

RESEARCH GOVERNANCE APPROVAL

Approved by the Institutional Review Board (IRB) on 12/22/2015 at 11:58 AM

Project Title: Phase II Study of Docetaxel and Celecoxib in Metastatic Breast Cancer

Principal Investigator: Dr. Robert Gray

Sponsor: Novartis

Site: Madison, WI

Protocol Number: 15-001

IRB Approval Number: 15-001

IRB Approval Date: 12/22/2015

IRB Approval Expires: 12/22/2017

IRB Approval Type: Initial

IRB Approval Category: Human Subjects Research

IRB Approval Sub-category: Phase II Clinical Trial

IRB Approval Sub-category: Interventional

IRB Approval Sub-category: Drug

IRB Approval Sub-category: Phase II Clinical Trial

IRB Approval Sub-category: Interventional

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IRB Approval Sub-category: Drug

IRB Approval Sub-category: Phase II Clinical Trial

IRB Approval Sub-category: Interventional

IRB Approval Sub-category: Drug

REGIONS, Abbreviations and Definitions

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CCCTO's remain in the sponsor's control and are not to be used for any other purpose without the sponsor's written approval.

Reporting Requirements

The sponsor must submit a copy of the report to the CCCTO within 30 days of the date of the report.

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Phase 1/2a

Phase 1/2a: Safety, efficacy, and toxicity of the combination of nivolumab and ipilimumab in patients with advanced melanoma.

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Phase 1/2b: Safety, efficacy, and toxicity of the combination of nivolumab and ipilimumab in patients with advanced melanoma. This study is a phase 1/2b study. The primary objective is to evaluate the safety and efficacy of the combination of nivolumab and ipilimumab in patients with advanced melanoma. The secondary objective is to evaluate the toxicity of the combination of nivolumab and ipilimumab in patients with advanced melanoma.

Phase 2: Safety, efficacy, and toxicity of the combination of nivolumab and ipilimumab in patients with advanced melanoma. This study is a phase 2 study. The primary objective is to evaluate the safety and efficacy of the combination of nivolumab and ipilimumab in patients with advanced melanoma. The secondary objective is to evaluate the toxicity of the combination of nivolumab and ipilimumab in patients with advanced melanoma.

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Phase 2: Safety, efficacy, and toxicity of the combination of nivolumab and ipilimumab in patients with advanced melanoma. This study is a phase 2 study. The primary objective is to evaluate the safety and efficacy of the combination of nivolumab and ipilimumab in patients with advanced melanoma. The secondary objective is to evaluate the toxicity of the combination of nivolumab and ipilimumab in patients with advanced melanoma.

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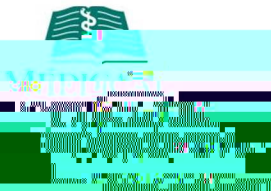
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Administrative Director

Administrative Director

Administrative Director

Administrative Director

eSignature Addendum

All eSignatures below were executed using Florence
21 CFR Part 11 compliant software for eSignatures

Current Electronic Signatures (v.10):

Signed electronically by:

Date: *11-Feb-2022 @ 04:07 PM CST*

Reason: *Approval*

Previous Electronic Signatures:

There are no signatures for any previous versions.