



12-month data from the clinical study of OssDsign Catalyst™ published in Biomedical Journal of Scientific & Technical Research

Uppsala, January 24, 2024. OssDsign AB (publ.) today announces that the previously communicated outstanding 12-month results from the clinical study TOP FUSION have been published in the peer-reviewed journal Biomedical Journal of Scientific & Technical Research. The results show a 93 % spinal fusion rate as well as improvements in quality of life and pain following surgery with the novel nanosynthetic bone graft OssDsign Catalyst.

"The publication of the outstanding clinical results in TOP FUSION is a crucial step in our process of establishing OssDsign Catalyst as a clinically proven synthetic bone graft. The favorable outcome of this first material clinical study paves the way for a strong position of OssDsign Catalyst in the U.S. market," said Morten Henneveld, CEO of OssDsign.

The data, published in the peer-reviewed journal Biomedical Journal of Scientific & Technical Research, clearly demonstrates that the use of OssDsign Catalyst leads to consistent and rapid bone healing and remodeling, with improved patient outcomes as a result.

High fusion rate and improved quality of life

The use of synthetic bone graft substitutes has become more common to avoid the need to source allograft or iliac crest autograft. A new nanosynthetic, silicate-enriched calcium phosphate bone graft substitute, OssDsign Catalyst, has been designed to deliver consistent and rapid bone healing and remodeling. The high level of substituted silicate (5.8%) in the porous granules combined with the nanoscale architecture is thought to promote early bone formation.

TOP FUSION includes 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 took place at 6 weeks, 3 months, 6 months and 12 months. CT scans were taken at 3, 6, and 12 months post-operatively to assess the presence of fusion. CTs were independently radiologically reviewed by Medical Metrics Inc.

Of the 17 patients recruited in TOP FUSION, three were withdrawn for reasons unrelated to Catalyst. All the remaining 14 patients completed the follow-up 12 months after surgery. The post-operative follow-ups showed that 4/14 (29%) of the patients were fused at 3 months, 9/14 (64%) at 6 months, and 13/14 (93%) at 12 months. The remaining patient has evidence of fusion progression so may be fused at the 24-month follow-up visit. All scores used to quantify pain and function including 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 stimulates the formation of healthy bone tissue in spinal fusion surgeries. The graft is composed of a proprietary nanocrystalline structure which is resorbed and replaced by new and healthy bone tissue in the body.

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, and a final follow-up will be made at 24 months.

<http://biomedres.us/pdfs/BJSTR.MS.ID.008571.pdf>

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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.