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First-in-patient case report of OssDsign Catalyst shows complete spinal fusion 6 months post-surgery

Uppsala, January 4, 2023. OssDsign AB (publ.) today announces that a first-in-patient case report from the clinical study TOP FUSION has been published in Biomedical Journal of Scientific & Technical Research. The peer-reviewed article presents data showing complete spinal fusion 6 months after surgery with the novel nanosynthetic bone graft OssDsign Catalyst.

Promising pre-clinical results from the BODEN model have translated into clinical success with early fusion and improvements in both pain and function outcomes.

In the case report, evidence of progression to fusion was observed at 3 months post-surgery, and complete spinal fusion achieved at 6 months. The results were assessed by independent radiologists from the imaging core lab Medical Metrics.

"Even though this is our first case report, we are very encouraged to see that the results from this case study are not only meeting but even surpassing our expectations for OssDsign Catalyst. The consistency between our preclinical data and the first in-patient results is an important checkpoint in the efforts to document the success of our unique synthetic bone graft, thereby paving way for continued rapid market uptake," says Morten Henneveld, CEO, OssDsign.

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) was initiated in September 2021 and include 17 patients suffering from degenerative disc disease, degenerative spondylolisthesis, or lumbar spinal stenosis. TOP FUSION will primarily evaluate the safety and efficacy of OssDsign Catalyst in patients undergoing spinal fusion surgery. The study's primary endpoints will be assessed by the rate of bone fusion at 12 months as well as the lack of device-related adverse events within the study period. The study is 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.

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About OssDsign

OssDsign is a developer and global provider of next generation bone replacement products. Based on cutting edge material science, the company develops and markets products that support the body's own healing capabilities and thereby improve the clinical outcome in a wide range of orthopedic areas with high medical needs. With a product portfolio consisting of patient-specific implants for cranial surgeries and an off-the-shelf synthetic bone graft for spine surgeries, OssDsign give back patients the life they deserve. The company has a strong commercial presence in the U.S., Europe and selected Asian countries. OssDsign's share is traded on Nasdaq First North Growth Market in Stockholm, Sweden.