Neo-tAnGo Eligibility Form

Trial no.: ☐☐☐☐

Patient's initials: ☐☐ *Give FIRST and SURNAME initials only*

Date of birth: ☐☐ ☐☐☐ ☐☐☐☐ *dd mon yyyy*

Hospital no.: ☐☐☐☐☐☐☐☐☐☐

Hospital: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

ELIGIBILITY CHECKLIST

All *'Yes'* boxes must be ticked for patient to be eligible.

	No	Yes
• Histological diagnosis of invasive breast carcinoma	☐	☐
• T2 tumour or above (tumour size > 20 mm), or T4 tumour of any size (inc. inflammatory disease)	☐	☐
• Definite indication for neo-adjuvant chemotherapy	☐	☐
• Patient is fit to receive treatment according to any of the study arms	☐	☐
• Adequate bone marrow, hepatic, renal, and cardiac function *(refer to recommendations below)*	☐	☐
• No evidence of metastatic disease	☐	☐
• No previous chemotherapy or radiotherapy	☐	☐
• No previous malignancy except basal cell carcinoma, cervical carcinoma *in situ* or DCIS	☐	☐
• Non-pregnant, non-lactating, and no risk of pregnancy during chemotherapy	☐	☐
• No concomitant medical or social problems likely to impede follow-up	☐	☐
• Patient has given written informed consent	☐	☐
• ECOG performance status is 0, 1, or 2	☐	☐
• Randomisation date is within **4 weeks** of diagnostic biopsy date	☐	☐
• Chemotherapy start date is within **4 weeks** of diagnostic biopsy date	☐	☐

Recommendations: *Hb > 9 g/dL; WBC > 3 × 10^9/L; platelets > 100 x 10^9/L*
No active, uncontrolled infection
Creatinine ≤ 1.5 x ULN
Bilirubin within normal range
Alkaline phosphatase ≤ 2 x ULN
AST/ALT ≤ 2 x ULN

SCREENING INVESTIGATIONS

Does the patient have: ALT/AST or alkaline phosphatase >2 × ULN: .....No ☐ Yes ☐

If '*Yes'* to the above: Liver ultrasound scan and/or whole body bone scintigraphy **must** be carried out accordingly on these patients, and results obtained prior to randomisation. Scan results **will** be verified at randomisation.

Does the patient have: clinical involvement of axillary nodes: .....No ☐ Yes ☐
inflammatory or locally advanced disease: .....No ☐ Yes ☐
an abnormal full blood count*.....No ☐ Yes ☐

*Hb ≤10 g/dL; WBC ≤3 x 10^9/L; platelets ≤150 x 10^9/L

If '*Yes'* to any of the above: **(i)** If ALT/AST and/or alkaline phosphatase **>**2 × ULN liver ultrasound scan and/or whole body bone scintigraphy **must** be carried out accordingly, and results obtained prior to randomisation. This **will** be verified at randomisation. **(ii)** Regardless of ALT/AST and alkaline phosphatase levels, liver ultrasound scan **and** whole body bone scintigraphy **must** be carried out on these patients. However, scan results in this case are not required prior to randomisation.

Please confirm results and dates of screening investigations below: *dd mon yyyy*

ALT/AST	≤2 × ULN ☐	>2 × ULN ☐	Date:	☐☐ ☐☐☐ ☐☐☐☐
alkaline phosphatase:	≤2 × ULN ☐	>2 × ULN ☐	Date:	☐☐ ☐☐☐ ☐☐☐☐
liver scan:	Clear ☐	Abnormal ☐	Date:	☐☐ ☐☐☐ ☐☐☐☐
bone scan:	Clear ☐	Abnormal ☐	Date:	☐☐ ☐☐☐ ☐☐☐☐

Comments: _____

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Signed:(by Randomising Investigator) _____ **Date:** ☐☐ ☐☐☐ ☐☐☐☐ *dd mon yyyy*

On completion, please send the top copy of this form to the trials office AS SOON AS POSSIBLE.
If awaiting scan results please retain form until all results are confirmed.