TaiNAC Study

Case Report Form

Center Number |__|__|

Subject Initial |__|__|__|

I-Code I|__|__|__|__|__|__|

ELIGIBILITY CHECKLIST

Screening No.：☐☐☐☐☐
I-Code：I ☐☐☐☐☐ Initial：☐☐☐

The patient must fulfill all of the following criteria：

Yes	No	
☐	☐	1) Histologically confirmed invasive breast carcinoma with documented Her2/neu negative, including score 0, 1+, or 2+ by IHC.
☐	☐	2) Clinical stage should be T2-4, N0-3, and M0; and tumor size >3 cm measured by estimated by CT scan or MRI
☐	☐	3) No prior therapy for breast cancer.
☐	☐	4) Performance status of ECOG 0 or 1.
☐	☐	5) Female with age older than 20 years of age.
☐	☐	6) ANC $\geqq$1500/mm^3, T-Bil $\leqq$2.0 times the upper limit of normal (ULM), AST or ALT $\leqq$2.5 times the ULM, platelets $\geqq$100,000/mm^3, serum creatinine $\leqq$1.5 x ULM and fasting serum triglyceride $\geqq$ 70 mg/dL.
☐	☐	7) Disease free of prior malignancy for $\geqq$5 years
☐	☐	8) Women of childbearing potential (WOCBP) have negative serum or urine pregnancy test within 7 days before the first dose of chemotherapy
☐	☐	9) Ability to understand and sign a written informed consent document

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The patient fulfill any of the following criteria will be **Excluded** from the trial：

Yes	No	
☐	☐	1) Evidence of breast cancer metastatic other than axillary lymph nodes or inflammatory breast cancer or bilateral breast cancer
☐	☐	2) Inadequate biopsy specimen for IHC study
☐	☐	3) Known allergy to any of the study drugs or agents containing Cremophor
☐	☐	4) Serious intercurrent infections or medical illnesses
☐	☐	5) Psychiatric disorders or other conditions regarding the subject incapable of complying with the requirements of the protocol
☐	☐	6) Evidence of baseline sensory or motor neuropathy
☐	☐	7) Other concurrent anti-tumor, chemotherapy, hormonal therapy, immunotherapy regimens or radiation therapy
☐	☐	8) Women who are currently pregnant or breast feeding
☐	☐	9) WOCBP who are unwilling or unable to use an acceptable method to avoid pregnancy

Is the patient eligible for enrollment? ☐Yes ☐No

Investigator：_____ Date：_____

On Study Form—Baseline

Screening No.：□□□□□
I-Code：I □□□□□ Initial：□□□

Date of signing informed consent：□□/□□/20□□(mm/dd/yyyy)
Brief history：_____
_____

On Study Condition

Date of birth：□□/□□/19□□(mm/dd/yyyy)
Date of tumor biopsy：□□/□□/□□□□；Pathology No.：_____
The lesion(s) is/are located in □Right side □Left side
Date of diagnosis breast carcinoma：□□/□□/□□□□
• Clinical T□ N□ M0
• Clinical □StageⅡ □StageⅢ
• Tumor grade：□Ⅰ □Ⅱ □Ⅲ
Histological type：
□Infiltrative ductal Ca. □Lobular Ca.
□Other, specify: _____
ER □+ □−；PR □+ □−；Her2/neu □0 □1+ □2+
PS of ECOG：□0 □1
Body Weight：□□□.□kg Body Height：□□□.□cm

Lab data

Date of blood sampling：□□/□□/20□□ (within 7 days to the 1st dosing date)
Menopause?
□Yes, the last menses cycle in □□/□□□□(mm/yyyy)
□No, urine or serum β-HCG：□Positive □Negative on □□/□□/20□□

Item	Result	Unit	Item	Result	Unit	Item	Result	Unit
WBC		/μL	GOT		U/L	Na		mmol/L
PLT		K/μL	GPT		U/L	K		mmol/L
Hb		g/dL	ALP		U/L	Ca		mmol/L
ANC		/μL	LDH		U/L	AC Sugar		mg/dL
Alb		g/dL	BUN		mg/dL	TG		mg/dL
Globulin		g/dL	Cre		mg/dL			
T-Bil		U/L	UA		mg/dL			

