

The impact of first line CDk4/6 inhibitors on HR+/HER2- mBC patients' financial toxicity, treatment compliance, QOL and outcome

An ancillary study of GIM 14 BIOMETA

Objectives

- **Primary objective:** to evaluate the impact of first line CDk4/6 inhibitors on HR+/HER2- mBC patients' financial toxicity
- **Primary endpoint:** on treatment variation of the PROFFIT score
- **Secondary objectives:**
 - to evaluate the correlation between baseline and on treatment financial toxicity (variation in the PROFFIT score) and treatment compliance, QOL and outcome
 - to describe treatment compliance, QOL and outcome with first line CDk4/6 inhibitors on HR+/HER2- mBC patients in a real life cohort
- **Exploratory objectives:** to explore differences to previously cited outcomes by CDk4/6 inhibitors type

Background

*ecancer*medicalsecience

Evidence on the cost of breast cancer drugs is required for rational decision making

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The association of financial difficulties with clinical outcomes in cancer patients: secondary analysis of 16 academic prospective clinical trials conducted in Italy[†]

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Recenti Prog Med 2015; 106: 11-13

Sostenibilità e nuovi farmaci antitumorali

Francesco Perrone¹

Looking for sustainability of new anticancer drugs.

Clin Breast Cancer. 2019 Aug;19(4):e519-e521. doi: 10.1016/j.clbc.2019.02.004. Epub 2019 Feb 16.

Palbociclib or Ribociclib in First-Line Treatment in Patients With Hormone Receptor-Positive/Human Epidermal Receptor 2-Negative Advanced or Metastatic Breast Cancer? A Perspective Based on Pharmacologic Costs.

Giuliani J¹, Bonelli A².

Methods -1

Ancillary study of GIM 14 BIOMETA, a multicentric prospective cohort study conducted within the Gruppo Italiano Mammella.

Inclusion criteria:

- Patients eligible for BIOMETA study
- HR+ HER2- patients newly diagnosed for mBC receiving first line CDk4/6 inhibitors
- Written informed consent

Methods - 2

- **PROFFIT:** baseline, day 1 cycle 3, day 1 cycle 5, every 6 months thereafter
- **PRO:** EORTC-QLQ-C30, FACT-B, COST-FACIT at baseline, day 1 cycle 3, day 1 cycle 5, every 6 months thereafter
- **Treatment compliance:** each clinical visit
- **Outcomes:** OS, PFS as BIOMETA study

Feasibility and realisation times

- Since BIOMETA Study Amendment approval: 24 months enrolment followed by 6 months of analysis
- 30 months
- Estimated sample size: 400 patients
- GIM-14 BIOMETA Study is ongoing
 - 22 centers
 - Retrospective cohort: 1710 patients
 - Prospective cohort: 570 patients

