OssDsign's Cranioplug receives marketing approval in the US

STOCKHOLM - October 20, 2014. OssDsign AB today announced that its bioceramic burr hole plug – Cranioplug – has received 510(k) clearance by the US Food and Drug Administration (FDA). Karolinska Development has a 26 percent ownership in OssDsign.

In the 500,000 open brain surgeries carried out annually worldwide, burr holes and circular cuts between the burr holes are made to allow the surgeon to remove a piece of the skull - the bone flap - and thereby access the brain for the intended intervention. The bone flap is then re-anchored to the surrounding skull bone after the procedure is completed. Cranial fixation today uses metal-based devices that anchor the bone flap to the skull. These devices typically leave the burr hole open, to the cosmetic and psychological detriment of patients. Cranioplug, based on bone-like ceramic materials, in contrast to metal-based competitors, has the potential of integrating with surrounding bone.

"Through its innovative design, Cranioplug provides effective fixation as well as excellent cosmetic results. The clearance from the FDA demonstrates OssDsign can effectively navigate the FDA regulatory process and access the world's largest market. It enables us to continue our preparations for the upcoming launch of our innovative products in the United States", said Bo Qwarnström, CEO, OssDsign.

"Founded only three years ago, OssDsign has already been able to get their first product through the US regulatory process. This is a good example of how a management team with a proper blend of competent project management, commercial experience and regulatory knowledge can achieve significant value creation within a very short timeframe", said Bruno Lucidi, CEO, Karolinska Development.

Note: Karolinska Development's ownership of 26% includes indirect ownership through KCIF Co-Investment Fund KB.

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TO THE EDITORS

About OssDsign AB
The mission of OssDsign is advancing bone repair based on its innovative bioceramics technology platform. OssDsign has started sales in selected EU countries of lead product OssDsign® Craniomosaic, a next generation patient-specific implant for cranial repair. OssDsign was founded by researchers at the Karolinska University Hospital and Uppsala University and is located in Uppsala, Sweden. For more information, please visit www.ossdsign.com.

About Karolinska Development AB
Karolinska Development aims to create value for patients, researchers, investors and society by developing innovations from world class science into differentiated products that can be partnered. The business model is to: SELECT the most commercially attractive medical innovations that can potentially satisfy unmet medical needs; DEVELOP innovations to the stage where the greatest return on investment can be achieved; and COMMERCIALIZE the innovations through the sale of companies or out-licensing of products. An exclusive deal flow agreement with Karolinska Institutet Innovations AB, along with other cooperation agreements with leading universities, delivers a continuous flow of innovations. Today, the portfolio consists of 33 projects, of which 16 are in clinical development. For more information, please visit www.karolinskadevelopment.com.

Karolinska Development is listed on NASDAQ OMX (KDEV). Karolinska Development may be required to disclose the information provided herein pursuant to the Securities Markets Act.