



OssDsign receives regulatory approval and prepares for launch in Japan

OssDsign AB (publ) today announced that the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) has granted approval of OssDsign Cranial PSI for the Japanese market. OssDsign plans to launch OssDsign Cranial PSI in Japan together with a national distribution partner immediately following formal reimbursement approval which is expected within the next two quarters.

As previously communicated, OssDsign has been pursuing a regulatory application in Japan since June 2019. The recent notice of regulatory approval from the PMDA is highly significant for OssDsign as the Japanese market for cranial reconstruction is the second largest among the OECD member countries, trailing only the USA.

Products used for cranioplasty are covered by the Japanese national reimbursement system. The exact level of reimbursement for OssDsign Cranial PSI will be negotiated over the next 1-2 quarters.

Following receipt of a reimbursement notice, OssDsign will launch OssDsign Cranial PSI in Japan utilizing a national distribution partner. Currently, discussions are ongoing with leading candidates that best fit OssDsign's defined go-to market strategy. The strategy has included a successful pre-launch phase during which leading Japanese neurosurgeons have been able to use OssDsign Cranial PSI clinically. This has resulted in valuable product awareness and positive clinical experiences that were presented at the 78th Annual Meeting of the Japan Neurosurgical Society held in Osaka in 2019. Anders Lundqvist, CEO of OssDsign says: *"We are extremely excited to pass this very significant milestone in the development and growth of OssDsign. It has been an intense process that has required a lot of resources but getting approval from the Japanese PMDA, with their stringent regulatory requirements, really shows that our material and product meet the highest standards.*

This approval means that we get access to one of the world's largest markets where our regenerative implant solution will have a unique position. Since the start of the approval process, we have actively built key opinion leader relationships within the Japanese neurosurgical community and the clinical experience so far has been excellent. So, it is with very high confidence that we enter the final stages of negotiations with a Japanese partner and continue the detailed preparations for a launch in Japan during the second half of 2020."

For further information, please contact:

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About OssDsign

OssDsign is a Swedish medical technology company that develops and manufactures regenerative implants for improved healing of bone defects. Providing neuro and plastic surgeons with innovative implants, OssDsign improves the outcome for patients with severe cranial and facial defects worldwide. By combining clinical knowledge with proprietary technology, OssDsign manufactures and sells a growing range of patient-specific solutions for treating cranial defects and facial reconstruction. OssDsign's technology is the result of collaboration between clinical researchers at Karolinska University Hospital in Stockholm and material scientists at the Ångström Laboratory at Uppsala University.

This information is information that OssDsign AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication through the agency of the contact person set out above, at 14:00 CET on March 30th, 2020