Powered by Roche

Fermata BREAST CANCER

COME CAMBIA IL MODELLO ORGANIZZATIVO IN OSPEDALE: EFFICACIA ED EFFICIENZA IN SANITÀ

Scenari futuri: la flessibilità delle terapie dal territorio al domicilio

Daniele Generali , MD Dphil

Breast Oncology Center - U.O. Multidisciplinare di Patologia Mammaria
Azienda Socio-Sanitaria Territoriale di Cremona
Viale Concordia 1; 26100 Cremona (Italia)

Dipartimento Universitario Clinico di Scienze Mediche, Chirurgiche e della Salute
Università degli Studi di Trieste

ROCHE CONNECTIONS
New pathways for oncology

Powered by Roche

Disclosure

ROCHE CONNECTIONS
New pathways for oncology

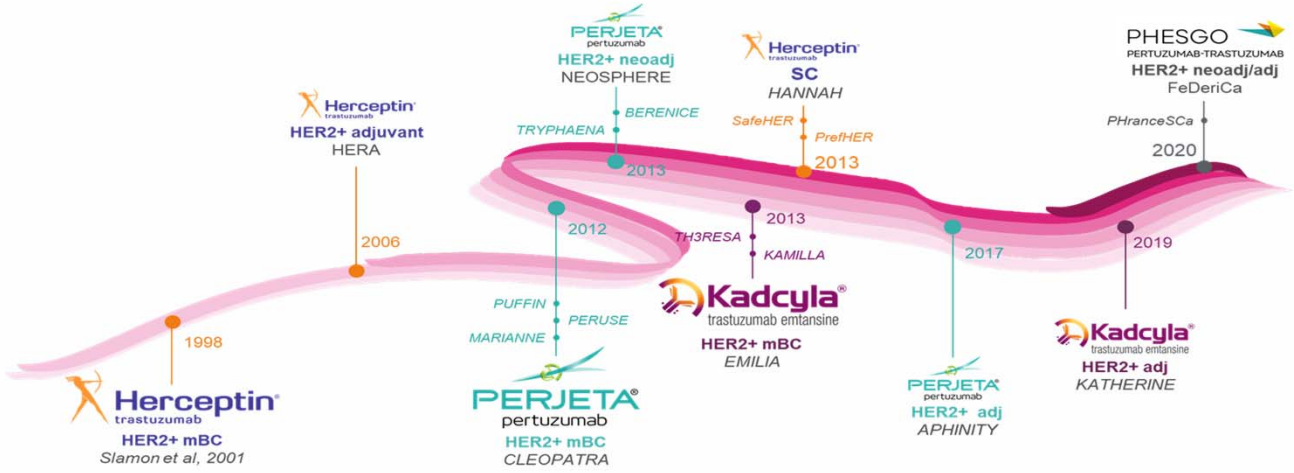
- **Advisory boards/consulting: Roche , Pfizer, Novartis, Lilly, MSD, Istituto Gentili**
- **Institutional/research funding: University of Trieste, Novartis, LILT, AstraZeneca**

Powered by Roche

ROCHE CONNECTIONS
New pathways for oncology

Treatments for HER2+ BC patients have significantly progressed in the last 20 years

Most women with HER2-positive breast cancer will receive **one or more chemotherapy drugs plus, the anti-HER2 therapy.**
These treatments **dramatically improve survival** for women with HER2-positive breast cancer

