### Lothian NHS Board

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Date: 01/03/2024

Your Ref:

Our Ref: 8423

Enquiries to: Richard Mutch Extension: 35687
Direct Line: 0131 465 5687
<a href="mailto:local-richard.mutch@nhs.scot">local-richard.mutch@nhs.scot</a>

Dear

#### FREEDOM OF INFORMATION - BREAST CANCER PRESCRIBING

I write in response to your request for information in relation to breast cancer prescribing.

#### Question:

- 1. How many patients have been treated for breast cancer (any stage) in the past 3 months with the following systemic anti-cancer therapies:
  - a) Abemaciclib + Aromatase Inhibitor (e.g. anastrazole, exemestane, letrozole)
  - b) Abemaciclib + Fulvestrant
  - c) Alpelisib + Fulvestrant
  - d) Anthracycline (e.g. doxorubicin or epirubicin) as a single agent
  - e) Atezolizumab +Nab-paclitaxel/Paclitaxel
  - f) Capecitabine as a single agent
  - g) Eribulin as a single agent or in combination
  - h) Everolimus + Exemestane
  - i) Fulvestrant as a single agent
  - j) Lapatinib
  - k) Neratinib
  - I) Parp Inhibitors (Olaparib/Talazoparib)
  - m) Palbociclib + Aromatase Inhibitor (e.g. anastrazole, exemestane, letrozole)
  - n) Palbociclib + Fulvestrant
  - o) Pembrolizumab
  - p) Platinum (e.g. carboplatin or cisplatin) as a single agent
  - q) Ribociclib + Aromatase Inhibitor (e.g. anastrazole, exemestane, letrozole)
  - r) Ribociclib + Fulvestrant
  - s) Sacituzumab Govitecan
  - t) Taxane (e.g. docetaxel, paclitaxel, nab-paclitaxel) as a single agent
  - u) Taxane and/or Anthracycline in combination
  - v) Trastuzumab as a single agent or in combination
  - w) Trastuzumab emtansine
  - x) Transtuzumab deruxtecan
  - y) Any other active systemic anti-cancer therapy









### Answer:

1a	Abemaciclib + Aromatase Inhibitor (e.g. anastrazole, exemestane, letrozole)	Nil
1b	Abemaciclib + Fulvestrant	5<
1c	Alpelisib + Fulvestrant	Nil
1d	Anthracycline (e.g. doxorubicin or epirubicin) as a single agent	5<
1e	Atezolizumab +Nab-paclitaxel/Paclitaxel	5<
1f	Capecitabine as a single agent	51
1g	Eribulin as a single agent or in combination	5<
1h	Everolimus + Exemestane	5<
1i	Fulvestrant as a single agent	50
1j	Lapatinib	Nil
1k	Neratinib	Nil
11	Parp Inhibitors (Olaparib/Talazoparib)	7
1m	Palbociclib + Aromatase Inhibitor (e.g. anastrazole, exemestane, letrozole)	54
1n	Palbociclib + Fulvestrant	13
10	Pembrolizumab	20
1p	Platinum (e.g. carboplatin or cisplatin) as a single agent	23
1q	Ribociclib + Aromatase Inhibitor (e.g. anastrazole, exemestane, letrozole)	47
1r	Ribociclib + Fulvestrant	9
1s	Sacituzumab Govitecan	5<
1t	Taxane (e.g. docetaxel, paclitaxel, nab-paclitaxel) as a single agent	48
1u	Taxane and/or Anthracycline in combination	Nil
1v	Trastuzumab as a single agent or in combination	142
1w	Trastuzumab emtansine	19
1x	Transtuzumab deruxtecan	11
1y	Any other active systemic anti-cancer therapy	134

# Question:

2. Does your trust participate in any clinical trials for breast cancer? If so, please provide the name of each trial, and the number of patients taking part.

