

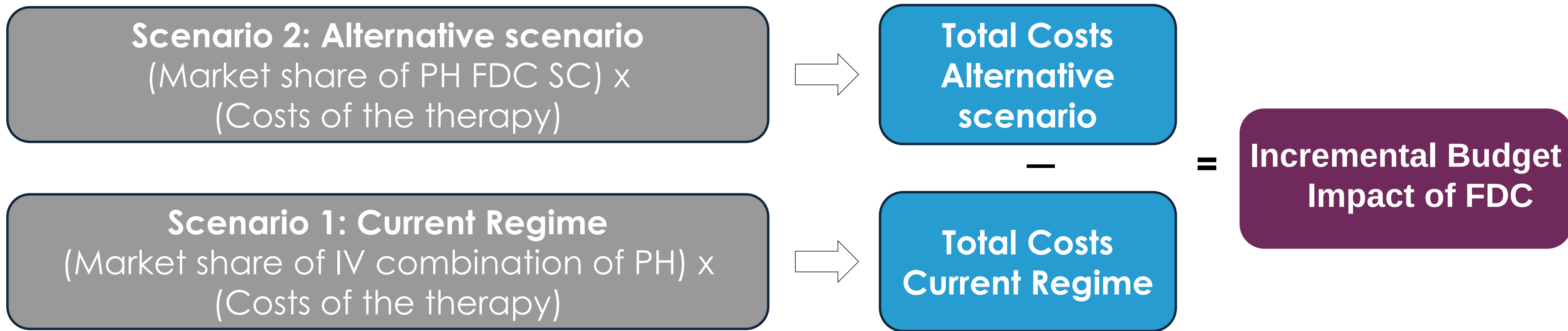
FIXED-DOSE COMBINATION OF PERTUZUMAB AND TRASTUZUMAB FOR SUBCUTANEOUS INJECTION IN THE TREATMENT OF HER2-POSITIVE BREAST CANCER (HER2+ BC) PATIENTS IN ITALY: A BUDGET IMPACT ANALYSIS

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Objective

- ◆ A new fixed-dose combination (FDC) of pertuzumab and trastuzumab (PH) administered by a single subcutaneous (SC) injection was recently approved for HER2+ BC treatment as an alternative to the conventional intravenous (IV) combination of PH, prepared and administered sequentially
- ◆ PH FDC SC has comparable safety and efficacy relative to IV combination [1]
- ◆ This research aims to estimate the budget impact of implementing PH FDC SC for the adjuvant and first-line metastatic treatment of HER2+ BC patients over three years in Italy from both a hospital and societal perspective

Figure 1. Model structure



Results

- ◆ In the next 3 years, in adjuvant and metastatic setting, 1,462 and 4,937 new patients, respectively, are expected to be eligible to receive PH FDC SC in Italy (**Table 1**)
- ◆ The introduction of PH FDC SC in Italian market should head to savings in 3 years, both from the Hospital perspective (€1.3 million and €5.9 million in adjuvant setting and metastatic, respectively) and Societal perspective (€1.7 million and €8 million, respectively) (**Table 3, Table 4**)
- ◆ **Figure 2** shows annual incremental savings by activity due to PH FDC SC relative to IV formulation from societal perspective

Methods

- ◆ A budget impact model was used to estimate costs with and without the adoption of PH FDC SC as a treatment option reimbursed by the Italian NHS (**Figure 1**)
- ◆ Number of eligible patients were estimated from published Italian epidemiological data and projected market shares [2] (**Table 1**). Switch from IV to SC was allowed and considered, as emerged in trial PHranceSCa [3]. Eligible patients entered the model simulation gradually and steadily over each year
- ◆ Hospital perspective included healthcare professionals (HCP) costs for drug preparation and administration activities, costs of non-drug consumables, central access catheter-related costs (CACs), adverse event management costs, and drug acquisition costs. Societal perspective included cost of lost productivity of patients and caregivers (**Table 2**)
- ◆ Resource consumption for the administration of IV and SC drugs was detected identifying all the phases that make up the patient's hospital time, from admission to discharge [4,5,6].
- ◆ Unit costs, updated to 2020-value, were collected from published literature and institutional Italian data [6,7,8,9,10]. For drugs, ex-factory price net of mandatory discounts (reported in Table 2) and further reductions agreed with AIFA (confidential discounts) was considered [10]
- ◆ The duration of the treatment is assumed to be 16.5 cycles in adjuvant setting, as reported in APHINITY trial and 27.50 cycles in metastatic setting (Roche analysis from AIFA registers)

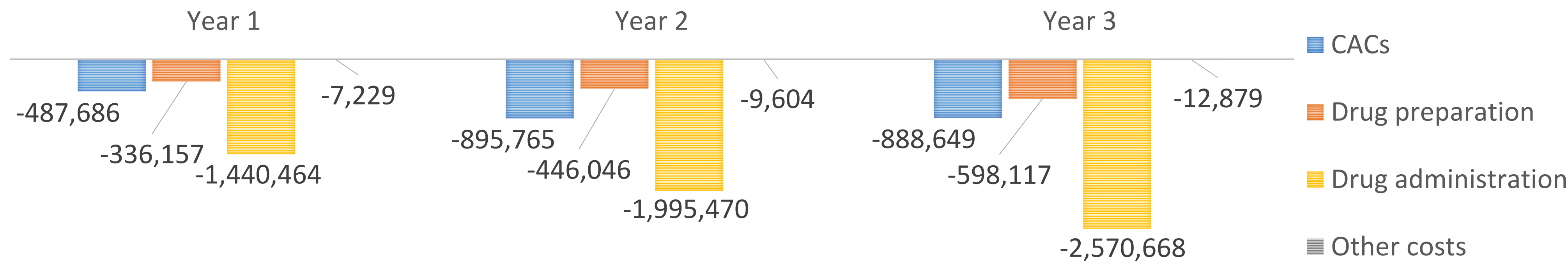
Table 3. BI results – Adjuvant from societal perspective by category