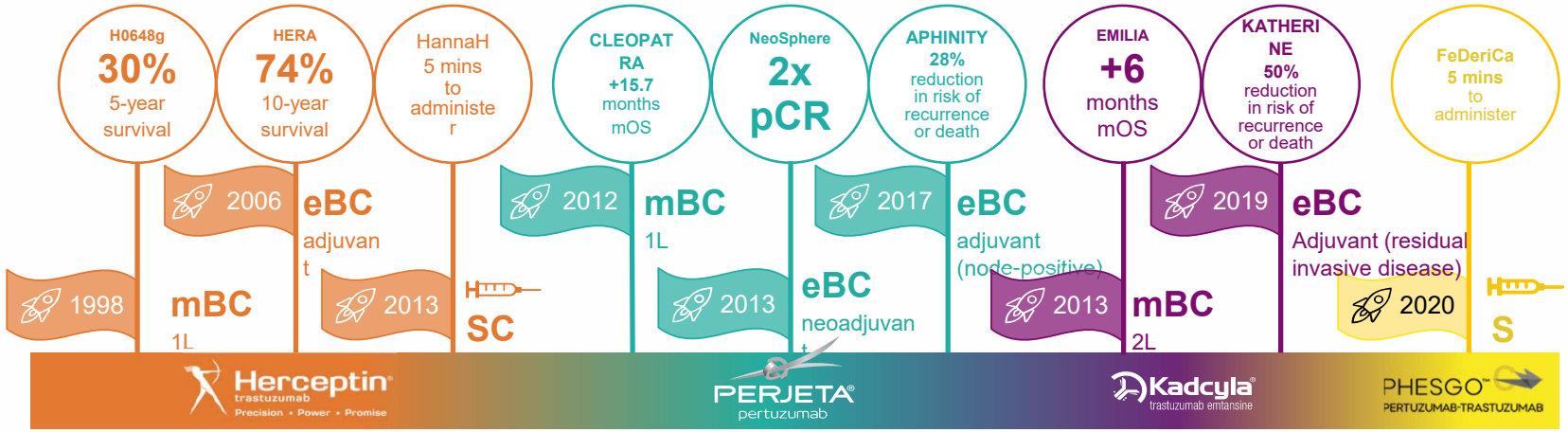


Fermata BREAST CANCER

F. Hoffmann-La Roche, data on file

Powered by Roche

ROCHE CONNECTIONS
New pathways for oncology



3,278,329[1]
patients treated in BC
1,290,132 in mBC

644,452[2]
patients treated in BC
224,172 in mBC

171,570[2]
patients treated in BC
145,847 in mBC

6,838[2]
patients treated in BC
2,244 in mBC

BC, breast cancer; eBC, early breast cancer; mBC, metastatic breast cancer; mOS, median overall survival; pCR, pathological complete response; SC, subcutaneous.
1. Roche, Data on file (approximate number of patients treated up to end of 2019); 2. Roche. Data on file (approximate number of patients treated up to February 2021).

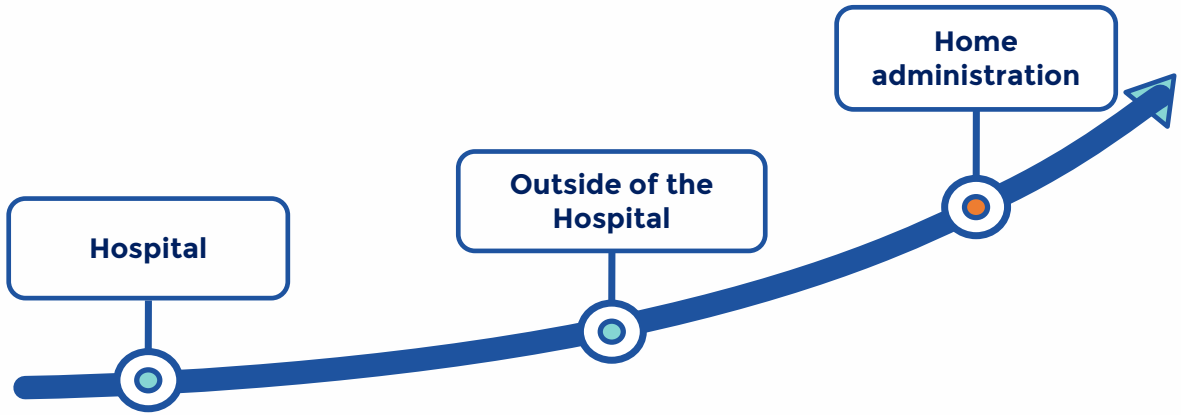
Fermata BREAST CANCER

F. Hoffmann-La Roche, data on file

Powered by Roche

ROCHE CONNECTIONS
New pathways for oncology

The steppingstone over time in Patient's journey for the Tx of «HER»2+ BC



Powered by Roche

Step 1

ROCHE CONNECTIONS
New pathways for oncology

Pertuzumab–Herceptin has transformed the treatment landscape and is a standard of care for patients with HER2-positive BC

