



King Hussein Cancer Center

مركز الحسين للسرطان

Institutional Review Board

اللجنة المؤسسية

Dear Dr. Hikmat Abdel Razeq,

In reference to the proposal entitled: **“A Phase III, Randomized, Open-label Study Evaluating The Efficacy And Safety Of Giredestrant In Combination With Phesgo Versus Phesgo After Induction Therapy With Phesgo+taxane In Patients With Previously Untreated Her2 Positive, Estrogen Receptor-positive Locally-advanced Or Metastatic Breast Cancer”** Proposal No. 23 KHCC 60.

You are kindly informed that the IRB has reviewed and approved the following document(s):

1. Research Application Form
2. WO43571 Protocol Version 3 dated 18-Nov-2022
3. PHESGO Investigator Brochure Version 5, dated September 2022
4. GIREDESTRANT Investigator Brochure version 6 dated May-2022
5. GIREDESTRANT Investigator Brochure version 6 Addendum 1, dated November 2022
6. SmPC PHESGO
7. WO43571 Unique eCRF dated 10-Mar-2023
8. WO43571, Site: 357841 ICF, English Ver. 1.0, dated 25-Apr-2023
9. WO43571, Site: 357841 ICF, Arabic Ver. 1.1, dated 15-Jun-2023
10. WO43571, JOR Pregnant Partner Authorization Form, English Ver. 1.0, dated 15-Apr-2023
11. WO43571, JOR Pregnant Partner Authorization Form, Arabic Ver. 1.1, dated 15-Jun-2023
12. WO43571, JOR Infant Authorization Form, English Ver. 1.0, dated 15-Apr-2023
13. WO43571, JOR Infant Authorization Form, Arabic Ver. 1.1, dated 15-Jun-2023
14. WO43571 Patient Diary V2.0\_13-Apr-2022\_Giredestrant capsule
15. WO43571, Master Patient Diary, Arabic Ver. 1.0, dated 13-April-2023
16. WO43571 Patient Participation Card Ver 1.0, dated 26-Jan-2022
17. WO43571 Master Patient Participation Card, Arabic Ver 1.0, dated 13 April 2023
18. BRIEF PAIN INVENTORY (BPI-SF) - English dated 1991
19. BRIEF PAIN INVENTORY (BPI-SF) - Arabic
20. EORTC QLQ – BR23 English ver 1.0 dated 1994
21. EORTC QLQ – BR23 Arabic ver 1.0 dated 1994
22. EORTC QLQ – C30 English ver 3.0 dated 1995
23. EORTC QLQ – C30 Arabic ver 3.0 dated 1995
24. EQ-5D-5L English ver 1.1 dated 2009
25. EQ-5D-5L Arabic dated 2013

The IRB consists of members of medical and non medical background including public, lawyers, nurses and pharmacists. It is the policy of the IRB to conduct random audits on a percentage of approved projects. These audits may be conducted at any time after the project starts. In cases where the IRB considers that there may be a risk of adverse events, or where participants may be especially vulnerable, the IRB may request the principal investigator to provide an outcomes report, including information on follow up of participants. KHCC-IRB is approved by JFDA and is compliant with GCP Guidelines and national Clinical Research Law (2011).

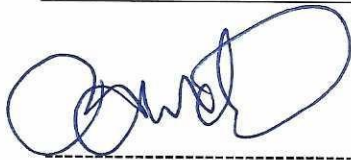
26. GP5 English Ver 4 16 November 2007
27. GP5 Arabic Ver 4 19 June 2013
28. PRO-CTCAE English ver 1.0 dated 11-Jan-2022
29. PRO-CTCAE Arabic ver 1.0 dated 09-Mar-2023
30. WPAI-GH – English
31. WPAI-GH Arabic Ver 2
32. WO43571, Master Cover page of PRO questionnaires booklet (cycles 54, 72 and 90), Arabic Version 1.0, dated 13 April 2023 & Master WO43571 Cover Page, English Version for UK
33. WO43571, Master Cover page of PRO questionnaires booklet (cycles 6, 12, 24 and 30), Arabic Version 1.0, dated 13 April 2023 & Master WO43571 Cover Page, English Version for UK
34. WO43571, Master Cover page of PRO questionnaires booklet (cycles 3, 9, 15, 39, 48, 57, 66, 75 and 84), Arabic Version 1.0, dated 13 April 2023 & Master WO43571 Cover Page, English Version for UK
35. WO43571, Master Cover page of PRO questionnaires booklet (cycles 1, 2, 3, 4, 5), Arabic Version 1.0, dated 13 April 2023 & Master WO43571 Cover Page, English Version for UK
36. WO43571, Master Cover page of PRO questionnaires booklet (cycles 1, 18, 36, and treatment discontinuation), Arabic Version 1.0, dated 13 April 2023 & Master WO43571 Cover Page, English Version for UK
37. WO43571, Master Cover page of PRO questionnaires booklet (cycles 2, 4, 5), Arabic Version 1.0, dated 13 April 2023 & Master WO43571 Cover Page, English Version for UK
38. WO43571 Jordan Insurance Certificate & insurance Policy

Kindly note that this proposal was approved by convened IRB review.

Kindly note if the study extends beyond one year you have to submit a **Renewal of Research Approval Form** and an interim update on the study. For any modifications on the approved proposal please complete the **Amendment to Approved Research Form**. At the end of the study, you are requested to complete **Study Closure/Termination Form** and submit to the IRB.

Please inform the IRB office of any publications/ abstracts that may result from this research.

On behalf of KHCC IRB, I would like to wish you a successful study.



**Dr. Rawad Rihani**

Deputy Chair, Institutional Review Board  
King Hussein Cancer Center



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