Investigator：_____ Date：_____

On Study Form—Baseline

Screening No.：☐☐☐☐☐
I-Code：I ☐☐☐☐☐ Initial：☐☐☐

Please attach the copy of subject's **Pathology Report** below：

Pathology Report

***Note：Please remove or conceal the name/ID of the subject.**

Remarks

On Study Form—Baseline

Screening No.：☐☐☐☐☐
I-Code：I ☐☐☐☐☐ Initial：☐☐☐

Tumor Assessment

Date of assessment：☐☐/☐☐/20☐☐ (mm/dd/yyyy)
Method of image：☐CT scan ☐MRI ☐Breast echo

Target Lesion (up to a maximum of five lesions)

	Site	Measurement
L1	☐Primary tumor ☐Axillary lymph node	☐☐.☐ cm
L2	☐Primary tumor ☐Axillary lymph node	☐☐.☐ cm
L3	☐Primary tumor ☐Axillary lymph node	☐☐.☐ cm
L4	☐Primary tumor ☐Axillary lymph node	☐☐.☐ cm
L5	☐Primary tumor ☐Axillary lymph node	☐☐.☐ cm
Sum of the longest diameter (LD)		☐☐.☐ cm

Please sketch or describe the location of L1~L5 here：

Investigator：_____ Date：_____

On Study Form—Randomization

I-Code：I ☐☐☐☐☐ Initial：☐☐☐

Date of randomization：☐☐/☐☐/20☐☐(mm/dd/yyyy)

Randomized group：

☐Arm A：Docetaxel / Epirubicin

☐Arm B：Tailored Regimen, please tick the assigned regimen below according to the IHC result (in Arm B subject only)：

- Topo-II：☐+ ☐−
- Tau score：☐0 ☐1 ☐2 ☐3
- ERCC1 score：☐0 ☐1 ☐2 ☐3

Regimen & Schedule		
☐ **TE**	Epirubicin 45 mg/m^2 on day 1 & day 8 Docetaxel 35mg/m^2 on day 1 & day 8 Lenograstim (G-CSF) 1 vail (100μg/vial) s.c. on day 10 & day 11	Cycled every **21 days**
☐ **E-HDFL**	Epirubicin 45 mg/m^2 on day 1 & day 8 5-FU 2000 mg/m^2 and Leucovorin 300 mg/m^2 24hrs ifusion Lenograstim (G-CSF) 1 vail (100μg/vial) s.c. on day 10 & day 11	
☐ **EP**	Epirubicin 45 mg/m^2 on day 1 & day 8 Cisplatin 35 mg/m^2 on day 1 and day 8 Lenograstim (G-CSF) 1 vail (100μg/vial) s.c. on day 10 & day 11	
☐ **N-HDFL**	Vinorelbine 25 mg/m^2 on day 1 & day 8 5-FU 2000 mg/m^2 and Leucovorin 300 mg/m^2 24hrs ifusion on day1 & day 8 Lenograstim (G-CSF) 1 vail (100μg/vial) s.c. on day 10 & day 11	
☐ **NP**	Vinorelbine 25 mg/m^2 on day 1 & day 8 Cisplatin 35 mg/m^2 on day 1 & day 8 Lenograstim (G-CSF) 1 vail (100μg/vial) s.c. on day 10 & day 11	
☐ **T-HDFL**	Docetaxel 35 mg/m^2 on day 1 & day 8 5-FU 2000 mg/m^2 and Leucovorin 300 mg/m^2 24hrs ifusion on day1 &day 8 Lenograstim (G-CSF) 1 vail (100μg/vial) s.c. on day 10 & day 11	
☐ **TP**	Docetaxel 35 mg/m^2 on day 1 & day 8 Cisplatin 35 mg/m^2 on day 1 & day 8 Lenograstim (G-CSF) 1 vail (100μg/vial) s.c. on day 10 & day 11	

