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Patient (pt) preference for the pertuzumab–trastuzumab fixed-dose combination for subcutaneous use (PH FDC SC) in HER2-positive early breast cancer (EBC): Primary analysis of the open-label, randomised crossover PHranceSCa study

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Disclosures

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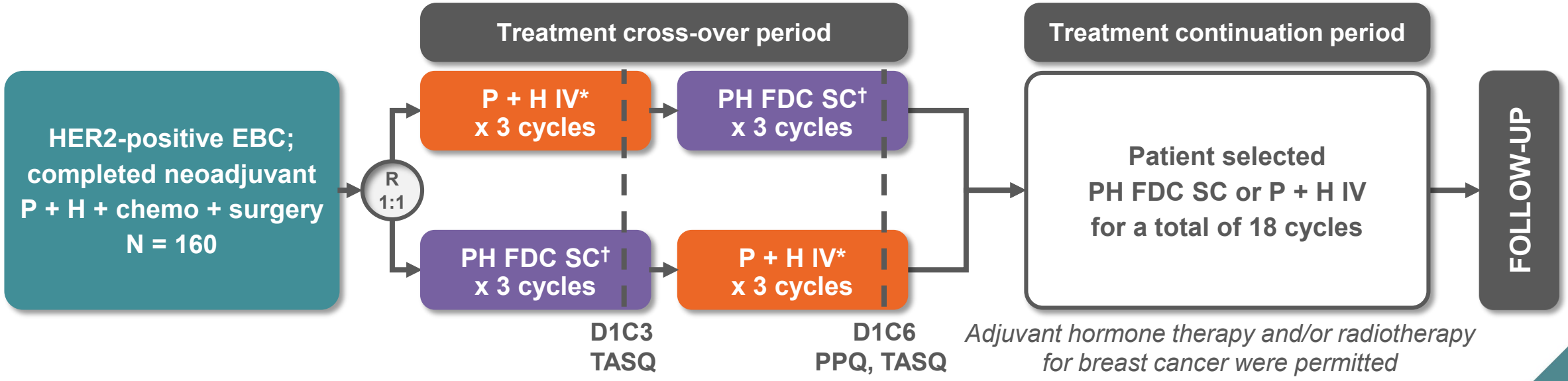
PHranceSCa is an open-label, randomised crossover study evaluating patient preference for PH FDC SC vs P + H IV (NCT03674112)



Stratification factors:
- NACT regimen
- pCR vs non-pCR
- HR status

Primary objective: Patient preference for PH FDC SC
Key secondary objectives: Patient satisfaction; patients' choice of formulation for the continuation period; health-related quality of life, HCP perception on time/resource use at each cycle during the treatment crossover period, safety and tolerability (including safety of switching from SC to IV formulations and vice versa), efficacy

All patients were female; median age was 49 years.
* P IV loading dose if needed: 840 mg; maintenance: 420 mg q3w. H IV loading dose if needed: 8 mg/kg; maintenance: 6 mg/kg IV q3w.
† PH FDC SC loading dose if needed: P 1200 mg/H 600 mg in 15 mL; maintenance: P 600 mg/H 600 mg in 10 mL q3w.
Loading doses were only required for patients who had ≥6 weeks since their last neoadjuvant dose of P + H IV at study entry, or had ≥6 weeks since their last study treatment during the study. Maintenance doses were used for subsequent administrations or dose delays <6 weeks.
DXCX; Day X Cycle X; EBC, early breast cancer; H, trastuzumab; HCP, healthcare professional; HR, hormone receptor; IV, intravenous; NACT, neoadjuvant chemotherapy; P, pertuzumab;pCR, pathological complete response; PH FDC SC, fixed-dose combination of pertuzumab and trastuzumab for subcutaneous injection; PPQ, Patient Preference Questionnaire; SC, subcutaneous; TASQ, Therapy Administration Satisfaction Questionnaire.