# Answer:

Full Title	Recruited
The HER2-RADiCAL study (Response ADaptive CAre pLan) – Tailoring treatment for HER2 positive early breast cancer	5<
TROPION-Breast02, A Phase 3, Open-label, Randomised Study of Datopotamab Deruxtecan (Dato-DXd) Versus Investigator's Choice of Chemotherapy in Patients who are not Candidates for PD-1/PD-L1 Inhibitor Therapy in First-line Locally Recurrent Inoperable or Metastatic Triple-negative Breast Cancer	5<

FAIM, Randomised Open-label Phase II study of induction standard of care Fulvestrant and CDK4/6 inhibition with the Addition of Ipatasertib in Metastatic ER+/HER2- breast cancer patients without ctDNA suppression  HER2CLIMB-05, A randomized, double-blind, phase 3 study of tucatinib or placebo in combination with trastuzumab and pertuzumab as maintenance therapy for metastatic HER2+ breast cancer  TROPION-Breast03, A Phase 3 Open-label, Randomised Study of Datopotamab Deruxtecan (DatoDXd) With or Without Durvalumab Versus Investigator's Choice of Therapy in Patients With Stage I-III Triple-negative Breast Cancer Who Have Residual Invasive Disease in the Breast and/or Axillary Lymph Nodes at Surgical Resection Following Neoadjuvant Systemic Therapy  TRAK-ER, A randomised trial of early detection of molecular relapse with circulating tumour DNA tracking and treatment with palbociclib plus fulvestrant versus standard endocrine therapy in patients with ER positive HER2 negative breast cancer  ASCENT-04, A Randomized, Open-label, Phase 3 Study of Sacituzumab Govitecan and Pembrolizumab Versus Treatment of Physician's Choice and Pembrolizumab in Patients With Previously Untreated, Locally Advanced Inoperable or Metastatic Triple-Negative Breast Cancer, Whose Tumors Express PD-L1  ADD ASPIRIN, A phase III double-blind placebo-controlled randomised trial assessing the effects of aspirin on disease recurrence and survival after primary therapy in common non-metastatic solid tumours.  INAVO121, A Phase III, Multicenter, Randomized, Open-label study evaluating the efficacy and safety of Inavolisib plus Fulvestrant versus Alpelisib plus Fulvestrant in patients with hormone receptor positive, HER2-negative, PIR3CA mutated, locally advanced or metastatic breast cancer who progressed during or after CDK4/6 inhibitor and endocrine combination therapy.  EMBER-4, A Randomized, Open-Label, Phase 3 Study of Adjuvant Imlunestrant vs Standard Adjuvant Endocrine Therapy in Patients who have Previously Breast Cancer with an Increased R		
placebo in combination with trastuzumab and pertuzumab as maintenance therapy for metastatic HER2+ breast cancer  TROPION-Breast03, A Phase 3 Open-label, Randomised Study of Datopotamab Deruxtecan (DatoDXd) With or Without Durvalumab Versus Investigator's Choice of Therapy in Patients With Stage I-III Triple-negative Breast Cancer Who Have Residual Invasive Disease in the Breast and/or Axillary Lymph Nodes at Surgical Resection Following Neoadjuvant Systemic Therapy  TRAK-ER, A randomised trial of early detection of molecular relapse with circulating tumour DNA tracking and treatment with palbociclib plus fulvestrant versus standard endocrine therapy in patients with ER positive HER2 negative breast cancer  ASCENT-04, A Randomized, Open-label, Phase 3 Study of Sacituzumab Govitecan and Pembrolizumab Versus Treatment of Physician's Choice and Pembrolizumab in Patients With Previously Untreated, Locally Advanced Inoperable or Metastatic Triple-Negative Breast Cancer, Whose Tumors Express PD-L1  ADD ASPIRIN, A phase III double-blind placebo-controlled randomised trial assessing the effects of aspirin on disease recurrence and survival after primary therapy in common non-metastatic solid tumours.  INAVO121, A Phase III, Multicenter, Randomized, Open-label study evaluating the efficacy and safety of Inavolisib plus Fulvestrant versus Alpelisib plus Fulvestrant in patients with hormone receptor positive, HER2-negative, PIK3CA mutated, locally advanced or metastatic breast cancer who progressed during or after CDK4/6 inhibitor and endocrine combination therapy.  EMBER-4, A Randomized, Open-Label, Phase 3 Study of Adjuvant Imlunestrant vs Standard Adjuvant Endocrine Therapy in Patients who have Previously Received 2 to 5 years of Adjuvant Endocrine Therapy for ER+, HER2- Early Breast Cancer with an Increased Risk of Recurrence	Fulvestrant and CDK4/6 inhibition with the Addition of Ipatasertib in Metastatic	0