Current	Year 1	Year 2	Year 3
PH IV Cost	17,414,042	20,046,329	20,372,006
Total Other Costs	1,744,221	1,938,089	1,958,731
Total Annual Cost	19,158,264	21,984,418	22,330,738
Alternative	Year 1	Year 2	Year 3
PH FDC SC Cost	5,223,266	9,094,200	11,202,565
PH IV Cost	12,189,829	10,950,487	9,167,403
Total Other Costs	1,396,243	1,309,937	1,243,166
Total Annual Cost	18,809,338	21,354,624	21,613,133
Budget Impact	-348,925	-629,794	-717,604

Table 4. BI results- Metastatic from societal perspective by category

Current	Year 1	Year 2	Year 3
PH IV Cost	118,022,032	116,951,857	115,791,591
Total Other Costs	9,707,590	9,618,290	9,521,959
Total Annual Cost	127,729,623	126,570,147	125,313,550
Alternative	Year 1	Year 2	Year 3
PH FDC SC Cost	35,400,076	45,513,731	61,136,870
PH IV Cost	82,615,423	71,429,793	54,643,446
Total Other Costs	7,784,024	6,899,556	6,167,214
Total Annual Cost	125,799,524	123,843,080	121,947,530
Budget Impact	-1,930,099	-2,727,067	-3,366,020

Figure 2: Delta Total Other costs in adjuvant and metastatic settings (aggregated) from societal perspective



Conclusions

- ◆ Cost analysis suggests that PH FDC SC is a cost-saving alternative to the IV combination of PH when treating HER2+ BC patients in Italy
- ◆ When indirect costs are considered, PH FDC SC even guarantees a reduction in overall therapy costs. On top of savings on consumables, the time-decrease in drug preparation and administration phases has a positive impact on indirect costs associated with the loss of productivity of the patient and caregiver, promoting cost savings from the societal perspective

Table 1. Market share in adjuvant and first-line metastatic settings

	Year 1	Year 2	Year 3
Adjuvant	All=760 (New=474)	All=889 (New=494)	All=906 (New=494)
Metastatic	All=4181 (New=1662)	All=4148 (New=1646)	All=4106 (New=1629)
Current Scenario			
PH IV	100%	100%	100%
Alternative Scenario			
PH FDC SC	30%	55%	55%
PH IV	70%	45%	45%

Table 2. Direct and Indirect Costs

Cost item	Reference	Value (€)
Hospital costs		
Drug ⁴	Trastuzumab IV 150 mg ⁵	462.37
	Trastuzumab IV 420 mg ⁵	1,294.64
	Pertuzumab IV ⁵	2,741.63
	PH FDC SC 10 ml (600mg/600mg) ⁶	7,449.43
	PH FDC SC 15 ml (1200mg/600mg) ⁶	13,274.99
	Pharmacist	62,159
HCPs year wage ⁷	Pharmacy technician	33,566
	Clinical nurse specialist	33,715
	Staff nurse	29,295
	Administrative staff	28,226
	Reception/Security staff	26,804
Consumables (per cycle)	IV therapy	25.19
	SC therapy	10.43
CACs (total cost per patient) ⁸	PH IV	1,213.35
	PH FDC SC	452.30
Societal costs		
Patient/Caregiver	Loss of productivity	29,380

⁴ For drugs weight-based, considering 72.2 Kg, according to AIFA register

⁵ Ex-factory price net of mandatory discounts. For drug cost, confidential discounts were applied (Hospital pricing)

⁶ Public gross price. For drug cost, ex-factory price net of mandatory and confidential discounts was used

⁷ Assuming HCP works 36 hours per week. Nurse takes care of six patients during waiting time

⁸ For PH FDC SC was considered 10%, 7% and 83% for PORT, PICC and “no usage”, respectively – assuming same distribution for both settings. For PH IV instead 30%,16% and 54%, respectively

References

[1] A.R.Tan. (2021). Fixed-dose combination of pertuzumab and trastuzumab for subcutaneous injection plus chemotherapy in HER2-positive early breast cancer (FeDeriCa): a randomised, open-label, multicentre, non-inferiority, phase 3 study. The Lancet Oncology, 22(1), 85-97 [2] IQVIA Market Research [3] O'Shaughnessy J, et al. Preference for the fixed-dose combination of pertuzumab and trastuzumab for subcutaneous injection in patients with HER2-positive early breast cancer (PHranceSCa): A randomised, open-label phase II study. Eur J Cancer, 2021;152:223-232 [4] L. O'Brien et al. (2019). Cost Minimization Analysis of Intravenous or Subcutaneous Trastuzumab Treatment in Patients With HER2-Positive Breast Cancer in Ireland. Clinical Breast Cancer, 19, 440-51 [5] J. Olsen et al. (2018). Costs of subcutaneous and intravenous administration of trastuzumab for patients with HER2-positive breast cancer. J Comp Eff Res, 7(5), 411-419 [6] Martella et al, (2015). A retrospective analysis of trabectedin infusion by peripherally inserted central venous catheters: a multicentric Italian experience, Anti-Cancer Drugs, 26, 990-994 [7] Osservatorio Job Pricing (2019), JP Salary Outlook 2019 [8] CCNL 2016-2018 del Comparto Sanità – Aran [9] SCuBa analysis 2018 [10] Hospital tender prices/Roche proposed price