

Additional data from SOLARIO study reveals further positive insights

BONESUPPORT™, a leading company in orthobiologics for the management of bone injuries, today announces additional information from the SOLARIO study presentation at the European Bone & Joint Infection Society (EBJIS) annual meeting in Barcelona last week, demonstrating the efficacy of local antibiotic treatment in reducing systemic antibiotic use.

"We are thrilled with the outcome of the SOLARIO study, which demonstrates how our innovative solutions can dramatically reduce the need for systemic antibiotics while maintaining excellent patient outcomes. This is a critical advancement in combating antimicrobial resistance while significantly reducing side effects," said Emil Billbäck, CEO of BONESUPPORT.

Professor Martin McNally, Nuffield Orthopaedic Centre, Oxford University Hospital, who originally designed the SOLARIO trial said "For years we have added longer systemic antimicrobial therapy to our treatment regimes with little evidence of any benefit. This study shows clearly how we can improve our use of antimicrobials, without loss of efficacy. We can help patients to have a better experience, with fewer side effects. Surgeons can safely deliver high doses of antibiotics directly to the infection site at surgery, avoiding problems with compliance or antimicrobial resistance. A shift from long systemic courses to short systemic and local therapy is potentially a major contribution to global antibiotic stewardship."

Key highlights from the SOLARIO study:

The group receiving a short course (max. 7 days) demonstrated a dramatically shorter systemic antibiotic usage over the one year follow up time, with a median duration of 5 calendar days on systemic antibiotics compared to 37 calendar days in the group with long-term antibiotic use (min four weeks). When considering that most patients were receiving two or more antibiotic drugs on each day, this resulted in a total reduction of 11,275 antibiotic days*. There was no difference in infection recurrence between the short arm and the long arm, highlighting the efficacy of local antibiotics in controlling infection while allowing systemic antibiotics to be stopped within seven days post-surgery resulting in substantially fewer adverse events.

In both the 6-week and 3-6 month follow-ups of the SOLARIO study, the group receiving a short course had significantly fewer adverse events compared to the group with long-term antibiotic use. After six weeks, 82.8% of patients in the short-course group had no adverse events, compared to 54.1% in the standard group, with severe adverse events being significantly lower (3.9% vs. 20.7%, $P < 0.0001$). By 3-6 months, 91.5% of the short-course group had no adverse events, compared to 79.6% in the standard group, and severe events remained lower (4.2% vs. 9.4%, $P < 0.049$).

With an average reduction of 47 antibiotic days* per patient, CERAMENT® G and CERAMENT® V, continue to offer effective solutions in the surgical management of bone infections, while significantly lowering the adverse effects associated with prolonged antibiotic

therapy. The results are poised to dramatically reshape clinical practices in managing bone infections and underscore the critical role local antibiotic eluting bone substitutes play in reducing systemic antibiotic use, a major victory for antimicrobial stewardship, patient safety, and well-being.

The SOLARIO study is a multi-centre, randomized controlled open-label non-inferiority trial involving 500 patients that investigates whether the duration of systemic antibiotic therapy can be reduced to less than 7 days when combined with the use of surgical treatment with local antibiotics. In 79% of the cases, bioresorbable products were used, of which 81% were CERAMENT G or CERAMENT V, equating to 64% of total procedures. Bone cement (PMMA) was used in 19% of the cases, primarily due to the specific needs of these patients (predominantly in patients with Prosthetic Joint Infections).

*Total antibiotic days – each antibiotic on each day reported separately – many of the antibiotics are prescribed in combination dosages.

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About BONESUPPORT™

BONESUPPORT (Nasdaq Stockholm: BONEX) develops and commercializes innovative injectable bio-ceramic bone graft substitutes that remodel to the patient's own bone and have the capability of eluting drugs. BONESUPPORT's bone graft substitutes are based on the patented technology platform **CERAMENT**. The company is conducting several clinical studies to further demonstrate the clinical and health economic benefits its products deliver. The company is based in Lund, Sweden, and the net sales amounted to SEK 591 million in 2023. Please visit www.bonesupport.com for more information.

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Attachments

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