

# DOSE CHARACTERISATION OF TIGILANOL TIGLATE (EBC-46) IN THE LOCAL TREATMENT OF CANINE MAST CELL TUMORS

## OBJECTIVES

- Characterise a safe and effective dose of intratumorally administered tigilanol tiglate (Stelfonta®) for the treatment of canine mast cell tumors (MCT).
- Investigate the systemic concentrations of tigilanol tiglate following treatment.

## MATERIALS & METHODS

- **Animals:**
  - 27 dogs diagnosed with a stage I/IIa MCT with a volume 0.1–6.0 cm<sup>3</sup>
- **Treatment administration:**
  - Dosing was based on tumor size (50% v/v tumor) and 3 drug concentrations (1.0, 0.5, 0.2 mg/mL) were evaluated. Dose de-escalation was used, and each dose cohort was fully recruited before the next, descending, cohort commenced recruitment.
- **Clinical Evaluation:**
  - Clinical examinations at days 1, 7, 14 and 21. At Day 21 efficacy was defined using solid tumor response criteria (RECIST).

## RESULTS

- **Response to treatment (see Figure 1):**
  - Cohort 1 (1.0mg/mL) (n=10)
    - 9 had a complete response (90%,  $p < 0.05$ )
    - 1 stable disease
  - Cohort 2 (0.5mg /mL) (n=10)
    - 5 had a complete response (50%)
    - 1 had a partial response, 3 stable disease and 1 progressive disease
  - Cohort 3 (0.2 mg/mL) (n=7)
    - 2 had a complete response (29%)
    - 1 partial response and 4 stable disease
- **Haematological and serum biochemistry were generally unremarkable with plasma concentration curves typical of a non-intravenous parenteral medication.**

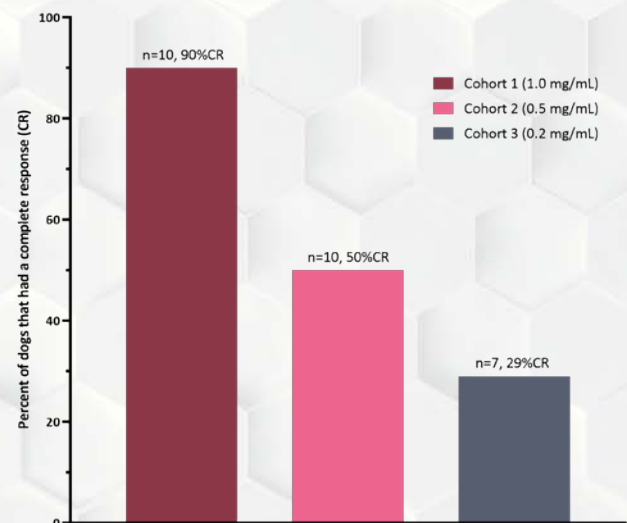


Figure 1: Comparative percentages of dogs that had a complete response for three tigilanol tiglate dose cohorts at day 21.

## CLINICAL INTEREST

**Intratumoral treatment of MCT with tigilanol tiglate at a concentration of 1.0 mg/mL was highly efficacious and well-tolerated.**

## REFERENCES

- Miller J, Campbell J, Blum A, Reddell P, Gordon V, Schmidt P, et al. Dose characterisation of the investigational anticancer drug tigilanol tiglate (EBC-46) in the local treatment of canine mast cell tumours. *Front Vet Sci.* 2019;6(APR):1–10.