Investigator：_____ Date：_____

On Study Form—Evaluation

I-Code：I □□□□□ Initial：□□□

Cycle ___

PS of ECOG：□0 □1 □2

BW：□□□.□kg BSA：□.□□m^2

BT：□□.□℃ HR / RR：□□□ / □□ times/min

Drug Administration

Day 1 on □□/□□/20□□(mm/dd/yyyy)	**Day 8 on** □□/□□/20□□(mm/dd/yyyy)
□5-FU _____ mg/m^2	□5-FU _____ mg/m^2
□Leucovorin _____ mg/m^2	□Leucovorin _____ mg/m^2
□Docetaxel _____ mg/m^2	□Docetaxel _____ mg/m^2
□Cisplatin _____ mg/m^2	□Cisplatin _____ mg/m^2
□Epirubucin _____mg/m^2	□Epirubucin _____mg/m^2
□Vinorelbine _____ mg/m^2	□Vinorelbine _____ mg/m^2

□Lenograstim (G-CSF) _____ μg/day for _____days in this cycle

Adverse Event

Is protocol treatment discontinued? □No □Yes	Is protocol treatment discontinued? □No □Yes
Is any adverse event noted? □No □Yes	Is any adverse event noted? □No □Yes
Is any dose reduction occurred? □No □Yes	Is any dose reduction occurred? □No □Yes
Is any dose delay occurred? □No □Yes	Is any dose delay occurred? □No □Yes

Please record the **worst grade of AE** during this cycle according to CTC-AE v3.0

Leukocyte		Hand-foot skin reaction		Skin	
Neutrophil		Alopecia		Hypersensitivity	
Hemoglobin		Nausea/Vomiting		Ototoxicity	
Platelet		Neurotoxicity		Nail change	
Infection		Cardiac			
Fever		Liver function			
Stomatitis		Respiratory			
Diarrhea		Nephrotocixity			

On Study Form—Evaluation

I-Code：I □□□□□ Initial：□□□

Physical Examination

Cycle ___ Date of PE：□□/□□/20□□(mm/dd/yyyy)

Item	Normal	Abnormal	Specify Abnormalities
HEENT	□	□	
Cardiovascular	□	□	
Respiratory	□	□	
Gastrointestinal	□	□	
Neurological	□	□	
Skeletal-muscular	□	□	
Others, specify_____	□	□	

Laboratory Data

Hematology

Date：□□/□□/20□□			Date：□□/□□/20□□			Date：□□/□□/20□□		
WBC		/μL	WBC		/μL	WBC		/μL
PLT		K/μL	PLT		K/μL	PLT		K/μL
Hb		g/dL	Hb		g/dL	Hb		g/dL
ANC		/μL	ANC		/μL	ANC		/μL

Date：□□/□□/20□□			Date：□□/□□/20□□			Date：□□/□□/20□□		
WBC		/μL	WBC		/μL	WBC		/μL
PLT		K/μL	PLT		K/μL	PLT		K/μL
Hb		g/dL	Hb		g/dL	Hb		g/dL
ANC		/μL	ANC		/μL	ANC		/μL

Chemistry

Date：□□/□□/20□□						Date：□□/□□/20□□					
Alb		g/dL	Cre		mg/dL	Alb		g/dL	Cre		mg/dL
Globulin		g/dL	UA		mg/dL	Globulin		g/dL	UA		mg/dL
T-Bil		U/L	Na		mmol/L	T-Bil		U/L	Na		mmol/L
GOT		U/L	K		mmol/L	GOT		U/L	K		mmol/L
GPT		U/L	Ca		mmol/L	GPT		U/L	Ca		mmol/L
ALP		U/L	AC Sugar		mg/dL	ALP		U/L	AC Sugar		mg/dL
LDH		U/L				LDH		U/L			
BUN		mg/dL				BUN		mg/dL			

On Study Form—Evaluation

I-Code：I ☐☐☐☐☐ Initial：☐☐☐

Tumor Assessment

Date of assessment：☐☐/☐☐/20☐☐(mm/dd/yyyy)
Method of image：☐CT scan ☐MRI ☐Breast echo

Target Lesion (up to a maximum of five lesions)

