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OssDsign AB files regulatory approval for OssDsign Cranial in Japan

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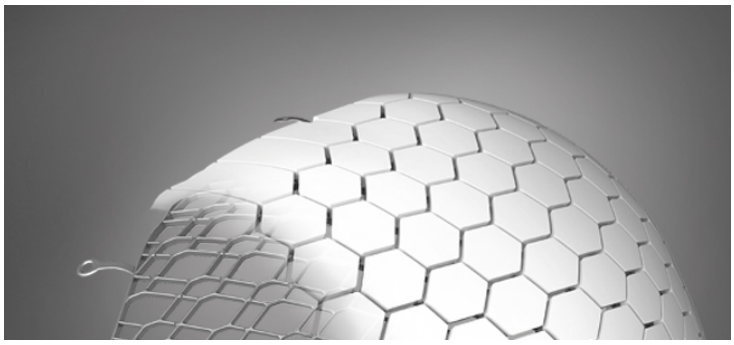

OssDsign AB (publ), the Swedish designer and manufacturer of innovative implants for bone regeneration, has filed for a Japanese regulatory approval of OssDsign Cranial. Subsequent to the filing, OssDsign initiates commercial planning for a market entry in Japan.

OssDsign has, as previously communicated, spent a significant amount of time and resources in order to compile a regulatory submission for Japan. This work has required further pre-clinical testing in order to comply with the stringent Japanese requirements. The complete file was submitted on June 28th and will now be reviewed by the Japanese Pharmaceutical and Medical Device Agency (PMDA). If granted approval, OssDsign Cranial will be the first product of its kind on the Japanese market, combining OssDsign's proprietary calcium phosphate composition with an internal titanium mesh reinforcement.

The Japanese market for cranioplasty implants is one of OssDsign's prioritized markets due to its value being second only to the US market. As communicated in the Company's prospectus, selected Japanese neurosurgeons have already gained experience from using OssDsign Cranial for cranial reconstructions. Surgeries to date have been performed under an ethical approval. OssDsign intends to build on these positive experiences when planning for a market introduction inJapan during 2020.