

# **MBQ Pharma announces the First-in-Human Dose of MBQ-167 for Advanced Breast Cancer in a Phase 1 Clinical Trial in Puerto Rico with the dual targeted Rac/Cdc42 inhibitor** <sup>[1]</sup>

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## **Calificación:**



No

## **CienciaPR Contribution:**

MBQ Pharma

## **Original Source:**



- MBQ-167 is a first-in-class small molecule and dual targeted inhibitor of over-expression of two proteins (Rac and Cdc42) that enable cancer metastasis and increased resistance to other anti-cancer agents.

- 90% of cancer-related deaths are related to cancer metastasis and MBQ-167 is being evaluated in this first human clinical trial to determine the best dose to evaluate this investigational drug in future studies to determine its safety and efficacy for reducing this terrible outcome.

SAN JUAN, PUERTO RICO, NOVEMBER 13, 2023 --

MBQ Pharma Inc., a pioneering clinical-stage biopharmaceutical company dedicated to advancing innovative treatments for solid tumor cancers, is thrilled to announce a significant milestone in its journey. We are proud to announce that we have dosed the first participant in our Phase 1 clinical trial of MBQ-167. MBQ-167 is the first-in-class drug as a dual inhibitor designed to target two GTPase proteins: Rac and Cdc42. Overexpression of these proteins in cancer cells are considered the primary drivers of solid tumor cancer spread and of cancer cells developing resistance to treatment. MBQ Pharma is extremely proud that MBQ-167 was discovered at the University of Puerto Rico by innovative scientists and that MBQ Pharma has successfully initiated this trial for patients who need additional options after all possible standard cancer therapies have been attempted. This exciting development marks a decisive step forward in the fight against Advanced Breast Cancer (ABC). MBQ Pharma is grateful to the volunteer participants and referring oncologists.

"We are thrilled to have provided this first dose to our first participant in this important study," said Dr.

José F. Rodríguez-Orengo, CEO of MBQ Pharma Inc. "We want to recognize and thank the patient volunteers who are suffering from this horrible disease, their family members and caregivers that support them. Additionally, I want to thank our team members and collaborators who have worked tirelessly to bring this innovative drug to eligible patients enduring a hard battle against ABC. We are committed to advancing MBQ-167 into the clinic with the hope of delivering a new safe and effective treatment option for patients with Advanced Breast Cancer who have failed all available standard of care therapies."

This Phase 1 clinical trial is an open-label, dose-escalation study aimed at establishing the maximum tolerated dose (MTD) of MBQ-167 in patients with ABC. MBQ-167 will be administered orally twice daily for a continuous period of 21 days. Eligible participants may continue to take MBQ-167 twice a day until stopping the drug due to disease progression or other reasons. The trial is being conducted by investigators at FDI Clinical Research in San Juan, PR. You can find further details about the

## Phase 1

trial of MBQ-167 and contact information for FDICR by visiting [ClinicalTrials.gov](https://clinicaltrials.gov) and using the identifier NCT06075810.

In November 2022, the Congressional Directed Medical Research Program (CDMRP) administered by the US Department of Defense awarded a breakthrough multimillion-dollar grant to MBQ Pharma to initiate the clinical phase of this promising product, aimed at improving patient care for participants with advanced cancer involving metastatic disease. The grant's support enables the rigorous testing and evaluation within this First-in-Human trial, bringing the innovative solution closer to becoming a reality for those in need.

## About MBQ-167

MBQ-167 represents a highly potent and selective small molecule inhibitor, specifically targeting GTPases Rac and Cdc42. We intend to demonstrate in this clinical trial that the inhibition of Rac and Cdc42 GTPases achieved by MBQ-167 can have a profound impact on cancer cells in humans by impeding the proliferation, migration, and invasion of these cells and effectively reducing or preventing their spread to other organs. Preclinical data have demonstrated that this inhibition not only curtails new metastasis but can also have a remarkable inhibition of tumor growth (90%). Notably, in participants with Advanced Breast Cancer (ABC) and in patients who suffer with many other common cancers such as Lung, Ovarian, Melanoma, Bladder and Pancreatic, the overexpression of Rac and Cdc42 in tumor cells is associated with elevated mortality rates, primarily due to an increased tendency for metastasis.

