24-month follow up data from the clinical study of OssDsign Catalyst® show 100% spinal fusion

Uppsala, April 9, 2025. OssDsign AB (publ.) today announces that the 24-month follow up results from the clinical study TOP FUSION will be published in the peer-reviewed journal, Biomedical Journal of Scientific & Technical Research. The results demonstrate a 100% spinal fusion rate and improved quality of life and pain after surgery with the innovative nanosynthetic bone graft OssDsign Catalyst.

The data, soon to be published in the peer-reviewed journal, Biomedical Journal of Scientific & Technical Research, demonstrates that using OssDsign Catalyst leads to consistent and rapid bone healing and remodeling, resulting in improved patient outcomes.

"In spine fusion surgery, the core clinical goal is to stabilize the spine and relieve pain, which requires bridging bone to be formed. The newly published peer-reviewed data, demonstrating 100% fusion rate and improved quality of life outcomes, validates OssDsign Catalyst's unique ability to form bridging bone consistently. These exceptional results not only strengthen our market position but reinforce OssDsign Catalyst's status as a true game-changer in spinal surgery," said Morten Henneveld, CEO of OssDsign.

The clinical study, TOP FUSION, included 17 patients suffering from degenerative disc disease, degenerative spondylolisthesis, or lumbar spinal stenosis to evaluate the safety and efficacy of OssDsign Catalyst in patients undergoing spinal Transforaminal Lumbar Interbody Fusion (TLIF) surgery.

Post-operative follow-up, including CT scans, occurred at 3, 6, 12, and 24 months to assess the presence of fusion. CTs were independently radiologically reviewed by Medical Metrics Inc. Three of the 17 patients recruited in TOP FUSION were withdrawn for reasons unrelated to OssDsign Catalyst. All the remaining patients (14) completed the follow-up 24 months after surgery. The post-operative follow-up showed that 4/14 (29%) of the patients were fused at 3 months, 9/14 (64%) at 6 months,13/14 (93%) at 12 months and 14/14 (100%) at 24 months. All scores used to quantify pain and function, including the Oswestry Disability Index (ODI), visual analog scale (VAS), and overall health in patients (SF-36), showed improvement in quality of life over time at all post-operative follow-up evaluations. No device-related Adverse Events (AEs) were observed during the study.

About OssDsign Catalyst
OssDsign Catalyst is a nanosynthetic bone graft that shows rapid and robust bone formation, even in poorly vascularized environments. OssDsign Catalyst’s patented nanocrystalline structure and incorporated silicon ions, which mimics the body’s natural bone, enable bone formation in the centre of the fusion mass. The result is a decreased non-union risk, making it highly applicable for both simple and complex patients.

About Top Fusion
The clinical study TOP FUSION (NCT05114135) is a first-in-patient open-label, prospective, single-center clinical study led by Dr. Péter Pál Varga and Dr. Àron Lazary at the National Center for Spinal Disorders at the Buda Health Clinic in Budapest, Hungary. The study's primary endpoint is assessed by the rate of bone fusion at 12 months by CT as well as the lack of device-related adverse events within the study period. TOP FUSION is a two-year study; a final follow-up was made at 24 months.

Reference: accepted data on file.

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Certified Adviser
The Company's Certified Adviser is Carnegie Investment Bank AB (publ)

About OssDsign
OssDsign is a developer and global provider of next generation orthobiologics products. Based on cutting edge material science, the company develops and markets products that support the body's own healing capabilities, giving patients back the life they deserve. The company has a strong presence in the U.S. market. OssDsign's share is traded on Nasdaq First North Growth Market in Stockholm, Sweden.