The impact of first line CDk4/6 inhibitors on HR+/HER2- metastatic breast cancer patients' financial toxicity, treatment compliance, quality of life and outcome

An ancillary study of GIM 14 BIO-META

Proposed session: Registri e studi osservazionali

BACKGROUND

- Recent clinical trials demonstrated the efficacy of CDK4/6 inhibitors in first-line treatment of HR+/HER2- metastatic breast cancer (mBC) patients and assessed their role as standard of care in this setting; However, these innovative drugs are very expensive and great efforts on the scientific community are on going to investigate the sustainability of these new agents
- A secondary analysis of 16 academic prospective trials conducted in Italy showed that even in a public health sistem, financial difficulties are associated with relevant cancer patients outcomes such as quality of life and survival *(Perrone F et al. The association of financial difficulties with clinical outcomes in cancer patients: secondary analysis of 16 academic prospective clinical trials conducted in Italy. Ann Oncol. 2016 Dec;27(12):2224-2229).*

PROJECT PLAN

- Protocol Amendment for GIM 14 BIO-META Study: Ancillary Study
- Multicenter, prospective, observational cohort study

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

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 assess differences to the previously cited outcomes according to the type of CDk4/6 inhibitors

METHODS

- 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: as per BIOMETA study

STUDY DURATION

- From Protocol Amendment approval: 24 months enrollment followed by 6 months of analysis (30 months)
- Estimated sample size: 400 patients

IMPACT

- 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

Thank you for your attention!

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