

# Targeting Trends

Reporting the latest news in Molecular Surgery



## SP-SAP Human Clinical Trial for Cancer Pain

### *An Anesthesiologist's Point of View*

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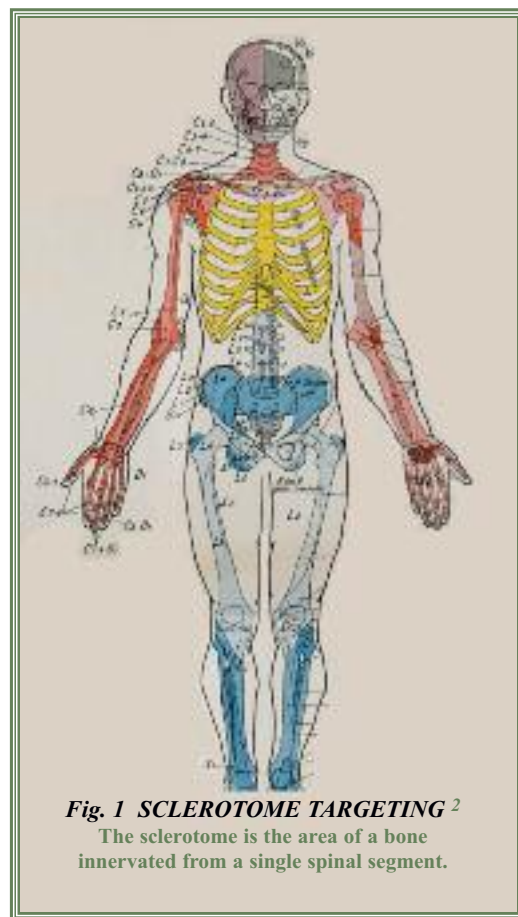
Intrathecal SP-SAP (Substance P attached to the ribosome-inactivating protein, saporin) has been studied in a Phase 1 clinical trial of patients with cancer pain at doses of 1, 2, 4, 8, 16 and 32 mcg. The first patient was treated April 10, 2014. Doses of 64 mcg and 90 mcg remain in Phase 1a of the clinical protocol. Phase 1b will treat multiple patients at the most effective dose. To date, no toxicity has been observed and the study is ongoing to evaluate response, safety, and tolerability. (For information about the trial, please visit: <http://clinicaltrials.gov/show/NCT02036281>).

SP-SAP is administered via an intrathecal catheter placed in the lumbar spine with the use of fluoroscopy and radiopaque contrast injection to ensure accurate delivery of the active drug. So far, the catheter placement has been at L5 vertebral level. The same location was used in the veterinary trial conducted by Dr. Dottie Brown in dogs with osteosarcoma.<sup>1</sup>

The lack of side effects or toxicity have led the clinical trial team to consider possible changes to the protocol that would enhance the effectiveness of SP-SAP in treating chronic pain. A primary endpoint of the trial is: response as defined by a 20% reduction in chronic pain or opioid dose within 4 weeks of treatment. One of the patients has clearly met this endpoint with reduction of pain medication by >20% during a 4-week period, following SP-SAP treatment.

Discussions are ongoing regarding several relevant issues that may affect efficiency of drug delivery and efficacy. 1) Modification of catheter placement may produce more selective responses and reduce required doses.

2) Targeting specific spinal segments using sclerotomes (Fig. 1) may be useful in delivering SP-SAP to a spinal cord location related to the pain origination. Cancer pain may be localized primarily to a bone; in these cases, using a sclerotomal map may help guide therapy to a specific nerve root and spinal cord location.



**Fig. 1 SCLEROTOME TARGETING<sup>2</sup>**

The sclerotome is the area of a bone innervated from a single spinal segment.

Denise Higgins, Editor



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