Andamento arruolamenti/centro al 25.06.2019

Responsabile centro	Località	Coorte	2015	2016	2017	2018												2019						Sub Tot.	Tot.
			11-12	01-12	01-12	01	02	03	04	05	06	07	08	09	10	11	12	01	02	03	04	05	06		
Stefania Russo		Retr.			575																	1	576	652	
UDINE		Pros.	0	0	0	0	31	8	4	4	0	0	0	0	1	0	0	0	0	13	13	0	2		76
24/07/2015																									
Claudia Bighin		Retr.		211	187	26	6	6	5	12	2	1	1	1	3		3	1		4	1		470	599	
GENOVA		Pros.	0	4	64	18	6	7	1	2	0	1	2	2	0	2	0	5	3	0	9	3	0		129
17/07/2015																									
Francesco Cognetti		Retr.			105	6		11	5	2	4	5	2	4			2	11	6	10			173	213	
ROMA		Pros.	0	0	2	0	0	4	6	8	10	3	1	2	0	0	0	0	1	1	2	0	40		
20/11/2015																									
Michelino De Laurentiis		Retr.		44	65			1															110	154	
NAPOLI		Pros.	0	5	36	0	0	0	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0		44
25/11/2015																									
Grazia Arpino		Retr.		11	25			10											1	18	16	4	85	137	
NAPOLI		Pros.	0		30	0	6	12	1	0	0	0	0	0	0	0	0	0	0	3	0		52		
04/12/2015																									
Andrea Fontana		Retr.		49	2			1	9	4	1									5	2		73	114	
PISA		Pros.	0	3	5	0	0	1	1	3	12	8	0	0	0	0	0	0	0	4	2	2	41		
10/12/2015																									
Palma Pugliese		Retr.		7	19	5	6	7	3		3												50	88	
SAN FERMO DELLA BATTAGLIA		Pros.	0	10	6	0	0	1	4	2	6	0	0	0	1	1	0	0	2	2	2	1	38		
10/11/2015																									
Ornella Garrone		Retr.			0			1															1	69	
CUNEO		Pros.	0	0	68	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	68		
30/10/2015																									
Ferdinando Riccardi		Retr.															14	19	9	1			43	51	
NAPOLI		Pros.								0	0	0	0	0	0	0	1	0	0	5	2	0	8		
22/06/2018																									
Antonella Ferzi		Retr.			11																	4	15	41	
LEGNANO		Pros.	0	0	26	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	26		
28/10/2015																									
Valentina Sini		Retr.				3		4	4	8	2												21	35	
ROMA		Pros.			0	0	0	0	0	3	3	0	0	0	1	3	0	1	0	0	1	2	0		14

Responsabile centro Località	Coorte	2015	2016	2017	2018												2019						Sub Tot.	Tot.
		Data apertura 11-12	01-12	01-12	01	02	03	04	05	06	07	08	09	10	11	12	01	02	03	04	05	06		
Filippo Montemurro	Retr.	2		17																			19	29
CANDIOLO	Pros.	0	0	10	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	10	
29/10/2015																								
Giuseppe Naso	Retr.				5	14	9																28	28
ROMA	Pros.		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
29/12/2016																								
Antonio Frassoldati	Retr.								8	2							6						16	23
FERRARA	Pros.				0	0	0	0	0	0	0	0	0	0	0	0	7	0	0	0	0	0	7	
23/02/2018																								
Antonio Bernardo	Retr.		1	9			1																11	17
PAVIA	Pros.	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	4	0	0	0	0	6	
20/10/2015																								
Antonio Pazzola	Retr.																						0	10
SASSARI	Pros.	0	0	10	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	10	
27/10/2015																								
Francesco Silvestris	Retr.		2	1													1	1	1				6	7
BARI	Pros.	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	
21/10/2015																								
Gabriella Farina	Retr.																5	2					7	7
MILANO	Pros.															0	0	0	0	0	0	0	0	
23/01/2019																								
Anna Turletti	Retr.	5		1																			6	6
TORINO	Pros.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
19/10/2015																								
Tot. centri aperti: 22	Coorte	2015	2016	2017	2018												2019						Sub Tot	Tot.
Tot. centri che arruolano: 19		11-12	01-12	01-12	01	02	03	04	05	06	07	08	09	10	11	12	01	02	03	04	05	06		
SubTotale	Retr.	7	325	1017	45	26	48	20	31	23	9	3	5	0	3	0	19	43	19	39	19	9	1710	2280
	Pros.	0	22	258	18	43	33	22	22	31	12	3	4	3	6	0	7	10	20	38	13	5	570	
Totale		7	347	1275	63	69	81	42	53	54	21	6	9	3	9	0	26	53	39	77	38	14*	2280	

* mese corrente

Potential applications

- Definition of the impact of first line CDk4/6 inhibitors on HR+/HER2-mBC patients' financial toxicity, treatment compliance, QOL and outcome in a real-life setting
- Further applications on public health practice
- Abstracts and publications on scientific magazines and presentation at Scientific Meetings

Thank you for your attention!

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