Post-market surveillance shows continued low complication rates with OssDsign Cranial PSI

Uppsala, December 2, 2021. OssDsign AB (publ.) today announces updated clinical data from a long-term follow-up of the company's innovative product OssDsign Cranial PSI, which is used in the treatment of cranial bone defects. The data, based on 1,480 surgeries, shows that the frequency of infections leading to implant removal was 1.6% after a median follow-up time of 22 months. This positive outcome exceeds what has been observed in previous follow-ups, thus highlighting the exceptional performance of OssDsign Cranial PSI.

OssDsign Cranial PSI is a patient-specific cranial implant made from 3D printed medical-grade titanium covered by a regenerative calcium phosphate composition. While the titanium skeleton reinforces the implant and resists physical and mechanical stress, the unique calcium phosphate composition provides healing and regenerative properties, allowing regrowth of the patient's own bone. Over time, the calcium phosphate composition degrades and is replaced with bone, leaving the patient with a well-integrated implant, potentially lasting a lifetime.
The results of the long-term follow-up show that complications in the form of infections leading to explantation of OssDsign Cranial PSI occurred in 1.6% of 1,480 surgeries (24) after a median follow-up time of 22 months (0–82 months). These positive results surpass those in the previous follow-up report, where the explantation rate was 1,9% in 1,055 patients (20) observed for a median time of 21 months. In earlier external studies, products available on the market have been shown to be associated with an infection complication rate of over 10% with a high rate of subsequent explantations. Furthermore, histological studies of explanted implants showed clear evidence of integration between the patient's own bone tissue in the skull and the implant already after 9 months. The analysis results are a testament to the regenerative capability of Cranial PSI and a confirmation of OssDsign's ability to develop innovative bone replacement products.
The data were collected as part of post-market surveillance in Europe, the U.S., and additional regulatory markets, in accordance with MEDDEV 2.7/1 rev. 4 and MDR 2017/745.
"The results from the long-term follow-up study of OssDsign Cranial PSI strengthen us in discussions with potential new partners and improve our position for further commercial growth. We are proud to continue delivering safe and effective products to patients in need of innovative solutions for skull defects," commented Morten Henneveld, CEO of OssDsign.

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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.