

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

## OBJECTIVES

Characterise a safe and effective dose of intratumourally administered tigilanol tiglate (Stelfonta®) for the treatment of canine mast cell tumours (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 tumour size (50% v/v tumour) 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 tumour 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.

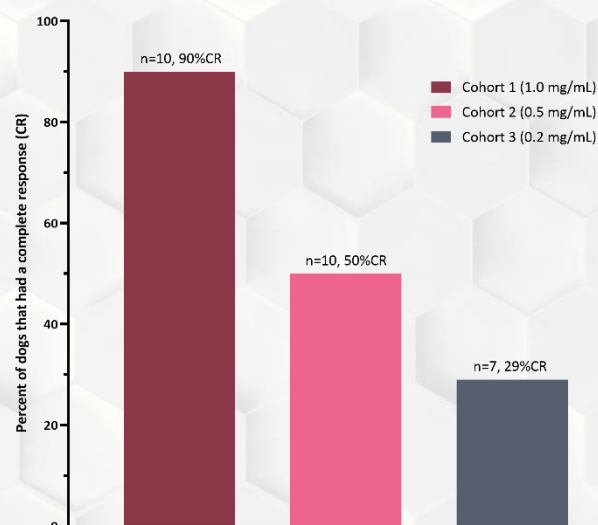


Figure 1: Comparative percentages of dogs that had a complete response for three tigilanol tiglate dose cohorts at day 21.

## CLINICAL INTEREST

**Intratumoural 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.