	Site	Measurement
L1	☐Primary tumor ☐Axillary lymph node	☐☐.☐ cm
L2	☐Primary tumor ☐Axillary lymph node	☐☐.☐ cm
L3	☐Primary tumor ☐Axillary lymph node	☐☐.☐ cm
L4	☐Primary tumor ☐Axillary lymph node	☐☐.☐ cm
L5	☐Primary tumor ☐Axillary lymph node	☐☐.☐ cm
Sum of the longest diameter (LD)		☐☐.☐ cm

Clinical Response

☐PD ☐SD ☐PR ☐CR

Pathological Response

Does the subject have a T-pCR? ☐No ☐Yes

If No, is the response graded as minimal residual disease? ☐No ☐Yes

If Yes, does residual DCIS exist? ☐No ☐Yes
does residual LCIS exist? ☐No ☐Yes

Does the subject have a N-pCR? ☐No ☐Yes
If No, is the response graded as micrometastetic disease? ☐No ☐Yes

Investigator：_____ Date：_____

On Study Form—Evaluation

I-Code：I □□□□□ Initial：□□□

Please attach the copy of subject's **Pathology Report** below：

Pathology Report

***Note：Please remove or conceal the name/ID of the subject.**

Remarks：

Summary Form

I-Code：I ☐☐☐☐☐ Initial：☐☐☐

Treatment Efficacy

Date of last dosing day：☐☐/☐☐/20☐☐(mm/dd/yyyy)
PS of ECOG in last dosing date：☐0 ☐1 ☐2 ☐3 ☐4

Maximal courses of Assigned Regimen

☐1 ☐2 ☐3 cycle(s), please tick the reason for premature termination from treatment：

- ☐ Objective disease progression
- ☐ Chemotherapy delay longer than 3 weeks
- ☐ Patient wishes to withdraw at her own request
- ☐ Patients develop any condition of the exclusion criteria
- ☐ Patients with poor compliance
- ☐ Investigator feels that patient withdrawal is better choice for patients
- ☐ Losing the patient to follow-up, date of last contact：☐☐/☐☐/20☐☐
- ☐ Administration of radiotherapy, non-protocol chemotherapy, or an experimental drug during protocol treatment
- ☐ Patient death, cause of death：_____
- ☐ Others, specify：_____

☐4 cycles, will the subject receive continued neoajuvant chemotherapy?

☐Yes,

Does the subject receive biopsy (residual < 3 cm) post C/T? ☐No ☐Yes
What regiment is given to this subject?
☐Continue protocol regimen
☐Salvage C/T for ____ cycles, please specify the drug below:
☐Docetaxel ☐Epirubicin ☐Vinorelbine ☐5-FU
☐Cisplatin ☐Gemcitabine ☐Xeloda ☐Paclitaxel
☐Cyclophosphamide ☐Other:_____

☐No,

What treatment is/are given to this subject?
☐None
☐Surgery
☐Adjuvant radiotherapy
☐Adjuvant hormone therapy (HRT)
☐Adjuvant C/T for ____ cycles, please specify the drug below:
☐Docetaxel ☐Epirubicin ☐Vinorelbine ☐5-FU
☐Cisplatin ☐Gemcitabine ☐Xeloda ☐Paclitaxel
☐Cyclophosphamide ☐Other:_____

Investigator：_____ Date：_____

Follow-Up Form

I-Code：I ☐☐☐☐☐ Initial：☐☐☐

Please record this form every 3 months after last dosing date for at least 2 year：

Follow-up Information

Date of follow-up：☐☐/☐☐/20☐☐(mm/dd/yyyy), by ☐OPD ☐Ward ☐Telephone

Status：
☐Alive without evidence of recurrence
☐Local recurrence in ☐axillary LN ☐chest wall ☐other:_____
Date of recurrence：☐☐/☐☐/20☐☐
☐Distant recurrence in ☐supraclavicular LN ☐lung ☐liver ☐bone
☐other:_____
Date of recurrence：☐☐/☐☐/20☐☐
☐Lost follow up, date last known to be alive：☐☐/☐☐/20☐☐
☐Dead, date of death：☐☐/☐☐/20☐☐
If dead, please specify the principal cause of death：_____

