DEVELOPMENT SCIENCES: Innovation & Technology

TITLE

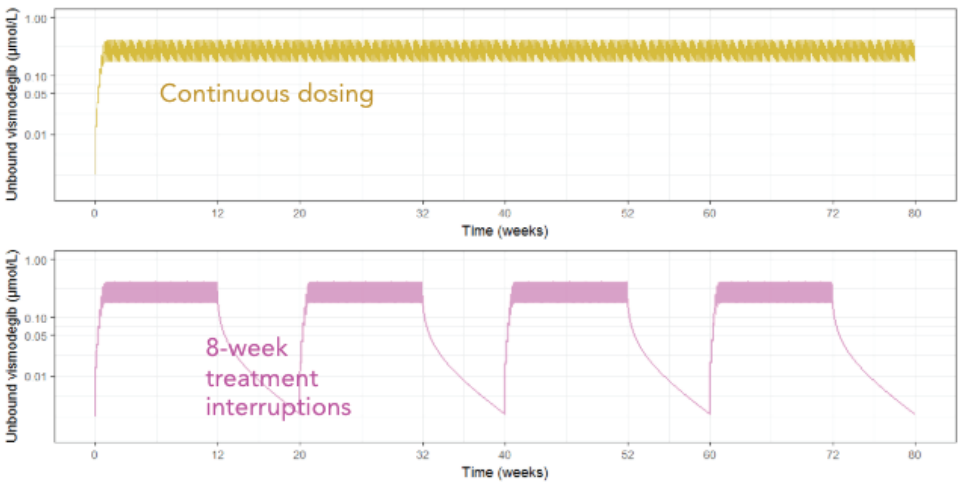
Getting Label Claims Approved by Simulating Virtual Trials Instead of Running Clinical Trials

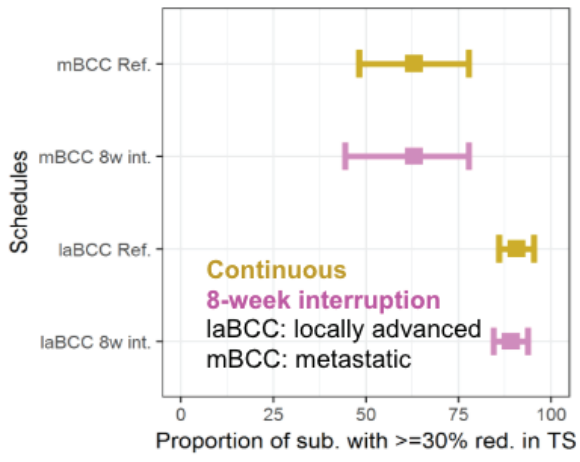
SUMMARY

Vismodegib (ERIVEDGE) is indicated for the treatment of locally advanced and metastatic basal cell carcinoma (BCC). Up to 31% patients experience treatment emergent adverse events leading to treatment discontinuation. The MIKIE study showed in a different BCC population that intermittent dosing (using 8-week treatment interruptions) can improve safety and preserve efficacy. The objective of this work was to simulate 8-week treatment interruption regimens in the labeled population and show that patients can still maintain efficacy when compared to continuous dosing.

IMPACT

- Provide recommendations to better manage safety and allow longer treatment duration with ERIVEDGE
- 8-week treatment interruptions have been added to the ERIVEDGE USPI
- Cost effective and accelerated way to expand labels





New USPI statement

"2.3 Dosage Modifications for Adverse Reactions

Withhold ERIVEDGE for up to 8 weeks for intolerable adverse reactions until improvement or resolution."

Efficacy as the proportion of responders is maintained with 8-week treatment interruptions regimens

CONTACT

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