Deruxtecan (DatoDXd) With or Without Durvalumab Versus Investigator's Choice of Therapy in Patients With Stage I-III Triple-negative Breast Cancer Who Have Residual Invasive Disease in the Breast and/or Axillary Lymph Nodes at Surgical Resection Following Neoadjuvant Systemic Therapy  TRAK-ER, A randomised trial of early detection of molecular relapse with circulating tumour DNA tracking and treatment with palbociclib plus fulvestrant versus standard endocrine therapy in patients with ER positive HER2 negative breast cancer  ASCENT-04, A Randomized, Open-label, Phase 3 Study of Sacituzumab Govitecan and Pembrolizumab Versus Treatment of Physician's Choice and Pembrolizumab in Patients With Previously Untreated, Locally Advanced Inoperable or Metastatic Triple-Negative Breast Cancer, Whose Tumors Express PD-L1  ADD ASPIRIN, A phase III double-blind placebo-controlled randomised trial assessing the effects of aspirin on disease recurrence and survival after primary therapy in common non-metastatic solid tumours.  INAVO121, A Phase III, Multicenter, Randomized, Open-label study evaluating the efficacy and safety of Inavolisib plus Fulvestrant versus Alpelisib plus Fulvestrant in patients with hormone receptor positive, HER2-negative, PIK3CA mutated, locally advanced or metastatic breast cancer who progressed during or after CDK4/6 inhibitor and endocrine combination therapy.  EMBER-4, A Randomized, Open-Label, Phase 3 Study of Adjuvant Imlunestrant vs Standard Adjuvant Endocrine Therapy in Patients who have Previously Received 2 to 5 years of Adjuvant Endocrine Therapy for ER+, HER2- Early Breast Cancer with an Increased Risk of Recurrence	placebo in combination with trastuzumab and pertuzumab as maintenance	0
circulating tumour DNA tracking and treatment with palbociclib plus fulvestrant versus standard endocrine therapy in patients with ER positive HER2 negative breast cancer  ASCENT-04, A Randomized, Open-label, Phase 3 Study of Sacituzumab Govitecan and Pembrolizumab Versus Treatment of Physician's Choice and Pembrolizumab in Patients With Previously Untreated, Locally Advanced Inoperable or Metastatic Triple-Negative Breast Cancer, Whose Tumors Express PD-L1  ADD ASPIRIN, A phase III double-blind placebo-controlled randomised trial assessing the effects of aspirin on disease recurrence and survival after primary therapy in common non-metastatic solid tumours.  INAVO121, A Phase III, Multicenter, Randomized, Open-label study evaluating the efficacy and safety of Inavolisib plus Fulvestrant versus Alpelisib plus Fulvestrant in patients with hormone receptor positive, HER2-negative, PIK3CA mutated, locally advanced or metastatic breast cancer who progressed during or after CDK4/6 inhibitor and endocrine combination therapy.  EMBER-4, A Randomized, Open-Label, Phase 3 Study of Adjuvant Imlunestrant vs Standard Adjuvant Endocrine Therapy in Patients who have Previously Received 2 to 5 years of Adjuvant Endocrine Therapy for ER+, HER2- Early Breast Cancer with an Increased Risk of Recurrence	Deruxtecan (DatoDXd) With or Without Durvalumab Versus Investigator's Choice of Therapy in Patients With Stage I-III Triple-negative Breast Cancer Who Have Residual Invasive Disease in the Breast and/or Axillary Lymph Nodes at Surgical Resection Following Neoadjuvant Systemic Therapy	5<
Govitecan and Pembrolizumab Versus Treatment of Physician's Choice and Pembrolizumab in Patients With Previously Untreated, Locally Advanced Inoperable or Metastatic Triple-Negative Breast Cancer, Whose Tumors Express PD-L1  ADD ASPIRIN, A phase III double-blind placebo-controlled randomised trial assessing the effects of aspirin on disease recurrence and survival after primary therapy in common non-metastatic solid tumours.  INAVO121, A Phase III, Multicenter, Randomized, Open-label study evaluating the efficacy and safety of Inavolisib plus Fulvestrant versus Alpelisib plus Fulvestrant in patients with hormone receptor positive, HER2-negative, PIK3CA mutated, locally advanced or metastatic breast cancer who progressed during or after CDK4/6 inhibitor and endocrine combination therapy.  EMBER-4, A Randomized, Open-Label, Phase 3 Study of Adjuvant Imlunestrant vs Standard Adjuvant Endocrine Therapy in Patients who have Previously Received 2 to 5 years of Adjuvant Endocrine Therapy for ER+, HER2- Early Breast Cancer with an Increased Risk of Recurrence	circulating tumour DNA tracking and treatment with palbociclib plus fulvestrant versus standard endocrine therapy in patients with ER positive HER2 negative	0
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the efficacy and safety of Inavolisib plus Fulvestrant versus Alpelisib plus Fulvestrant in patients with hormone receptor positive, HER2-negative, PIK3CA mutated, locally advanced or metastatic breast cancer who progressed during or after CDK4/6 inhibitor and endocrine combination therapy.  EMBER-4, A Randomized, Open-Label, Phase 3 Study of Adjuvant Imlunestrant vs Standard Adjuvant Endocrine Therapy in Patients who have Previously Received 2 to 5 years of Adjuvant Endocrine Therapy for ER+, HER2- Early Breast Cancer with an Increased Risk of Recurrence	assessing the effects of aspirin on disease recurrence and survival after primary	129*
vs Standard Adjuvant Endocrine Therapy in Patients who have Previously Received 2 to 5 years of Adjuvant Endocrine Therapy for ER+, HER2- Early Breast Cancer with an Increased Risk of Recurrence	the efficacy and safety of Inavolisib plus Fulvestrant versus Alpelisib plus Fulvestrant in patients with hormone receptor positive, HER2-negative, PIK3CA mutated, locally advanced or metastatic breast cancer who progressed during or	12
* Number of breast cancer patients	vs Standard Adjuvant Endocrine Therapy in Patients who have Previously Received 2 to 5 years of Adjuvant Endocrine Therapy for ER+, HER2- Early Breast Cancer with an Increased Risk of Recurrence	0
	* Number of breast cancer patients	

