Pressrelease 2016-04-11

BrainCool AB announces FDA grants Expedited Access Programme (EAP) for the Cooral System.

BrainCool announced today that, based on recent communication and presentation of the clinical development plan of BrainCool AB to the U.S. Food and Drug Administration ("FDA"), the Company has been granted and been selected as part of the FDA "The Expedited Access Pathway (EAP) and priority review for the product The Cooral System for prevention of the oral mucositis – a severe side effect of oncology treatment".

The product have in August 2015 been confirmed as the route for market clearance in the US for Cooral System by way of a De Novo 510(k).

The Agency has in August 2015 confirmed Cooral System for 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.

Martin Waleij, Chief Executive Officer of BrainCool AB commented:

Being selected for the EAP programme is of great importance to the company and the product which further underlies the great medical value of the product and is a very good signal to other markets and future potential partners and customers.

We continue with a our ongoing, open dialogue we have maintained with the Agency in the regulatory processes, for the US markets of our products, of the company.

EAP is a program is a program for certain medical devices that demonstrate the potential to address unmet medical needs for life threatening or irreversibly debilitating diseases or conditions that are subject to premarket approval applications (PMA) or are eligible for *de novo* requests.

Under EAP, the FDA will work with BrainCool AB to try to reduce the time and cost from development to marketing decision without changing, the standards for granting *de novo* requests, or the standard of valid scientific evidence. Components of the program include priority review, more interactive review, senior management involvement, and assignment of a case manager.

OM significantly affects the quality of life for cancer patients in terms of pain, ability to eat, swallow and talk. The symptoms are often of such severity resulting in requiring an interruption and curtailment of therapy. It can also lead to dose reduction of the cancer therapy or even treatment delays. In many cases these patients require hospitalization.

OM has a direct and significant effect on the duration of the disease remission and cure rates due to the dose limiting toxicity. Also in some cases it affects the survival because of the risk for infection and there is a significant impact on quality of life and cost of care. It is clear that the presence of OM is a major driver of health-care cost.

For the patented product, The Cooral System, it is yet another quality stamp that certifies the importance of this project not only as a QoL improving product but a matter of life and death product.

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.