin\)](#), for the topical treatment of actinic keratosis (AK) of the face or scalp.
- AK is a pre-cancerous skin lesion and is the second most common diagnosis made by dermatologists in the U.S. If left untreated, 10-15% of AK lesions will develop into skin cancers. Other treatment options for AK include cryotherapy, surgical removal of the lesion, or topical treatment with [fluorouracil](#), [imiquimod](#), or photodynamic therapy.
- Klisyri is a microtubule inhibitor. The mechanism of action of Klisyri for the topical treatment of AK is unknown.
- The efficacy of Klisyri was established in two double-blind, vehicle-controlled clinical studies conducted in 702 adult subjects with AK on the face or scalp. The primary efficacy endpoint was complete (100%) clearance of AK lesions in the treatment area, defined as the proportion of subjects at day 57 with no clinically visible AK lesions in the treatment area.
  - In study 1, 44% of Klisyri treated patients vs. 5% of vehicle treated patients achieved 100% clearance rates at day 57 (treatment difference: 40%; 95% CI: 31.6, 47.5).
  - In study 2, 54% of Klisyri treated patients vs. 13% of vehicle treated patients achieved 100% clearance rates at day 57 (treatment difference: 42%; 95% CI: 33.1, 50.7).
  - Of the 174 subjects treated with Klisyri who were followed, the recurrence rate at 12 months post-day 57 was 73%.
- Warnings and precautions for Klisyri include ophthalmic adverse reactions and local skin reactions.
- The most common adverse reactions (≥ 2%) with Klisyri use were local skin reactions, application site pruritus, and application site pain.
- Apply a sufficient amount of Klisyri to evenly cover up to 25 cm<sup>2</sup> treatment field on the face or scalp once daily for 5 consecutive days using one single-dose packet per application.
- Athenex plans to launch Klisyri in the first quarter of 2021. Klisyri will be available as a 1% ointment in a single-dose packet (2.5 mg tirbanibulin in 250 mg).