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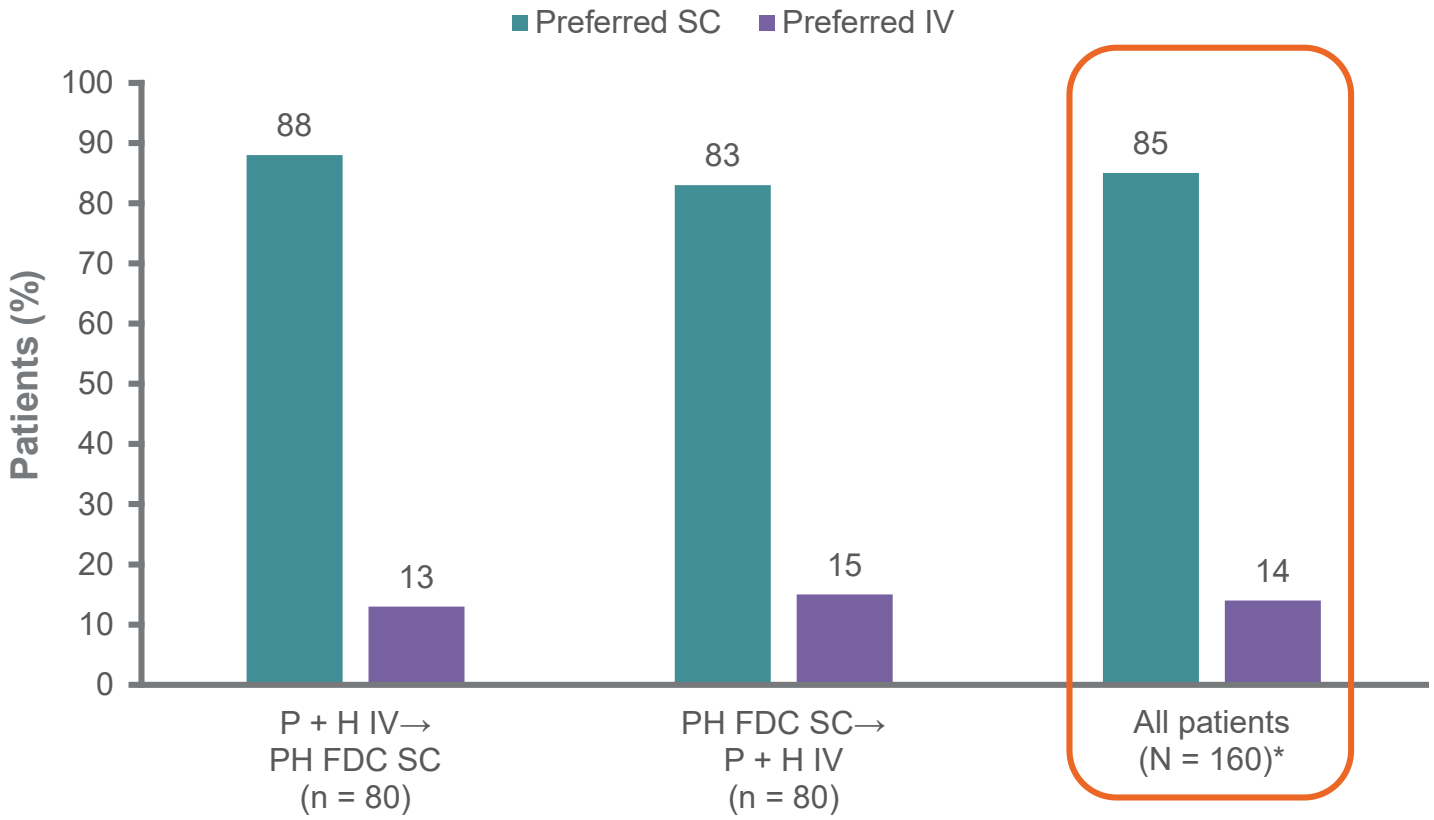
At the primary analysis, 85% of patients preferred PH FDC SC, regardless of sequencing

PPQ Q1: "All things considered, which method of administration did you prefer?"



- Preference for PH FDC SC was very or fairly strong for a majority of patients (93%)
- Main reasons for SC preference:
  - "Less time in clinic" (42%)
  - "More comfortable during administration" (26%)
- Findings consistent with the interim analysis[1]
- 87% chose PH FDC SC to continue treatment (vs 13% P + H IV, supporting PPQ results)

Clinical cut-off: 24 February, 2020.