Follow-up Information

Date of follow-up：☐☐/☐☐/20☐☐(mm/dd/yyyy), by ☐OPD ☐Ward ☐Telephone

Status：
☐Alive without evidence of recurrence
☐Local recurrence in ☐axillary LN ☐chest wall ☐other:_____
Date of recurrence：☐☐/☐☐/20☐☐
☐Distaant recurrence in ☐supraclavicular LN ☐lung ☐liver ☐bone
☐other:_____
Date of recurrence：☐☐/☐☐/20☐☐
☐Lost follow up, date last known to be alive：☐☐/☐☐/20☐☐
☐Dead, date of death：☐☐/☐☐/20☐☐
If dead, please specify the principal cause of death：_____

Follow-up Information

Date of follow-up：☐☐/☐☐/20☐☐(mm/dd/yyyy), by ☐OPD ☐Ward ☐Telephone

Status：
☐Alive without evidence of recurrence
☐Local recurrence in ☐axillary LN ☐chest wall ☐other:_____
Date of recurrence：☐☐/☐☐/20☐☐
☐Distant recurrence in ☐supraclavical LN ☐lung ☐liver ☐bone
☐other:_____
Date of recurrence：☐☐/☐☐/20☐☐
☐Lost follow up, date last known to be alive：☐☐/☐☐/20☐☐
☐Dead, date of death：☐☐/☐☐/20☐☐
If dead, please specify the principal cause of death：_____

Operation / Radiotherapy Information

I-Code：I ☐☐☐☐☐ Initial：☐☐☐

Operation

Operation Date	Procedure
☐☐/☐☐/20☐☐ (mm/dd/yyyy)	☐Breast conserving therapy (BCT) ☐Total mastectomy ☐Sentinel lymph node dissection (SLND) ☐Radical axillary lymph node dissection (ALND) ☐Other, please specify：_____
☐☐/☐☐/20☐☐ (mm/dd/yyyy)	☐Breast conserving therapy (BCT) ☐Total mastectomy ☐Sentinel lymph node dissection (SLND) ☐Radical axillary lymph node dissection (ALND) ☐Other, please specify：_____

Radiotherapy

Radiotherapy duration：from ☐☐/☐☐/20☐☐ to ☐☐/☐☐/20☐☐
Total dose of R/T：☐☐☐☐cGy

Delivery of radiotherapy：
- ☐Conventional
- ☐Twice a day
- ☐DCRT
- ☐IMRT
- ☐Others：_____

Remarks：

Investigator：_____ Date：_____

SAE Report Form

Please fax this page to central office while you know the event and complete the SAE report form within 3 days.

☐Initial report ☐Follow-up report

I-Code：I ☐☐☐☐☐ | Center：

Subject description：Initial：☐☐☐ Date of birth：☐☐/☐☐/19☐☐

Body Weight：☐☐☐.☐kg Body Height：☐☐☐.☐cm

Randomization arm：

☐Arm A

☐Arm B：☐TE ☐E-HDFL ☐EP ☐N-HDFL ☐NP ☐T-HDFL ☐TP

Adverse Event	AE Started (mm/dd/yyyy)	AE Stopped (mm/dd/yyyy)

Date of AE met serious criteria：☐☐/☐☐/20☐☐

Date of investigator aware of the SAE：☐☐/☐☐/20☐☐

The event is serious due to (tick one or more criteria)：

☐Death ☐Life-threatening ☐Requires/prolongs hospitalization

☐Persistent or significant disability/incapacity ☐Congenital abnormality/birth defect

☐Important medical event ☐Others：_____

If hospitalisation, please also provide the information below：

Date of hospitalisation：☐☐/☐☐/20☐☐

Date of discharge：☐☐/☐☐/20☐☐

Investigational Products	Total Dose	Route	Started (mm/dd/yy)	Stopped (mm/dd/yy)	Causality
					☐Yes ☐No
					☐Yes ☐No
					☐Yes ☐No
					☐Yes ☐No
					☐Yes ☐No

Action taken regarding investigational product：

☐None ☐Dose modification ☐Study plan temporarily stopped

☐Termination of treatment

Outcome：

☐Recovered/Resolved

☐Ongoing

☐Death

If fatal outcome, date of death：☐☐/☐☐/20☐☐

Probable cause of death：_____

_____

_____

Investigator：_____ Date of Report：_____ (mm-dd-yyyy)