

*Riunione Annuale*

**GIM** GRUPPO  
ITALIANO  
MAMMELLA



**26-27 SETTEMBRE 2025 BERGAMO**

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PIAZZA DELLA REPUBBLICA, 6

# DANDY.1

Retrospective analysis of the optimal **D**uration of **A**djuvante **e**NDocrine therap**Y** to validate the prognostic and predictive value of CTS5

## BACKGROUND

- Extended adjuvant endocrine treatment of 7 or 10 years represents the standard of care for intermediate and high risk patients.
- Anti-hormonal therapy related side effects hamper compliance to endocrine treatment.
- CTS5 score was developed to better tailor treatment durations and was validated from data collected in the ATAC and BIG 1–98 study trials.
- However, both trials considered only patients receiving 5 years of endocrine treatment, demonstrating the prognostic role of this tool.
- An attempt to validate the predictive role of the CTS5 has been conducted by the Austrian group using data collected in ABCSG trials

# TRIAL DESIGN

## AIM OF THE STUDY

To validate the prognostic role of CTS5 score using data collected in the GIM3 trial and explore its role using different endocrine treatment compounds

To validate the potentially predictive role of CTS5 score using data collected in the GIM4 trials.

## PRIMARY ENDOPOINT

- iDFS at 10 years

# DANDY.2

Retrospective analysis of the optimal **D**uration of **A**djuvante **e**NDocrine therap**Y** to validate the prognostic and predictive value of CTS5

## BACKGROUND

- Extended adjuvant endocrine treatment of 7 or 10 years represents the standard of care for intermediate and high risk patients.
- Anti-hormonal therapy related side effects hamper compliance to endocrine treatment.
- CTS5 score was developed to better tailor treatment durations and was validated from data collected in the ATAC and BIG 1–98 study trials.
- In recent years, the landscape of adjuvant treatment for intermediate- and high-risk patients has significantly changed after the introduction of two CDK4/6 inhibitors (abemaciclib and ribociclib), leading to a further reduction in recurrence risk
- Currently, decisions regarding endocrine treatment duration are still guided by clinico-pathological factors and mostly do not take into account the addition of CDK4/6 inhibitors. **As the CTS5 score does not incorporate these agents into its evaluation of the recurrence risk, it offers no guidance in this context, raising concerns about the potential overtreatment of patients receiving both CDK4/6 inhibition and an extended adjuvant approach.**

# TRIAL DESIGN

## AIM OF THE STUDY

To define if a de-escalation of adjuvant endocrine treatment duration (according to the CTS5 score) is safe in patients also receiving a CDK4/6 inhibitor as adjuvant treatment.

## Main inclusion criteria

- Histologically confirmed invasive breast adenocarcinoma ER and/or PgR positive, HER2-negative;
- Planned to receive abemaciclib or ribociclib in the adjuvant setting
- Adjuvant chemotherapy allowed
- **CTS5 score resulting in “Intermediate” risk**

## Preliminary Sample Size

- Assumptions: non-inferiority margin HR=1.20, one-sided  $\alpha=0.025$ , 80% power, true effect HR=1.00.
- Required sample size: 496 per arm (992 total). With an anticipated 10% attrition, the adjusted sample size is 545 per arm (1,090 total).

R

CDK4/6i + 5 years of ET

CDK4/6i + 7 years of ET

## Primary endpoint

- iDFS at 10 years

## Secondary endpoints

- OS
- QoL

# TRIAL DESIGN

## AIM OF THE STUDY

To define if a de-escalation of adjuvant endocrine treatment duration (according to the CTS5 score) is safe in patients also receiving a CDK4/6 inhibitor as adjuvant treatment.

## Main inclusion criteria

- Histologically confirmed invasive breast adenocarcinoma ER and/or PgR positive, HER2-negative;
- Planned to receive abemaciclib or ribociclib in the adjuvant setting
- Adjuvant chemotherapy allowed
- **CTS5 score resulting in “High” risk**

## Preliminary Sample Size

- Assumptions: non-inferiority margin HR=1.20, one-sided  $\alpha=0.025$ , 80% power, true effect HR=1.00.
- Required sample size: 496 per arm (992 total). With an anticipated 10% attrition, the adjusted sample size is 545 per arm (1,090 total).

R

CDK4/6i + 7 years of ET

CDK4/6i + 10 years of ET

## Primary endpoint

- iDFS at 10 years

## Secondary endpoints

- OS
- QoL