* Two patients stated "no preference." 95% CI for PH FDC SC preference: 79–90.

1. O'Shaughnessy J, *et al.* ESMO Breast Cancer Virtual Meeting 2020; Abstract 80O.

CI, confidence interval; H, trastuzumab; IV, intravenous; P, pertuzumab; PH FDC SC, fixed-dose combination of pertuzumab and trastuzumab for subcutaneous injection; PPQ, Patient Preference Questionnaire; SC, subcutaneous.

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More patients were “very satisfied” or “satisfied” with PH FDC SC and P + H IV (88% and 68%)

TASQ Q1: “How satisfied or dissatisfied were you with the SC injection/IV infusion?”

- Treatment had no impact on patient–HCP speaking time:
  - PH FDC SC: 85%
  - P + H IV: 79%
- Most patients had more than enough time to talk to their HCP during treatment:
  - PH FDC SC: 90%
  - P + H IV: 83%

* Two patients did not answer the question.
H, trastuzumab; HCP, healthcare professional (nurse or doctor); IV, intravenous; P, pertuzumab; PH FDC SC, fixed-dose combination of pertuzumab and trastuzumab for subcutaneous injection; SC, subcutaneous; TASQ, Therapy Administration Satisfaction Questionnaire.

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Majority of HCPs perceived that switching from IV infusions to SC injections would save time and resources during preparation and treatment

Drug preparation room
- Median SC vs IV preparation time: **5 min vs 15–20 min**
- PH FDC SC was perceived to be quickest from start of preparation to completion of administration for 88% of patients
- PH FDC SC required less resource usage for preparation and administration for 87% of patients

Treatment room
- Median SC vs IV administration time: **7–8 min vs 60–150 min**
- Median SC vs IV patient time in the treatment room: **33–50 min vs 130–300 min**

HCP perceptions of PH FDC SC vs P + H IV

Patient cases, n (%)	Cases where HCPs 'strongly agreed' or 'agreed'
Perceptions from HCPs in drug preparation room*†	N = 160
Less drug wastage with ready-to-use PH FDC SC	123 (76.9)
Reduced staff time associated with preparation procedures	128 (80.0)
Perceptions from HCPs in the treatment room‡§	N = 159
Less time from start of preparation to finish of administration	152 (95.6)
Less resource needed for administration¶	137 (86.2)
More convenient for patient	138 (86.8)
Better for care optimisation within their treatment site	126 (79.2)

Time ranges refer to the various cycles during the treatment cross-over period.

* The vast majority of HCPs in the drug preparation room completed at least one question of the HCPQ during the treatment cross-over period (957/960 HCPQs, 99.7%). † The majority of time the HCPQ was completed in the drug preparation room by the pharmacist (52%) or nurse (31%). ‡ The vast majority of HCPs in the treatment room completed at least one question from the HCPQ during the treatment cross-over period (950/960 HCPQs, 99%).§The majority of time the HCPQ was completed in the drug treatment room by the nurse (98%).
¶ E.g., nursing time, facility costs, equipment. H, trastuzumab; HCP, healthcare professional; HCPQ, healthcare professional questionnaire; IV, intravenous; P, pertuzumab; PH FDC SC, fixed-dose combination of pertuzumab and trastuzumab for subcutaneous injection; SC, subcutaneous.

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No new safety signals observed with PH FDC SC at the primary analysis; investigator-reported AEs in line with previous studies of P + H IV[1,2] and PH FDC SC[3]

Patients with ≥1 of the following, n (%)	P + H IV pooled crossover (N = 160)	PH FDC SC pooled crossover (N = 160)	P + H IV pooled continuation (N = 21)	PH FDC SC pooled continuation (N = 137)	All patients (N = 160)
Any AE	113 (70.6)	120 (75.0)	13 (61.9)	70 (51.1)	144 (90.0)
SAE*	6 (3.8)	2 (1.3)	0	3 (2.2)	10 (6.3)
Grade ≥3 AE*	6 (3.8)	4 (2.5)	2 (9.5)	4 (2.9)	13 (8.1)
Five most common AEs (in >5% of patients)					
Radiation skin injury	27 (16.9)	17 (10.6)	0	1 (0.7)	44 (27.5)
Injection site reaction†	0	36 (22.5)	0	10 (7.3)	42 (26.3)
Diarrhoea	16 (10.0)	13 (8.1)	4 (19.0)	14 (10.2)	35 (21.9)
Fatigue	9 (5.6)	9 (5.6)	1 (4.8)	4 (2.9)	17 (10.6)
Arthralgia	6 (3.8)	8 (5.0)	2 (9.5)	1 (0.7)	17 (10.6)
AE with fatal outcome	0	0	0	0	0
AE leading to any study treatment discontinuation	0	1 (0.6)	1 (4.8)	0	2 (1.3)