Setting	Neoadjuvant (eBC at high risk of recurrence)[1,2]	Adjuvant (eBC at high risk of recurrence)[1,2]	Metastatic (1L mBC)[1,2]
Pivotal study	NeoSphere[3]	APHINITY[7]	CLEOPATRA[11,12]
Key findings	• Addition of P to H + chemo significantly improved bpCR rates from 31% to 49% compared with H + chemo alone[3]	• APHINITY met its primary objective: 19% reduction in risk of an IDFS event with P + H vs. pla + H. At the primary analysis, the node-positive and HR-negative subgroups showed the most pronounced benefit from PH[7] • Results at the second[8] and third[9] interim analyses were consistent with the primary analysis	• Addition of P to H + chemo significantly increased median PFS from 12.4 months to 18.5 months vs. H + chemo + pla[11] • Median OS was also significantly increased in the PH + chemo arm (56.5 months) vs. H + chemo + pla arm (40.8)[12]
Additional supporting studies	TRYPHAENA,[4] BERENICE,[5] PEONY[6]	BERENICE[10]	PUFFIN,[13] PERUSE[14]

•1. PERJETA SmPC 2021; 2. PERJETA PI 2021; 3. Gianni L, *et al. Lancet Oncol* 2012; **13**:25–32; 4. Schneeweiss A, *et al. Ann Oncol* 2013; **24**:2278–2284; 5. Swain SM, *et al. Ann Oncol* 2018; **29**:646–653; 6. Shao Z, *et al. JAMA Oncol* 2020; **6**:e193692; 7. von Minckwitz G, *et al. N Engl J Med* 2017; **377**:122–131 (suppl info); 8. Piccart M, *et al.* SABCS 2019 (Abstract GS1-04; oral presentation); 9. Loibl S, *et al.* ESMO Virtual Plenary July 2022; 10. Dang C, *et al. Cancers* 2022; **14**:2596; 11. Baselga J, *et al. N Engl J Med* 2012; **366**:109–119; 12. Swain SM, *et al. N Engl J Med* 2015; **372**:724–734; 13. Xu B, *et al.* ASCO 2019 (Abstract 1026; poster presentation);
14. Bachelot T, *et al. Ann Oncol* 2019; **30**:766–773; 15. AGO Breast Cancer Guidelines 2021; 16. NCCN Breast Cancer Guidelines – Version 4. 2022; 17. Gennari A, *et al. Ann Oncol* 2021; **32**:1475–1495; 18. Cardoso F, *et al. Ann Oncol* 2019; **30**:1194–1220; 19. Burstein HJ, *et al. Ann Oncol* 2021; **32**:1216–1235.

Powered by Roche

IV infusion of Pertuzumab–Herceptin is well established, but can present challenges to patients and healthcare systems

ROCHE CONNECTIONS
New pathways for oncology

Long infusion and observation time/ congestion at clinics & hospitals

- P is infused over 30–60 minutes, followed by observation for 30–60 minutes (for maintenance and loading doses, respectively)[1,2]
- H is infused over 30–90 minutes;[3,4] observation for 2–6 hours (for maintenance and loading doses, respectively)

Challenge of improving resource utilisation

- Preparation time is long, requires high resource utilisation which has associated costs[5,6]

Placement and maintenance of indwelling venous access

- Indwelling venous access can have increased cost, risk of infection, thrombosis and discomfort[5,7–9]

Challenge of venous access in some patients

- Establishing IV access can be particularly burdensome for patients with poor venous access[9]

Fermata BREAST CANCER

•1. PERJETA SmPC 2021; 2. PERJETA PI 2021; 3. Herceptin SmPC 2021; 4. Herceptin PI 2019; 5. De Cock E, *et al. Cancer Med* 2016; **5**:389–397; 6. De Cock E, *et al.* St. Gallen 2013 (Abstract 209; poster presentation); 7. Shivakumar SP, *et al. J Clin Oncol* 2009; **27**:4858–4864; 8. Jackisch C, *et al. Geburtshilfe Frauenheilkd* 2014; **74**:343–349; 9. Fallowfield L, *et al. The Breast* 2015; **24**:166–170.