Additional preclinical investigations have showcased the remarkable effectiveness of MBQ-167, as it exhibited potent and highly selective inhibition of the proliferation of various breast cancer cell lines, encompassing both HER2+ and TNBC (Triple-Negative Breast Cancer) subtypes and in a Pancreatic cancer cell line. MBQ Pharma's extensive preclinical data reveal, not only the robustness of this inhibition, but also its capacity to deliver enduring antitumor effects with minimal associated toxicity. These findings underscore the promising potential of MBQ-167 as an alternative therapeutic option both as a single-agent and in combination therapy for a broad spectrum of breast cancer patients and

potentially many other highly metastatic cancer types.

### **About MBQ Pharma**

With this exciting news, MBQ Pharma achieves a fundamental step forward by becoming a clinical-stage biopharmaceutical company. We continue to be dedicated to advancing precision targeting strategies for GTPases in the context of cancer treatment and have now demonstrated that we can successfully take the monumental leap from pre-clinical (laboratory) investigations into clinical (human) investigations. The company's portfolio comprises of several small molecule drug candidates designed to selectively target specific signaling pathways, supported by robust scientific and clinical reasoning, with the overarching goal of enhancing outcomes for patients facing advanced disease who may benefit from novel treatments. At the forefront of MBQ Pharma's drug development efforts stands MBQ-167, an inhibitor of Rac and Cdc42 GTPases, currently being investigated in a clinical trial for recurrent or metastatic breast cancer. In the United States, where approximately 44,000 patients succumb to Advanced Breast Cancer each year, MBQ Pharma's work carries a profound sense of urgency and promise. To access further details about MBQ Pharma, please visit our website at [mbqpharma.com](http://mbqpharma.com).

### **About CDMRP/DOD**

The CDMRP fills research gaps by funding high impact, high risk and high gain projects that other agencies may not venture to fund. While individual programs are unique in their focus, all of the programs managed by the CDMRP share the common goal of advancing paradigm shifting research, solutions that will lead to cures or improvements in patient care, or breakthrough technologies and resources for clinical benefit. The CDMRP strives to transform health care for Service Members and the American public through innovative and impactful research.

### **Forward-Looking Statements**

This news release contains certain forward-looking statements that involve risks and uncertainties that could cause actual results to be materially different from historical results or from any future results expressed or implied by such forward-looking statements. Such forward-looking statements include statements regarding, among other things, the efficacy, safety, and the therapeutic potential of MBQ Pharma's product candidate MBQ-167, the progress and expected timing of MBQ Pharma's drug development programs and clinical trials. Factors that may cause actual results to differ materially include the risk that compounds that appeared promising in early research or clinical trials do not

demonstrate safety and/or efficacy in later preclinical studies or clinical trials, the risk that MBQ Pharma may not obtain approval to market its product candidates, uncertainties associated with performing clinical trials, regulatory filings and applications, risks associated with reliance on third parties to successfully conduct clinical trials, the risks associated with reliance on outside financing to

meet capital requirements, risks that the actual benefits of the clinical trial will not be as expected and

other risks associated with the process of discovering, developing, and commercializing drugs that are

safe and effective for use as human therapeutics, and in the endeavor of building a business around

such drugs. You are urged to consider statements that include the words, “may”, “will”, “promise”, “potential”, “designed”, “goal”, or the negative of those words or other comparable words to be uncertain and forward-looking. For a further list and description of the risks and uncertainties MBQ

Pharma faces, please refer to our website at [mbqpharma.com](http://mbqpharma.com). Such forward-looking statements are

current only as of the date they are made and MBQ Pharma assumes no obligation to update any forward-looking statements, whether because of new information, future events or otherwise.

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