Patients could be counted in multiple study periods but once in the "All patients" column.

* Low incidence of SAEs and grade ≥3 AEs with PH FDC SC across both treatment periods. No grade 4 or 5 AEs had been reported during the study at the clinical cut-off date.

† More injection site reactions with PH FDC SC, as expected (all grade 1 or 2). No discontinuations due to local injection site reactions with PH FDC SC.

1. von Minckwitz G, *et al. N Engl J Med* 2017;377:122–131; 2. Baselga J, *et al. N Engl J Med* 2012;366:109–119; 3. Tan AR, *et al.* SABCS 2019 (Abstract PD4-07).

AE, adverse event; H, trastuzumab; IV, intravenous; P, pertuzumab; PH FDC SC, fixed-dose combination of pertuzumab and trastuzumab for subcutaneous injection; SAE, serious adverse event; SC, subcutaneous.

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Investigator-reported AE rates before and after switching were similar (P + H IV → PH FDC SC: 78% → 73%; PH FDC SC → P + H IV: 78%→64%), with no new safety signals

Five most common AEs (in ≥5% of patients), n (%)	P + H IV → PH FDC SC		PH FDC SC → P + H IV		All patients (N = 160)
	P + H IV Cycles 1–3 (n = 80)	PH FDC SC Cycles 4–6 (n = 80)	PH FDC SC Cycles 1–3 (n = 80)	P + H IV Cycles 4–6 (n = 80)	
Radiation skin injury	17 (21.3)	7 (8.8)	10 (12.5)	10 (12.5)	43 (26.9)
Injection site reaction	0	12 (15.0)	24 (30.0)	0	36 (22.5)
Diarrhoea	12 (15.0)	7 (8.8)	6 (7.5)	4 (5.0)	25 (15.6)
Fatigue	5 (6.3)	4 (5.0)	5 (6.3)	4 (5.0)	15 (9.4)
Hot flush	6 (7.5)	4 (5.0)	5 (6.3)	0	15 (9.4)

Patients could be counted in multiple study periods but once in the "All patients" column.
AE, adverse event; H, trastuzumab; IV, intravenous; P, pertuzumab;
PH FDC SC, fixed-dose combination of pertuzumab and trastuzumab for subcutaneous injection.

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PHranceSCa primary analysis summary

Patient preference

- 85% of patients (136/160; 95% CI: 79–90%) preferred PH FDC SC; 14% (22/160) preferred P + H IV*
- Main reasons for PH FDC SC preference:
  - "Less time in clinic"
  - "More comfortable during administration"

Patient satisfaction

- More patients were "very satisfied" or "satisfied" with PH FDC SC vs P + H IV
- Most patients indicated that treatment had no impact on the amount of time they had to talk to their nurse/doctor, and that while receiving treatment they had more than enough time to talk to their nurse/doctor

HCP perception on time/resource impact

- HCPs indicated PH FDC SC had marked time savings and required fewer resources compared with P + H IV

Safety

- PH FDC SC was generally well tolerated, with a safety profile in line with previous studies using P + H IV[1,2]
- No new safety signals were observed, including when switching from IV to SC and vice-versa
- Safety results support those seen with PH FDC SC in the FeDeriCa study[3]

* Two patients stated "no preference."

1. von Minckwitz G, *et al. N Engl J Med* 2017;377:122–131; 2. Baselga J, *et al. N Engl J Med* 2012;366:109–119; 3. Tan AR, *et al*. SABCS 2019 (Abstract PD4-07).

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Thank you!

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