POSTER **MSR83**

Eliciting Patients and Clinicians Preferences on Adjuvant Treatment for HR+/HER2- Early Breast Cancer: Design of a Probabilistic Threshold Technique in Italy

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Objectives

- Hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) early breast cancer (eBC) is usually managed with surgery with or without radiotherapy or chemotherapy, followed by adjuvant endocrine therapy (ET) to reduce recurrence risk.[1] Recently, cyclin-dependent kinase 4/6 inhibitors (CDK4/6is) + ET emerged as adjuvant treatment for high-risk HR+/HER2− eBC[1]
- In an evolving therapeutic landscape, understanding risk-benefit trade-offs is key to support informed choices among available treatment options[2]
- Probabilistic Threshold Technique (PTT) is a preference elicitation approach designed to quantitatively explore respondents' preferences and identify combinations of attributes and levels that make respondents indifferent between proposed alternatives[2]
- Despite the growing adoption of PTT over time,[2] there remains a lack of evidence regarding its application to novel therapies in the adjuvant treatment of eBC in Italy
- The aim of this work is to describe the design of a PTT to quantify the minimum additional benefit (MAB) in terms of efficacy required by Italian patients and clinicians to accept a novel oral adjuvant therapy for HR+/HER2− eBC

Methods

- The PTT was designed around two hypothetical treatment options, modeled on the profiles of ET alone (reference option) and ribociclib+ET (target option)
- Options were described using six attributes identified as relevant in a focus group with three clinicians and three patients: 5-year invasive disease-free survival (iDFS), incidence of grade≥3 neutropenia, incidence of grade≥3 diarrhea, treatment schedule and duration, potential for dose modifications, and impact on sexual health
- Attribute levels were primarily informed by data from the NATALEE trial.[3] For 5-year iDFS, which was not available at the time of design, values were extrapolated from the Kaplan-Meier curve of ET arm[3] and validated through literature[4] and expert input. Impact on sexual health was based on published evidence regarding ET alone and in combination with CDK4/6is[5-10]

Results

- Two identical online questionnaires were developed, one for patients and one for clinicians, with simplified clinical wording for the former
- Since the 5-year iDFS rate was established as the key attribute, both reference and target options were set at a 72% iDFS in the initial question, to reflect the expected real-world efficacy of the reference option (Figure 1 – Question 1)
- Based on the respondent's choice, only the 5-year iDFS of the target option was adjusted upward or downward in subsequent questions, with incremental variations from 1 to 4 percentage points (Figure 1 – Question 2)
- The iterative process continued until the respondent expressed indifference or changed preference, allowing estimation of the MAB in 5-year iDFS required to prefer the target option over the reference (Figure 1 – Question 3)
- Respondents, blinded to the real-world identity of the hypothetical treatments, could answer up to 17 questions, with target iDFS ranging from 44% to 100%, depending on individual preferences

Conclusions

- **This study outlines the methodological framework for applying an increasingly adopted preference elicitation technique to investigate how Italian patients and clinicians weigh risk-benefit profiles in adjuvant treatment for HR+/HER2− eBC**
- **As the first application of PTT in Italy with this specific focus, this study provides methodological guidance to address an evidence gap in shared decision-making by enabling direct comparison of preferences between patients and clinicians**
- **Findings are expected to inform clinical and regulatory decisions by clarifying the trade-offs patients and clinicians are willing to accept for new treatments**

Figure 1. Example of PTT iterative process (clinicians' questionnaire)

PTT: Question 1

Attribute	Alternative A	Alternative B
5-year iDFS	72%	72%
Treatment schedule and duration	One drug, oral, daily for 5 years	Two drugs: 1) Oral, daily for 5 years; 2) Oral, daily for 21 days followed by 7 days off for 3 years
Grade ≥3 neutropenia	1%	44%
Grade ≥3 diarrhea	0%	1%
Potential for dose modification	No	Yes
Impact on sexual health	Negative impact	Negative impact
Which one do you prefer?	☑	☐
	Indifferent ☐	

PTT: Question 2

Attribute	Alternative A	Alternative B
5-year iDFS	72%	~~72%~~ **73%**
Treatment schedule and duration	One drug, oral, daily for 5 years	Two drugs: 1) Oral, daily for 5 years; 2) Oral, daily for 21 days followed by 7 days off for 3 years
Grade ≥3 neutropenia	1%	44%
Grade ≥3 diarrhea	0%	1%
Potential for dose modification	No	Yes
Impact on sexual health	Negative impact	Negative impact
Which one do you prefer?	☑	☐
	Indifferent ☐	

PTT: Question 3

Attribute	Alternative A	Alternative B
5-year iDFS	72%	~~73%~~ **74%**
Treatment schedule and duration	One drug, oral, daily for 5 years	Two drugs: 1) Oral, daily for 5 years; 2) Oral, daily for 21 days followed by 7 days off for 3 years
Grade ≥3 neutropenia	1%	44%
Grade ≥3 diarrhea	0%	1%
Potential for dose modification	No	Yes
Impact on sexual health	Negative impact	Negative impact
Which one do you prefer?	☐	☐
	Indifferent ☑	

Indifference is reached: the iteration stops and the MAB is +2%

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ACRONYMS: BC = Breast Cancer; CDK4/6i = Cyclin-Dependent Kinase 4/6 Inhibitor; eBC = Early Breast Cancer; ET = Endocrine Therapy; HR+/HER2- = Hormone Receptor-positive, Human Epidermal Growth Factor Receptor 2-negative; iDFS = Invasive Disease-Free Survival; MAB = Minimum Additional Benefit; PTT = Probabilistic Threshold Technique

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