Forty-one pts (68%) discontinued inavolisib; 36 due to radiographic progression, three due to symptomatic unacceptability toxicity.

All but two pts had received a prior CDK4/6i before study treatment.

The data cut-off date for this analysis was July 26, 2021; 60 pts were enrolled; 19 were still on study treatment.

Safety

- Common adverse events are shown in Table 2.
- Thirty-five pts (58%) had an adverse event leading to dose modification. Six pts (10%) required dose reductions. No treatment-related adverse event resulted in treatment withdrawal.
- Dose modifications included withdrawals, reductions, and interruptions. Reductions may have resulted in pharmacodynamic modifications in 21 pts (35%).
- Two pts were enrolled without prior CDK4/6i when not required in the inclusion criteria.
- A PK profile similar to that of inavolisib alone, lack of drug–drug interactions, and pharmacodynamic modifications using CDA4.

PIK3CA-mutated HR+/HER2– mBC

PIK3CA mutation per local or central testing

Prior treatment with CDK4/6i

Measurable disease per RECIST 1.1

ECOG PS 0–1

PIK3CA-mutated HR+/HER2– mBC

Safety

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PIK3CA-mutated HR+/HER2– mBC

PIK3CA mutation per local or central testing

Prior treatment with CDK4/6i

Measurable disease per RECIST 1.1

ECOG PS 0–1

PIK3CA-mutated HR+/HER2– mBC

EXPANSION

Safety

- Common adverse events are shown in Table 2.
- Thirty-five pts (58%) had an adverse event leading to dose modification. Six pts (10%) required dose reductions. No treatment-related adverse event resulted in treatment withdrawal.
- Dose modifications included withdrawals, reductions, and interruptions. Reductions may have resulted in pharmacodynamic modifications in 21 pts (35%).
- Two pts were enrolled without prior CDK4/6i when not required in the inclusion criteria.
- A PK profile similar to that of inavolisib alone, lack of drug–drug interactions, and pharmacodynamic modifications using CDA4.