European Society of Veterinary Oncology

Presented at ESVONC 2019

Controlled, Randomized Study of Intratumoral Tigilanol Tiglate (EBC-46) for Treatment of Canine Mast Cell Tumors

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Introduction

Tigilanol tiglate, isolated from the Australian rainforest plant *Fontainea picrosperma*, possesses antitumor activity and enhanced wound healing stimulation at the treatment site via activation of protein kinase C. Tigilanol tiglate may be effective when injected intratumorally as treatment for canine mast cell tumor (MCT).

Materials & Methods

Dogs with cutaneous or lower limb subcutaneous MCT were enrolled and randomized 2:1 to treatment with a single intratumoral injection of tigilanol tiglate or sham treatment (untreated controls) in an investigator- and owner-masked multicenter study. Primary efficacy outcome was complete response (CR; disappearance of target lesion) on Day 28. Treated dogs with less than CR could receive a second intratumoral injection on Day 30 and untreated dogs could be crossed over to treatment.

Results

Enrolled dogs numbered 123 with 118 evaluable. Sixty of 80 dogs (75%) randomized to tigilanol tiglate treatment achieved CR after initial injection compared with 2/38 untreated dogs (5.3%) by Day 28 ($P < 0.0001$). Eighteen of 20 treated dogs not achieving CR received a second injection. Eighty-seven percent (68/78 evaluable) of treated dogs achieved CR within the two-dose treatment strategy. Ninety-six percent (55/57 evaluable) dogs achieving CR after first injection remained tumor-free at day 84.

The most frequent adverse events were transient reactions at the treatment site, anticipated pathology associated with drug mechanism of action. Wounds developed in 92.5% (74/80) of treated dogs and healed rapidly from Day 7.

Conclusions

Tigilanol tiglate was highly effective for treatment of cutaneous and lower limb subcutaneous MCT in dogs and was well tolerated with manageable side effects.

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