Powered by Roche

Step 2

Development of SC versus IV formulations offers improvements for patients beyond efficacy

ROCHE CONNECTIONS
New pathways for oncology

Trastuzumab (IV) transformed the treatment landscape of HER2-positive BC[1,2]

Development of a subcutaneous formulation, trastuzumab SC

- Time savings and improved convenience for patients and HCPs[11–14] ✓
- Comparable drug exposure, efficacy and safety for trastuzumab SC and IV[15,16] ✓

Dual blockade with pertuzumab + trastuzumab (IV) improved survival outcomes while maintaining safety and tolerability profiles[3–10]

Development of a subcutaneous formulation, PH FDC SC[17–20]

- First to combine two mAbs (pertuzumab + trastuzumab) in a single syringe for SC injection[17]
- Faster and less invasive than two separate IV infusions[17,20]

Powered by Roche

FeDeriCa: PH FDC SC showed non-inferior PK vs. pertuzumab + trastuzumab IV, with comparable efficacy and safety

ROCHE CONNECTIONS
New pathways for oncology

PH FDC SC was non-inferior to pertuzumab + trastuzumab IV, based on Cycle 7 (pre-dose Cycle 8) pertuzumab and trastuzumab serum C_{trough} concentrations[1]

The tpCR rate of PH FDC SC (59.7%) was nearly identical to that of pertuzumab + trastuzumab IV (59.5%)[1] and consistent with previous data from trials with pertuzumab + trastuzumab IV + chemotherapy[2–5]

The safety profile of PH FDC SC was comparable to that of pertuzumab + trastuzumab IV[1] and was consistent with previous pertuzumab + trastuzumab IV + chemotherapy trials;[2,3,6] no new safety signals were identified[1]

1. Tan AR, *et al. Lancet Oncol* 2021; 2. Schneeweiss A, *et al. Ann Oncol* 2013; 3. Swain SM, *et al. Ann Oncol* 2018; 4. Loibl S, *et al. Ann Oncol* 2017; 5. Hurvitz SA, *et al. Lancet Oncol* 2018; 6. Gianni L, *et al. Lancet Oncol* 2012.

Powered by Roche

ROCHE CONNECTIONS
New pathways for oncology

PHranceSCa is a Phase II, open-label, randomised crossover study evaluating patient preference for PH FDC SC vs. P + H IV

85% of patients (136/160; 95% CI = 79, 90%, 100% completion rate) had a preference for PH FDC administration vs. 14% (22/160) of patients who preferred P + H IV administration[1*]

TASQ results supported patient preference: **more patients were "Very satisfied" or "Satisfied" with PH FDC administration vs. P + H IV[1]**

Most patients (87%) chose PH FDC to complete their treatment[1]

