Lawsuits threatened over osteoarthritis drug

By Josh Loeb

PET owners in the UK who say their animals suffered adverse side effects from being treated with an injectable anti-nerve growth factor (anti-NGF) monoclonal antibody are hoping to launch a lawsuit against the company that sells the medicine.

Bedinvetmab is sold by Zoetis in jurisdictions including the UK, EU, USA and Canada under the brand name Librela for use in canine osteoarthritis pain management. It is also approved in Australia under the brand name Beransa.

In the USA, papers for a class action lawsuit alleging that potential side effects from Librela were 'not adequately disclosed' by Zoetis were filed last year. The case is at the initial, 'pleading' stage, according to US lawyer Jason Wolf.

In the UK, a group of pet owners is considering trying to take similar action. It is understood that a key argument applicants would seek to make in any lawsuit relates to differences between information given on the leaflet for Librela in the USA compared with in the UK.

In the USA, the datasheet contains a postapproval experience section listing muscle weakness, muscle tremors and lameness as adverse events, based on postapproval adverse drug experience reporting.

This same wording does not appear on the datasheet for Librela in the UK. At present, there is no specific mention in the datasheet for Librela in the UK of musculoskeletal adverse events.

Jessica Mikaelson, a trainee lawyer who runs an organisation for pets in Cambridgeshire, said she was part of a group that was 'gathering evidence, supporting affected individuals and consulting with several law firms'. This would determine the most suitable firm to take forward a case concerning Librela, she said.

A spokesperson for Zoetis said: 'While we cannot comment on ongoing or potential litigation, we remain confident in the safety and efficacy of Librela and in the transparency of our communications with regulators, veterinarians and pet owners.'

This follows the publication of a paper comparing the frequency of musculoskeletal adverse event reports submitted for Librela and for six comparator veterinary analgesics over the same period, using data from the EU's EudraVigilance database. According to the paper, ligament/tendon injuries, polyarthritis, fractures, musculoskeletal neoplasia and septic arthritis were reported many times more frequently in Librela-treated dogs compared with in dogs treated with the six comparators (*VR*, 21/28 June 2025, vol 196, p 461).

The paper stated that a significant proportion of severe musculoskeletal adverse event reports, such as reports of ligament ruptures, luxations, fractures, limb collapse and septic arthritis, had been filed as 'not serious'.

The European Medicines Agency defines a serious adverse event as an 'adverse reaction that results in death, is life-threatening, requires hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a birth defect'.

Mike Farrell, a veterinary orthopaedic specialist and corresponding author of the paper, has accused Zoetis of seeking to downplay adverse events in dogs treated with Librela.

Zoetis' spokesperson said not all events that 'may sound serious' would necessarily meet the criteria for 'persistent or significant disability or incapacity', adding that they could not comment on individual cases without access to the full clinical context.

In clinical trials of anti-NGF monoclonal antibody therapy for people, rapidly progressive osteoarthritis was reported. No such product is licensed for use in people. The UK datasheet for Librela mentions the human clinical trials, stating that the incidence of these adverse events increased with high doses and in human patients who received long-term (more than 90 days) non-steroidal anti-inflammatory drugs concomitantly with an anti-NGF monoclonal antibody, adding: 'Dogs have no reported equivalent of human rapidly progressive osteoarthritis.'

"The VMD said it constantly reviews adverse event report data

Earlier this year the Veterinary Medicines Directorate (VMD) issued an update on Librela, stating that it was 'aware of media reports and concerns, including those raised on social media, following cases of serious adverse events in dogs administered Librela'. The summary of product characteristics was updated to state that, in rare cases, diarrhoea, emesis, ataxia, urinary incontinence, anorexia and lethargy had been reported, and, in very rare cases, seizure had been reported after administration of Librela.

The VMD said it was 'constantly reviewing adverse event report data to ensure that the overall benefits of each UK licensed veterinary medicine product outweigh the risk posed by their potential adverse events...Based on periodic safety update report data that have been received across all strengths of Librela Solution for Injection for Dogs since authorisation, the incidence of adverse events in animals was 0.0015. This means that, according to the data the VMD has received, fewer than 15 animals have experienced a suspected adverse event for every 10,000 doses of Librela sold.'

Zoetis' spokesperson said: 'We continue to monitor all pharmacovigilance data globally and share relevant updates with regulatory agencies as appropriate.'