



BrainCool AB (publ) - BrainCool provides an update on Medicare Coverage of Innovative Technology (MCIT) rule

Medicare Coverage of Innovative Technology (MCIT) rule is to provide a coverage pathway for medicare beneficiaries to access FDA-cleared or approved breakthrough devices during an initial four-year period after FDA clearance or approval.

Following a previously announced delay in the implementation of the final rule establishing the MCIT pathway, the Centers for Medicare & Medicaid Services (CMS) has now issued a proposal to repeal the final rule prior to implementation on December 15, 2021.

CMS states that it believes there are other ways to achieve the goal of providing innovation and access to important new technologies including future policies and potential rulemaking. CMS is now providing a public comment period of 30 days to allow stakeholders to provide input on the proposed repeal.

Independent of MCIT and the possible outcome, BrainCool has continued the dialogue with Medicare and private healthcare providers of the established clinical evidence for Cooral[®] System in order to enable a fast access for reimbursement for the product on the US market.

CEO Martin Waleij comments:

"The proposed repeal of the rule is a disappointing setback for the industry and medical device innovation in general. Given Cooral's clinical evidence and large healthcare costs derived from the unmet medical need of Oral Mucositis, however, we do not believe there will be a material impact on BrainCool's oncology business plan and we are confident of continuing success to secure a comprehensive government and private insurance reimbursement for the Cooral[®] System"

This disclosure contains information that BrainCool is obliged to make public pursuant to the EU Market Abuse Regulation (EU nr 596/2014). The information was submitted for publication, through the agency of the contact person, on 2021-09-14 22:06 CET.

For more information

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About BrainCool AB (publ)

BrainCool AB (publ) is an innovative medical device company that develops, markets, and sells leading medical cooling systems for indications and areas with significant medical benefits within the healthcare sector. The company focuses on two business segments, Brain Cooling and Oncology. BrainCool AB (publ) is based in Lund,

Sweden, and its share is listed on Spotlight Stock Market.