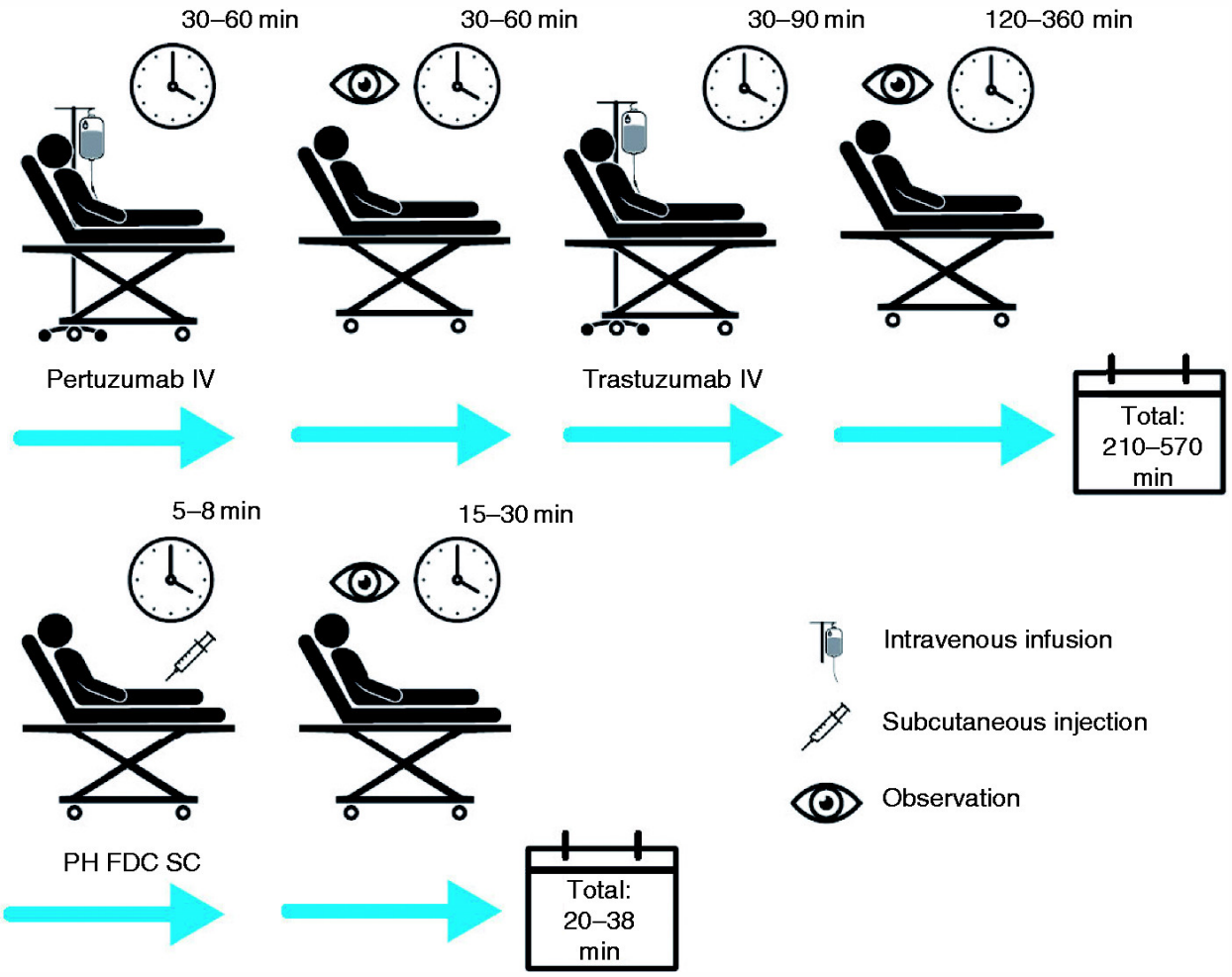
PH FDC was generally well tolerated, with a safety profile in line with previous studies using P + H IV administration[1–3]

No new safety signals were observed, including when switching from IV to SC[1]

Safety results support those seen with PH FDC in the FeDeriCa study[1,4]

H, trastuzumab; IV, intravenous; P, pèertuzumab; SC, subcutaneous.

1. O'Shaughnessy J, et al. Eur J Cancer 2021.;
2. von Minckwitz G, et al. N Engl J Med 2017;377:122–131;
3. Baselga J, et al. N Engl J Med 2012;366:109–119;
4, Tan AR,et al. Lancet Oncol 2021.



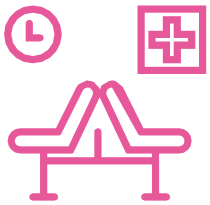
Manevy F, et al. ASCO 2021 DOI: 10.1200/JCO.2021.39.15_suppl.544 Journal of Clinical Oncology 39, no. 15_suppl (May 20, 2021) 544-544..

Powered by Roche

Switching from pertuzumab + trastuzumab IV to PH FDC SC can lead to a reduction in non-drug costs of approximately 80%

ROCHE CONNECTIONS
New pathways for oncology

For a typical patient receiving treatment for HER2-positive eBC in Western Europe*, switching from PH IV to PH FDC SC can lead to:



Up to
85%
savings on chair time costs

Up to
65%
savings on patients' productivity losses

Up to
76%
savings on active HCP time costs

Up to
69%
savings on non-drug consumables costs

Manevy F, et al. ASCO 2021 DOI: 10.1200/JCO.2021.39.15_suppl.544 Journal of Clinical Oncology 39, no. 15_suppl (May 20, 2021) 544-544..

