Press release August 19, 2015

BrainCool AB (publ) announces a De Novo 510(k) process for the Cooral System.

FDA Meeting confirmed regulatory pathway for COORAL System

BrainCool announced today that, based on a recent meeting with the U.S. Food and Drug Administration ("FDA"), the Company have confirmed the route for market clearance in the US for Cooral System will be by way of a De Novo 510(k).

The Cooral System is an oral cooling medical device for prevention of Oral Mucositis, one of the most severe side effects of cancer treatment.

The Agency confirmed the De Novo 510(k) pathway. The De Novo process was introduced by FDA for instances where a device is novel and there is therefore no suitable predicate device to support a standard 510(k) submission. To qualify for the De Novo pathway, the new device must also present no more than moderate risk. Therefore, the Company plans to pursue a De Novo pathway based on the discussions with FDA.

Martin Waleij, Chief Executive Officer of BrainCool AB commented: "We are pleased with the outcome of our recent meeting with the FDA and the ongoing, open dialogue we have maintained with the Agency in the initial regulatory process.

Another clear feedback is that the current Swedish Clinical Trial of the COORAL SYSTEM will be of value to the process and could form the clinical evidence base for an approval however we will closely evaluate submitting an IDE for conducting clinical trials in the US since it might be beneficial both for the regulatory process and moreover being of strategic marketing value once the product is cleared for market approval."

For further questions please contact;

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This press release is submitted both in English and Swedish, in case of any discrepancies, the English version will apply.