

## Guidelines for the Sodium Pentosan Polysulfate Study

The study will be starting the first of February 2010. There will be 7 weekly visits you will have to be able to do and all costs are covered by the company.

Species - Domestic horse

Age - No restriction

Gender - Male or female (reproductively intact or neutered)

Breed/class - Any equine breed

Initial weight - No restriction

Physiological state - Non-pregnant, non-lactating, diagnosed with osteoarthritis

The animal must meet *all* the following criteria to be eligible for enrollment:

- Conform to the required animal description (see section 9.2)
- Be manageable and cooperative with study procedures
- Have a lameness at minimum AAEP Grade 2, isolated to a joint (using peripheral nerve blocks and/or joint blocks if needed)
- Have joint swelling of the affected joint diagnosed at minimum Grade 1 using Joint Swelling Score **and/or** have joint flexion of the affected joint diagnosed at minimum Grade 1 using Joint Flexion Score
- Have confirmation of OA by radiographic or, in early cases of OA where radiographic changes may not have developed, other suitable diagnostic imaging (MRI, ultrasound, CT scan). Where diagnostic imaging other than radiographs is used, the diagnosis of osteoarthritis will be confirmed based on review of those images by a board certified radiologist.
- Have no history of: (a) treatment with nonsteroidal antiinflammatory drugs (NSAIDs) or analgesics (with the exception of those required for radiography as needed) within the seven days preceding the day -7 baseline visit; (b) treatment with polysulfated glycosaminoglycan agents (PSGAGs), corticosteroids, IRAP (Interleukin Receptor Antagonist Protein), hyaluronic acid, or joint supplement nutraceuticals within 28 days preceding the day -7 baseline visit; (c) shockwave therapy, acupuncture or acupressure within 28 days preceding the day -7 baseline visit
- Have no history of surgery (including arthroscopy) involving the affected joint within the three months preceding day 0.
- Have no clinical evidence of other untreated, uncontrolled illness that would confound the ability to assess effectiveness or safety of the investigational veterinary product
- Be in sufficiently good health based on medical history, physical examinations, and laboratory analyses to be considered a reasonable prospect for completing the study.