NEO-ALTTO

Neo-**A**djuvant **L**apatinib and/or **T**rastuzumab **T**reatment **O**ptimisation

CASE REPORT FORM

Protocol number BIG 1-06 / EGF 106903

Amended survival follow-up from Protocol Amendment 4 Approval

Centre No. | | | | | | |

Subject No. | | | | | | |

Centre No. | | | | | | |

Subject No. | 2 | 0 | | | | |

Patient status

Patient was last contacted:
- ☐ Via a phone call
- ☐ During a standard of care visit
- ☐ Not Done

Date of patient's status evaluation (phone call or standard of care visit) DD MMM YYYY

Are there any changes from last patient status?
- ☐ No → *Please sign and date at the bottom of the page*
- ☐ Yes → *Specify below and sign and date at the bottom of the page*

Changes
- ☐ Recurrence of disease *(complete the next page "Event and radiological examinations")*
- ☐ Second primary malignancy or contralateral breast cancer *(complete the next page "Event and radiological examinations")*
- ☐ Death *(complete the "Death" section below)*
- ☐ Lost to follow-up
- ☐ Patient withdrew study consent

→ Date of last contact (*or date study consent withdrawn*) DD MMM YYYY

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Death

Date of death DD MMM YYYY

Every effort should be made to exercise diligence in reporting the complete date of death. Overall survival is an important study endpoint.

Primary cause of death *(check one)*
- ☐ Breast cancer progression
- ☐ Malignant disease other than breast cancer
- ☐ Other, specify: _____

Signature

All data entered in this case report form have been entered under my authority and to the best of my knowledge are accurate and complete.

Investigator's signature _____

(A medically qualified sub-investigator is allowed to sign the CRF if he/she is listed on the form FDA 1572)

Date DD MMM YYYY

* Type of event:

Type of event code	Description
	Local Recurrence
1a	Breast surgical scar
1b	Ipsilateral breast
1c	Ipsilateral anterior chest wall
1d	Skin or soft tissue within local area
	Regional Recurrence
2a	Ipsilateral axillary
2b	Infraclavicular
2c	Internal mammary
2d	Skin or soft tissue within the regional area

Type of event code	Description
	Distant Recurrence
3a	Skin or lymph nodes other than specified for local/regional recurrence
3b	Bone
3c	Lung
3d	Liver
3e	Pleural effusion
3f	Other distant site (description to be provided)
	Central nervous system
4a	Brain metastasis
4b	Meningitis carcinomatosa
5	**Contralateral breast cancer**
6	**Second primary malignancy (description to be provided)**

** Method of evaluation: C = clinical; R = radiological (please report the radiological test in the second section of facing page).

*** BS=Bone scan (scintigraphy); C=CT scan; E=Endoscopy; L=Lymphangiogram; M=MRI; MA=Mammography; NS=Nuclear scan; PC=PET/CT Scan; PT=PET scan; TU=Transvaginal ultrasound; UL=Ultrasound (echography); XR=X-ray

**** See table below for anatomical site codes

Anatomical site	Description
AB	Abdomen/abdominal wall
AD	Adrenals
BE	Bone
BR	Bladder
BT	Breast
CL	Colon
CR	Colorectal
CS	CNS (brain)
CW	Chest
CX	Cervix
EO	Esophagus/Oesophagus

Anatomical site	Description
HN	Head and neck
HT	Heart
K	Kidney
LG	Lung
LN	Lymph nodes
LV	Liver
OC	Oral cavity
OT	Other
OV	Ovary
PA	Pleura
PM	Peritoneum

Anatomical site	Description
PR	Prostate
PS	Pancreas
PV	Pelvis
RC	Rectum
SH	Stomach
SI	Small intestine
SK	Skin
SP	Spleen
TD	Thyroid
TE	Testicle
WB	Whole body

Amended survival FU from Protocol Amendment 4 Approval Event and Radiological examinations

Centre No. | Subject No. 20

For all events, please complete "Type of event code".
For "Other distant site" or "Second Primary malignancy", please provide description of event.

