Hope for sufferers of post-amputation pain

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Chronic residual limb pain following amputation is a major problem for many patients, yet no effective pharmaceutical treatment is currently available. However, as a result of the very encouraging results of a Phase IIa study in amputated limb stump pain with a novel topical medication from SantoSolve, the company has just initiated recruitment in a 3 month multi-national, double-blind, placebo-controlled Phase III study in 150 patients suffering moderate-to-severe residual limb pain following amputation.

The Phase IIa trial with SantoSolve's development compound, 2PX, reported early in 2008 and showed that after 4 weeks administration, the treatment group experienced a reduction in average pain intensity of 47.7% compared to 21.8% for the placebo group. Corresponding reduction in worst pain intensity was 42.0% for 2PX compared with 17.8% for placebo. The results for other endpoints, including sleep disturbance, use of rescue medication, and quality of life were consistent with the results on pain intensity.

About SantoSolve
SantoSolve is a privately held Norwegian biopharmaceutical company, founded in 2002, and located in Oslo. The company is developing targeted pain therapeutics, based on a novel class of active ingredients. The company's technology is covered by a broad range of patents and patent applications, providing strong IPR protection.

About 2PX
2PX is a topical formulation containing non-radioactive strontium as the active ingredient. The compound is in development for the management of both nociceptive and neuropathic pain conditions. 2PX is based on a novel active substance and shows promising efficacy with a favourable safety profile. The company believes that 2PX will address an unmet need in the pain market which is currently estimated to have a value of approximately USD 30bn.

In addition to being studied in post-amputation pain, 2PX is also being documented in patients with osteoarthritis of the knee. During November 2008 SantoSolve successfully raised a further round of financing, to be used to fund a 6 month, multi-national, double-blind, placebo-controlled trial Phase III trial in 250 patients, which is expected to start during Q2 2009.

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