Powered by Roche

ROCHE CONNECTIONS
New pathways for oncology

Progetto S.M.A.R.T. Care

Soluzioni e Metodi Avanzati di Riorganizzazione Territoriale in Sanità

24 pazienti arruolati di cui 16 assistiti da Caregiver

Prestazioni previdenziali, ferie, permessi e sospensioni dal lavoro richieste dal Caregiver

Richiesta di permessi retribuiti legge 104/92	4 persone
Richiesta di giorni di ferie	4 persone
Richiesta di sospensione dal lavoro	4 persone
Richiesta di giorni di permesso	4 persone

Powered by Roche

ROCHE CONNECTIONS
New pathways for oncology

Progetto S.M.A.R.T. Care

Soluzioni e Metodi Avanzati di Riorganizzazione Territoriale in Sanità

	TERAPIA OSPEDALIERA	TERAPIA TERRITORIALE
Richiesto accompagnamento da Caregiver	50%	30%
Il paziente riesce a recarsi da solo in struttura	50%	70%
Evita al Caregiver di chiedere permessi sul lavoro	0%	70%
Durata media di ogni accesso Come dichiarato dai pazienti	2 – 4 ore	15 min – 1 ora

Powered by Roche

The opportunity OBI represents the next stepping stone in the revolution of the Tx of HER2+ BC patients

ROCHE CONNECTIONS
New pathways for oncology

PHESGO "On Body Injector" (OBI) vision

*PHESGO On Body Injector (OBI) revolutionizes the **treatment with PH in all HER2+ indications**, allowing **more flexibility and time** for life for patients, **improving the healthcare systems efficiency** and ability to **move care outside of the hospital***

Step 3

Home administration

Or

PHESGO OBI at any location

Patient-centric wearable injector

- **Hidden needle**
- User loaded
- Ready to use sterile
- Intuitive user interface
- Enhanced ergonomics

Technology

- Formulation which supports **10mL volume**
- Allow for steady delivery within 4-10 mins (incl. prep time)

Storage and Disposal

- **Single-use** on body injector with pre-filled cartridge
- Store at **2°C to 8°C**. Do not use if it is left out of the refrigerator for more than 24 hours.
- **Size of outer carton**: 225 x 135 x 52 mm
- Can be disposed in a standard **sharps bin**

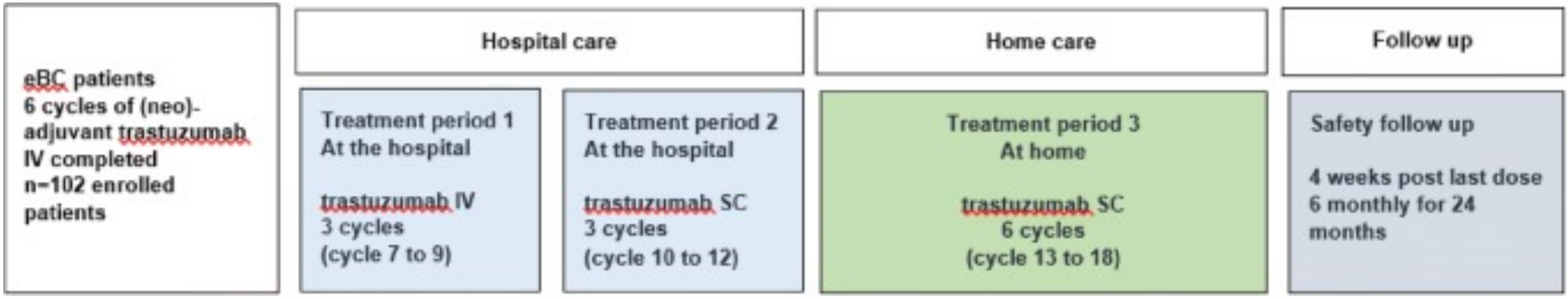
Fermata BREAST CANCER

Powered by Roche

ROCHE CONNECTIONS
New pathways for oncology

Study Design:

Safety and tolerability of subcutaneous trastuzumab at home administration, results of the phase IIIb ìopen-label BELIS study in HER2-positive early breast cancer