Type of event*	Description of event	Recurrence date (dd/mmm/yyyy)	Method of evaluation** C	Method of evaluation** R	Biopsy No	Biopsy Yes	Biopsy date	Histology type
			☐	☐	☐	☐		
			☐	☐	☐	☐		
			☐	☐	☐	☐		
			☐	☐	☐	☐		

Type of radiological examination***	Anatomical site****	Side (L or R or Both)	Date of test (dd/mmm/yyyy)	Are there any clinically significant abnormalities? (Please report a short description)
				☐ No ☐ Yes → Specify
				☐ No ☐ Yes → Specify
				☐ No ☐ Yes → Specify
				☐ No ☐ Yes → Specify

Centre No. | | | | | | |

Subject No. | 2 | 0 | | | | |

Patient status

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- ☐ Death *(complete the "Death" section below)*
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Death

Date of death DD MMM YYYY

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Primary cause of death *(check one)*

- ☐ Breast cancer progression
- ☐ Malignant disease other than breast cancer
- ☐ Other, specify: _____

Signature

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Investigator's signature _____

(A medically qualified sub-investigator is allowed to sign the CRF if he/she is listed on the form FDA 1572)

Date DD MMM YYYY

* Type of event:

Type of event code	Description
	Local Recurrence
1a	Breast surgical scar
1b	Ipsilateral breast
1c	Ipsilateral anterior chest wall
1d	Skin or soft tissue within local area
	Regional Recurrence
2a	Ipsilateral axillary
2b	Infraclavicular
2c	Internal mammary
2d	Skin or soft tissue within the regional area

Type of event code	Description
	Distant Recurrence
3a	Skin or lymph nodes other than specified for local/regional recurrence
3b	Bone
3c	Lung
3d	Liver
3e	Pleural effusion
3f	Other distant site (description to be provided)
	Central nervous system
4a	Brain metastasis
4b	Meningitis carcinomatosa
5	**Contralateral breast cancer**
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** Method of evaluation: C = clinical; R = radiological (please report the radiological test in the second section of facing page).

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Anatomical site	Description
HN	Head and neck
HT	Heart
K	Kidney
LG	Lung
LN	Lymph nodes
LV	Liver
OC	Oral cavity
OT	Other
OV	Ovary
PA	Pleura
PM	Peritoneum

Anatomical site	Description
PR	Prostate
PS	Pancreas
PV	Pelvis
RC	Rectum
SH	Stomach
SI	Small intestine
SK	Skin
SP	Spleen
TD	Thyroid
TE	Testicle
WB	Whole body

Amended survival FU from Protocol Amendment 4 Approval Event and Radiological examinations

Centre No. | Subject No. 20

For all events, please complete "Type of event code".
For "Other distant site" or "Second Primary malignancy", please provide description of event.

Type of event*	Description of event	Recurrence date (dd/mmm/yyyy)	Method of evaluation** C	Method of evaluation** R	Biopsy No	Biopsy Yes	Biopsy date	Histology type
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			☐	☐	☐	☐		
			☐	☐	☐	☐		
			☐	☐	☐	☐		

Type of radiological examination***	Anatomical site****	Side (L or R or Both)	Date of test (dd/mmm/yyyy)	Are there any <u>clinically significant</u> abnormalities? *(Please report a short description)*
				☐ No ☐ Yes → Specify
				☐ No ☐ Yes → Specify
				☐ No ☐ Yes → Specify
				☐ No ☐ Yes → Specify

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Primary cause of death *(check one)*
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Amended survival FU from Protocol Amendment 4 Approval Event and Radiological examinations

Centre No. | Subject No. 20

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				☐ No ☐ Yes → Specify
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Amended survival FU from Protocol Amendment 4 Approval Event and Radiological examinations

Centre No. | Subject No. 20

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Amended survival FU from Protocol Amendment 4 Approval Event and Radiological examinations

Centre No. | Subject No. 20

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Type of radiological examination***	Anatomical site****	Side (L or R or Both)	Date of test (dd/mmm/yyyy)	Are there any <u>clinically significant</u> abnormalities? *(Please report a short description)*
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Centre No. | | | | | | |

Subject No. | 2 | 0 | | | | |

Did the patient sign the Main Informed Consent version nb ____ corresponding to Protocol Amendment 4?

☐ No
☐ Yes → *Specify date of consent below*

Date Main Informed Consent was signed? DD MMM YYYY

Did the patient sign the PGx Informed Consent version nb _____ corresponding to Protocol Amendment 4?

☐ No
☐ Yes → *Specify date of consent below*

Date PGx Informed Consent was signed? DD MMM YYYY

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