

The specialist of osteoarticular disease treatments in companion animals

PRESS RELEASE – Inside Information – Regulated Information

# TheraVet announces positive safety and efficacy results for BIOCERA-VET® in canine osteosarcoma

- ▼ Improvement of Quality of Life and reduction of Pain with BIOCERA-VET® palliative cementoplasty
- **▼** Low complications rate

Gosselies (Wallonia, Belgium), November 15, 2021 – 7:30 am CET – TheraVet (ISIN: BE0974387194 - ticker: ALVET), a pioneering company in the management of osteoarticular diseases in pets, today announces the positive safety and efficacy results for BIOCERA-VET® used in cementoplasty as palliative treatment for canine osteosarcoma.

## BIOCERA-VET®: a new palliative option for canine osteosarcoma

BIOCERA-VET®, TheraVet's bone substitute, was assessed in a prospective non-controlled multicentric clinical study in client-owned dogs suffering from osteosarcoma. Twelve dogs were treated by a percutaneous cementoplasty using BIOCERA-VET® as palliative treatment of osteosarcoma and followed up for 6 months. The main objective of the study was to assess the effect of BIOCERA-VET® cementoplasty on dog pain, using scores such as veterinary score¹ pain and validated owner questionnaires CBPI (Canine Brief Pain Inventory)² and VAS pain³. Quality of life was assessed by the owner with the CBPI questionnaire. Also, the complications and the adverse events were collected as safety evaluation. In this study, BIOCERA-VET® was used alone, non-combined with chemotherapy.

Among the animals satisfying the different follow-up visits, BIOCERA-VET® cementoplasty improved significantly the pain as measured by VAS pain and CBPI. Indeed, 67% of the dogs at 1 month and 50% at 2 and 6 months experienced a reduction of at least 50% in pain. The same reduction levels were measured with the pain severity (PSS) and with the pain interference with the function (PIS) scores of the CBPI, although slightly less4. Quality of Life was improved in 78% of the dogs at 1 month and in 50% of the dogs at 2 and 6 months.

BIOCERA-VET® was well-tolerated with a low rate of complications Indeed, only 3 complications (25%) were reported: one dog displayed at surgical site infection, one dog displayed a swelling at the surgical site and one dog suffered from a fracture at the site of the tumor.

This low rate of complications is very promising. First, in a similar approach of cementoplasty associated with PMMA<sup>5</sup> in a multimodal management of canine osteosarcoma, complication rate reached 75% (including wound swelling, surgical site infection, exacerbation of the lameness, thromboembolism in combination with cough and anemia) for only limited benefit on lameness<sup>6</sup>.

<sup>&</sup>lt;sup>6</sup> Böttcher P et al., Percutaneous cementoplasty in the palliative, multimodal treatment of primary bone tumors of the distal aspect of the radius in four dogs. Vet Surg. 2009 Oct;38(7):888-901.



<sup>&</sup>lt;sup>1</sup> Numerical Rating scale including 4 components: lameness, support on the affected limb, ease in lifting the contralateral limb and handling pain

<sup>&</sup>lt;sup>2</sup> CBPI is composed of 3 score components: Pain Severity Score (PSS) and Pain Interference Score (PIS) and a score of Quality of Life (QoL)

<sup>&</sup>lt;sup>3</sup> VAS: Visual Analogue Scale

<sup>&</sup>lt;sup>4</sup> PIS: reduction in 56% and 66% of the dogs at 1 and 2 months; PSS: reduction in 33 % and 50% the dogs at 1 and 2 months

<sup>&</sup>lt;sup>5</sup> PMMA: polymethyl methacrylate



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Second, the fracture incidence of 8% in the BIOCERA-VET® study compares very favorably with the incidence of pathological fractures in canine osteosarcoma is  $\sim 40\%$ <sup>7</sup>.

Taken together, the results of this first multicentric prospective study demonstrate the important potential of cementoplasty associated with BIOCERA-VET® in relieving pain and improving the quality of life of dogs suffering from osteosarcoma.

"When carefully selected, according to their breed and their tumor presentation, canine patients can really benefit from such an innovative and minimally invasive approach that provides short-term pain relief and prevents pathological fracture. It may open new horizons in the palliative treatment of canine osteosarcoma for the future, especially when the BIOCERA-VET® is used as a local anticancer drug delivery device." said Olivier Gauthier, Pr. Professor of Small Animal Surgery and Dentistry at the Oniris College of Veterinary Medicine (Nantes, France).

**Enrico Bastianelli, Chief Executive Officer of TheraVet, concludes:** "These results of BIOCERA-VET® are very promising in such painful and aggressive bone cancer. By improving the quality of life and by relieving pain, BIOCERA-VET® may now represent a unique palliative option for the pets and their owners".

### **About TheraVet SA**

TheraVet is a veterinary biotechnology company specialising in osteoarticular treatments for animals. The Company develops targeted, safe and effective treatments to improve the quality of life of pets suffering from osteoarticular diseases. For pet owners, the health of their pets is a major concern and TheraVet's mission is to address the need for innovative and curative treatments. TheraVet works closely with international opinion leaders in order to provide a more effective response to ever-growing needs in the field of veterinary medicine. TheraVet is listed on Euronext Growth® Paris et Brussels, its head office is in Gosselies, Belgium, and it has a subsidiary in the US.

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<sup>&</sup>lt;sup>7</sup> Rubin J et al., Factors associated with pathological fractures in dogs with appendicular primary bone neoplasia: 84 cases (2007-2013). J Am Vet Med Assoc. 2015 Oct 15;247(8):917-23.