

Approval of Submission

Jennifer Wu

February 24, 2016

Jennifer.Wu@nyumc.org

Dear Jennifer Wu:

On 2/23/2016 9:00 AM , the IRB reviewed the submission below: All conditions for approval were met on 2/23/2016.

principal investigator	Jennifer Wu
email	Jennifer.Wu@nyumc.org
study number	i14-01758
study title	A PHASE 1B, PROOF OF MECHANISM, OPEN-LABEL STUDY OF RO7070179, A HYPOXIA-INDUCIBLE FACTOR 1A (HIF1A) mRNA ANTAGONIST IN ADULT SUBJECTS WITH HEPATOCELLULAR CARCINOMA (HCC)
performance period	2/23/2016 to 2/22/2017 inclusive. Before 2/22/2017 or within 30 days of study closure, whichever is earlier, you are to submit a continuing review with required explanations. You can submit a continuing review by navigating to the active study and clicking Create Modification / CR. If continuing review approval is not granted before the expiration date of 2/22/2017, approval of this study expires on that date.
location(s)	Bellevue Hospital (Bellevue), Clinical Cancer Center (NYUMC Locations), Tisch Hospital (NYUMC Locations)
sponsor(s)	Name: ROCHE GLOBAL DEVELOPMENT;
review type	Initial Study
board name	Board C
materials approved for use	<ul style="list-style-type: none"> • Clean Pregnant Partner ICF dtd 11/3/15, Category: Consent Form; • Clean Main ICF 2-18-16, Category: Consent Form; • Investigator Brochure May 2015, Category: Drug Attachment; • FDA 1572 dtd 9.30.pdf, Category: Drug Attachment; • NP29700 NYU Memo to clarify safety reporting 11 9 15.pdf, Category: IRB Protocol; • s14-01758 Protocol 6/3/2015, Category: IRB Protocol; • s14-01758 Memo regarding location of safety information in protocol, Category: IRB Protocol; • Pregnant_Partner_Card_Template_2014_09_08.pdf, Category: Recruitment Materials;

The current IRB Status of your study is: Approved. This study was reviewed by the NYU School of Medicine's Institutional Review Board (IRB). During the review of your study, the IRB specifically considered:

1. the risks and anticipated benefits (if any) to your subjects
2. the selection of subjects
3. the procedures for securing and documenting informed consent
4. the safety of your subjects
5. the privacy of your subjects and confidentiality of the data

Your study cannot commence until all ancillary review decisions are complete. In order to determine the state of all ancillary reviews please go the My Studies page of this study in Research Navigator. Ancillary review statuses will be found on the right side of the header section.

Please note; if your study includes a clinical trial agreement or budget you will need to ensure approval has been issued from My Agreements/CRMS and The Office of Clinical Trials before you proceed with any aspects of this study including the enrollment of human subjects.

Review Notes:

For NIH Grant funded research: the IRB has found the IRB approved protocol referenced above to be consistent with the NIH grant application.



February 24, 2016

Helen Panageas Director (Acting), Institutional Review Board OHRP #FWA00004952

Notes

- You must submit all changes to this study (e.g., protocol, recruitment materials, consent forms, etc.) via eSubmission to the IRB for review and approval prior to initiation of the change(s), except where necessary to eliminate apparent immediate hazards to the subject(s). Changes made to eliminate apparent immediate hazards to subjects must be reported to the IRB within 24 hours.
- You must report all adverse and/or unanticipated event(s) that occur during the course of this study to IRB via eSubmission in accordance with IRB Policy.
- Use only IRB-approved copies of your consent form(s), questionnaire(s), letter(s), advertisement(s), etc. in your study. Do not use expired consent forms.
- You must inform all research staff listed on this study of changes or adverse events that occur.
- IRB's approval is valid until the end date of the performance period indicated above. A reminder for renewal should be e-mailed to you from the IRB 90, 60 and 30 days before this study's approval is scheduled to expire. However, you are responsible for submitting all renewal materials at least eight weeks before expiration regardless of whether or not you receive a reminder notice.
- All IRB policy documents can be found on our website: <http://irb.med.nyu.edu/library>
- Prior to initiating an IRB-approved study, you must receive written approval from an authorized representative for each site where your study will take place. Key contacts are:
 - **Bellevue Hospital:** when Bellevue Hospital is listed as a site where your study can take place, please note that you may have to complete additional work in BHC's Reason system. Bellevue will be contacting you with any additional needed information. For questions on Bellevue Hospital research, please contact BellevueResearch@bellevue.nychhc.org
 - CTSI - Clinical and Translational Science Institute, NYU School of Medicine [formerly General Clinical Research Center (GCRC)], ctsi@nyumc.org.
 - NYU Langone Medical Center (Tisch Hospital/Rusk Institute/Co-op Care/HJD/Perlmutter Cancer Center) site approval is handled for you automatically (as needed) by the Office of Clinical Trials
- The IRB may terminate studies that are not in compliance with NYU Langone Medical Center/School of Medicine Policies & Procedures and the requirements of the Institution's Federal Wide Assurance with the Federal Government. Direct IRB questions, correspondence and forms (e.g., continuing reviews, amendments, adverse events, etc.) to 212-263-4110 or IRB-INFO@nyumc.org.
- Prior to initiating an IRB-approved study, you must receive written approval from an authorized representative of the Office of Clinical Trials. You may contact the Office of Clinical Trials at 212.263.4210 or clinicaltrials@nyumc.org.

NYU SoM IRB operates in accordance with Good Clinical Practices (GCP) and applicable laws and regulations. The NYU SoM IRB Federal Wide Assurance number is 00004952.