



Date: May 30, 2016

Prof. Ibrahim Al Janahi
Executive Director of Research
Medical Research Center
Hamad Medical Corporation

Dear Prof. Al Janahi,

This letter is in reference to the HMC's submission of the clinical trial titled "A Phase III Randomized, Open-Label, Multi-Center, Global Study of MEDI4736 in Combination with Tremelimumab Therapy Versus Standard of Care Platinum-Based Chemotherapy in First Line Treatment of Patients with Advanced or Metastatic Non Small-Cell Lung Cancer (NSCLC)" / NEPTUNE study. We acknowledge receipt of your submission dated May 2, 2016. We have completed our review of the below submitted documents

Research proposal	Reviewed Document
16092/16	<ol style="list-style-type: none">1. 16092_CaseReportForm_V4_02Jul15_50Pages2. 16092_EuropeLabManual_V1_24Aug15_94Pages3. 16092_InformedConsent_Ara_V1_15Nov15_16Pages4. 16092_InformedConsent_Eng_V1_15Nov15_17Pages5. 16092_InformedConsentAddendum1_Ara_V1_15Nov15_03Pages6. 16092_InformedConsentAddendum1_Eng_V1_15Nov15_03Pages7. 16092_InformedConsentAddendum2_Ara_V1_15Nov15_06Pages8. 16092_InformedConsentAddendum2_Eng_V1_15Nov15_05Pages9. 16092_InformedConsentAddendum3_Ara_V1_15Nov15_04Pages10. 16092_InformedConsentAddendum3_Eng_V1_15Nov15_04Pages11. 16092_InformedConsentAddendum4_Ara_V1_15Nov15_02Pages12. 16092_InformedConsentAddendum4_Eng_V1_15Nov15_02Pages13. 16092_InformedConsentAddendum5_Ara_V1_15Nov15_02Pages14. 16092_InformedConsentAddendum5_Eng_V1_15Nov15_02Pages15. 16092_InformedConsentAddendum6_Ara_V1_15Nov15_02Pages16. 16092_InformedConsentAddendum6_Eng_V1_15Nov15_02Pages17. 16092_InformedConsentPregantPartners_Ara_V1_15Nov15_06Pages18. 16092_InformedConsentPregantPartners_Eng_V1_15Nov15_06Pages19. 16092_InitialApplication_25Nov15_06Pages20. 16092_InvestigatorBrochure_V5_21May15_161Pages21. 16092_InvestigatorBrochure_V8_01Sep15_251Pages22. 16092_NewSafetyInformation_30Sep15_08Pages23. 16092_PathologistManual_V1_14Aug15_17Pages24. 16092_PatientParticipationCard_Ara_V1_05Jun15_01Page25. 16092_PatientParticipationCard_Eng_V1_05Jun15_01Page



Research proposal	Reviewed Document
16092/16	26. 16092_PatientVisitScheduleReminder_Ara_V1_31Aug15_02Pages 27. 16092_PatientVisitScheduleReminder_Eng_V1_31Aug15_02Pages 28. 16092_protocol_V2_28Aug15_175Pages 29. 16092_PatientThankYouCard_Ara_28May15_02Pages 30. 16092_PatientThankYouCard_Eng_09Sep15_02Pages

Along with HMC-IRB's approval of the study, we concluded that adequate information has been presented to protect the safety and wellbeing of participated subjects. Accordingly, this application is approved effective on the date of this letter.

Sincerely yours,

For 
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Dr. Eman Sadoun
Manager, Human Research
Ministry of Public Health