

## **SANTOSOLVE REPORTS POSITIVE PHASE II RESULTS IN PATIENTS WITH OSTEOARTHRITIS**

SantoSolve, a biopharmaceutical company focused on developing novel pain therapies today announced positive results from its Phase II study of 2PX, the company's topical analgesic, in patients with osteoarthritis (OA). The study, a multi-center, double-blind, placebo-controlled Phase II trial met its pre-specified primary endpoint: reduction in pain from baseline to study week 4 ( $p=0.038$ ). The study demonstrated a 35% reduction in pain from baseline after 4 weeks of twice-daily administration of 2PX, as compared to a 21% reduction in the control group.

The study evaluated 84 patients enrolled at study sites in Norway. The study was designed as a two-arm, 4 + 4 week cross-over trial. During the trial 2PX or placebo was self-administered twice daily with a proprietary applicator to the site of pain.

### **Overall conclusions**

- The reduction in OA-associated pain (as measured by WOMAC subscale for pain) was significantly larger with 2PX than placebo ( $p=0.0382$ ) after 4 weeks
- No statistically significant differences were found for other efficacy variables in the 4 weeks parallel group comparison, despite consistent uni-directional trends in favor of 2PX
- In the cross-over study phase, 2PX was significantly more efficacious than placebo for WOMAC pain, physical functioning and total scores, for pain relief and for pain intensity, and borderline more effective for WOMAC stiffness.
- The overall safety profile of 2PX was good, and comparable to placebo, except for erythema which occurred more often with 2PX.
- This study demonstrated clearly that the topical application of 2PX in patients with osteoarthritis pain enjoyed significantly reduced levels of pain and that the treatment was well tolerated. Thus, proof of concept for 2PX was obtained.

Dr. Stuart Ratcliffe, Coordinating Investigator, St Bartholomew's Hospital, London, commented "We are very encouraged by these clinical results, and believe that 2PX has the potential to provide an important and safer therapeutic alternative to traditional and COX-2 anti-inflammatory agents for patients suffering from pain associated with osteoarthritis in the knee – a chronic and progressive disease affecting more than 20 million individuals in the US alone".

In addition to being studied in osteoarthritis, 2PX use is also being explored in patients with other types of pain and further results are expected during 1Q 2008.

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About SantoSolve:

SantoSolve is a privately held Norwegian biotech 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 patent applications, providing strong IPR protection.

About 2PX:

2PX is a topical formulation of strontium for local pain treatment. It is based on a novel active substance and with a favourable safety profile and promising efficacy. In addition to the recently completed phase II trial in osteoarthritis, the product is also being developed for the treatment of neuropathic pain conditions. The company believes that 2PX has the potential to effectively address a significant gap in the USDbn 30 pain market.

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