OssDsign reports exceptional data from the clinical study TOP FUSION

Uppsala, January 9, 2024. OssDsign AB (publ.) today announces that positive data from the clinical study TOP FUSION has been submitted to a peer-reviewed scientific journal. Top-line results show a 93 % spinal fusion rate at 12 months as assessed with CT by independent radiological review from Medical Metrics Inc. after surgery with the novel nanosynthetic bone graft OssDsign Catalyst.

The data indicates that the use of OssDsign Catalyst leads to consistent and rapid bone healing and remodeling, with improved patient outcomes as a result. They also confirm the previously reported best-in-class pre-clinical results achieved in the most demanding preclinical model for spinal fusion – the BODEN model.

“I am very encouraged to see the solid consistency between the clinical results in TOP FUSION, the previously published first in-patient case report and our pre-clinical data. The successful outcome of this first important clinical study marks a pivotally important milestone for OssDsign Catalyst and will boost our efforts to establish our unique nanosynthetic bone graft on the U.S. market,” says Morten Henneveld, CEO of OssDsign.

TOP FUSION 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.

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 includes 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 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.

Morten Henneveld
CEO
+46 18 55 39 93
morten.henneveld@ossdsign.com