To protect the identity of the individuals involved any figure of 5 or less has not been shown in the tables above. Since we do not have their consent to release this data from their records, the information is exempt under section 38(1)(b) of the Freedom of Information (Scotland) Act i.e. to provide it would breach the Data Protection Act (2018).

# I hope the information provided helps with your request.

If you are unhappy with our response to your request, you do have the right to request us to review it. Your request should be made within 40 working days of receipt of this letter, and we will reply within 20 working days of receipt. If our decision is unchanged following a review and you remain dissatisfied with this, you then have the right to make a formal complaint to the Scottish Information Commissioner within 6 months of receipt of our review response. You can do this by using the Scottish Information Commissioner's Office online appeals service at <a href="https://www.itspublicknowledge.info/Appeal">www.itspublicknowledge.info/Appeal</a>. If you remain dissatisfied with the Commissioner's response you then have the option to appeal to the Court of Session on a point of law.

If you require a review of our decision to be carried out, please write to the FOI Reviewer at the email address at the head of this letter. The review will be undertaken by a Reviewer who was not involved in the original decision-making process.

FOI responses (subject to redaction of personal information) may appear on NHS Lothian's Freedom of Information website at: https://org.nhslothian.scot/FOI/Pages/default.aspx

Yours sincerely

ALISON MACDONALD
Executive Director, Nursing, Midwifery and AHPs

Cc: Chief Executive