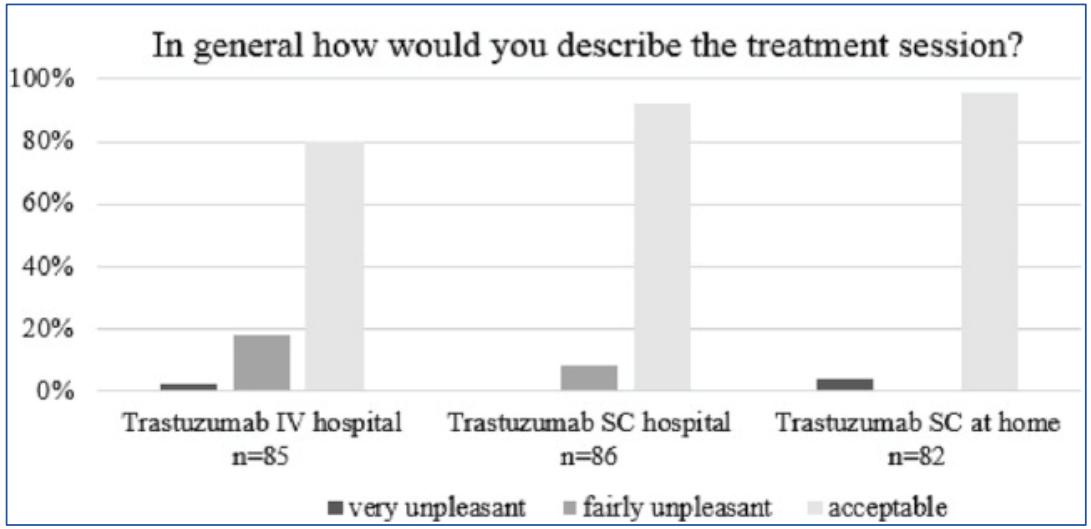
Fermata BREAST CANCER

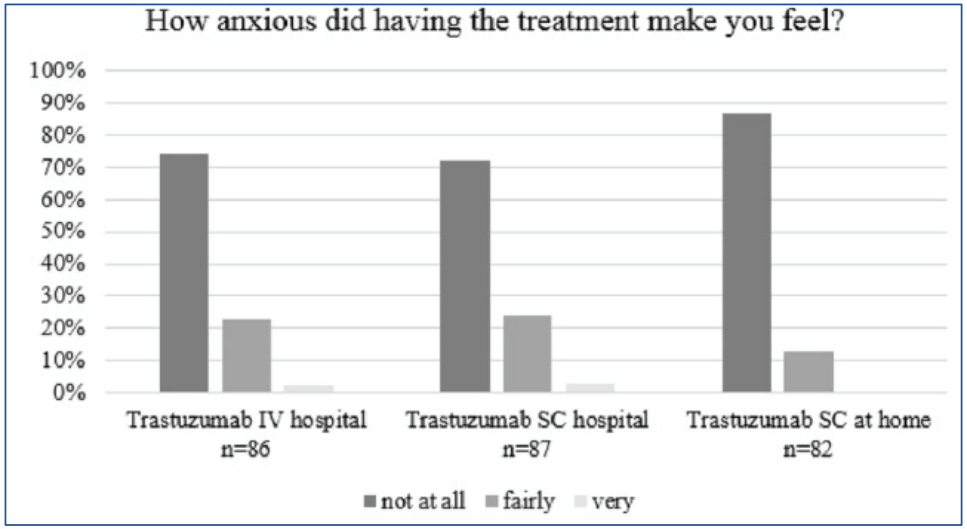
Denys H, at al Breast Cancer Res Treat. 2020 May;181(1):97-105

Powered by Roche

ROCHE CONNECTIONS
New pathways for oncology

Treatment experience with trastuzumab at the hospital (IV and SC) and at home (SC)





Fermata BREAST CANCER

Denys H, at al Breast Cancer Res Treat. 2020 May;181(1):97-105

Powered by Roche

Conclusions

ROCHE CONNECTIONS
New pathways for oncology

Data from clinical trials show that, compared to in travenous administration, subcutaneous trastuzumab is **preferred by patients, saves time for medical staff, shortens the time of drug preparation and administration, and reduces direct and indirect costs**;

Home-based treatment with subcutaneously administered trastuzumab is safe and easy to organize, positively perceived by both patients and nurses. *It can be particularly important for disabled patients who have difficulty reaching the hospital, as well as for professionally active patients.*

The **FlexCare project** was an example of the growing popularity of initiatives that reduce the burden of patients traveling to cancer centers.

Moving **treatment closer to patients or even to their homes by setting up satellite centers or mobile offices increases** the possibilities of therapy and is accepted.