Health-related quality of life and pain outcomes for patients with metastatic castration-resistant prostate cancer who received olaparib and abiraterone versus abiraterone and placebo in the Phase III PROpel trial

Introduction

PROpel met its primary endpoint and showed a statistically significant and clinically meaningful rPFS benefit for patients with mCRPC. In patients who had baseline HRQoL scores similar to those in PROpel, rPFS was 20.6 months longer with olaparib plus abiraterone versus placebo plus abiraterone in an investigator-rated first-line treatment of patients with mCRPC (HR 0.33, 95% CI 0.18, 0.59).

Objectives

- To investigate patient-reported outcomes in the PROpel trial, including health-related quality of life (HRQoL) and pain outcomes.

Conclusions

- Additional endpoints of importance to patients with metastatic castration-resistant prostate cancer (mCRPC) are also reported.
- PROpel included a unique analysis of symptom burden in mCRPC, which was previously unexplored.
- PROpel was the first mCRPC trial to evaluate symptom burden as a primary endpoint.
- Additional endpoints of importance to patients with metastatic castration-resistant prostate cancer (mCRPC) are also reported.

Results

Baseline characteristics

- Table 1: Baseline characteristics of patients with a BPI-SF Item 3 pain score of 4–<6 (moderate pain) were similar between arms throughout the treatment period.
- No meaningful difference in time to first SSRE was observed in the ITT population (median time to first SSRE 12.3 months in both arms).
- Os (final prespecified) (n=397)

FACT-P

- Table 4: LS mean changes from baseline in FACT-P total score was similar in both arms.
- Table 3: FACT-P total score was similar between the arms throughout the treatment period.
- No meaningful difference in time to first SSRE was observed in the ITT population (median time to first SSRE 12.3 months in both arms).

Compliance

- Table 2: Questionnaire compliance was in line with what is typically observed for randomized trials.
- No meaningful difference in time to first SSRE was observed in the ITT population (median time to first SSRE 12.3 months in both arms).
- Os (final prespecified) (n=397)

Pain

- Table 5: Pain: LS mean changes from baseline in BPISF Item 3 pain scores at post, pain severity, and pain interference showed no overall difference between the arms.
- No meaningful difference in time to first SSRE was observed in the ITT population (median time to first SSRE 12.3 months in both arms).
- Os (final prespecified) (n=397)

Supporting information

- See supplement for endpoint definitions and statistical analysis.
- PROpel included a unique analysis of symptom burden in mCRPC, which was previously unexplored.
- PROpel was the first mCRPC trial to evaluate symptom burden as a primary endpoint.
- Additional endpoints of importance to patients with metastatic castration-resistant prostate cancer (mCRPC) are also reported.

Statistical analysis

- Analysis of time to cytotoxic chemotherapy was post hoc. See supplement for endpoint definitions and statistical analysis.

Reference


Trial registration

- NCT03724720

Acknowledgments

- The authors thank all the PROpel investigators, patients, and staff.
- The authors thank all the PROpel investigators, patients, and staff.
- The authors thank all the PROpel investigators, patients, and staff.

Methods

- PROpel was randomized, double-blind trial in first-line mCRPC.
- Patients received either olaparib plus abiraterone, placebo plus abiraterone, or placebo plus abiraterone.
- Patients were randomized 2:1:1 to receive olaparib plus abiraterone, placebo plus abiraterone, or placebo plus abiraterone.
- Patients were randomized 2:1:1 to receive olaparib plus abiraterone, placebo plus abiraterone, or placebo plus abiraterone.

Objectives

- To investigate patient-reported outcomes in the PROpel trial, including health-related quality of life (HRQoL) and pain outcomes.
- Additional endpoints of importance to patients with metastatic castration-resistant prostate cancer (mCRPC) are also reported.
- PROpel included a unique analysis of symptom burden in mCRPC, which was previously unexplored.
- PROpel was the first mCRPC trial to evaluate symptom burden as a primary endpoint.
- Additional endpoints of importance to patients with metastatic castration-resistant prostate cancer (mCRPC) are also reported.

Conclusions

- Additional endpoints of importance to patients with metastatic castration-resistant prostate cancer (mCRPC) are also reported.
- PROpel included a unique analysis of symptom burden in mCRPC, which was previously unexplored.
- PROpel was the first mCRPC trial to evaluate symptom burden as a primary endpoint.
- Additional endpoints of importance to patients with metastatic castration-resistant prostate cancer (mCRPC) are also reported.

Results

Baseline characteristics

- Table 1: Baseline characteristics of patients with a BPI-SF Item 3 pain score of 4–<6 (moderate pain) were similar between arms throughout the treatment period.
- No meaningful difference in time to first SSRE was observed in the ITT population (median time to first SSRE 12.3 months in both arms).
- Os (final prespecified) (n=397)

FACT-P

- Table 4: LS mean changes from baseline in FACT-P total score was similar in both arms.
- Table 3: FACT-P total score was similar between the arms throughout the treatment period.
- No meaningful difference in time to first SSRE was observed in the ITT population (median time to first SSRE 12.3 months in both arms).

Compliance

- Table 2: Questionnaire compliance was in line with what is typically observed for randomized trials.
- No meaningful difference in time to first SSRE was observed in the ITT population (median time to first SSRE 12.3 months in both arms).
- Os (final prespecified) (n=397)

Pain

- Table 5: Pain: LS mean changes from baseline in BPISF Item 3 pain scores at post, pain severity, and pain interference showed no overall difference between the arms.
- No meaningful difference in time to first SSRE was observed in the ITT population (median time to first SSRE 12.3 months in both arms).
- Os (final prespecified) (n=397)

Supporting information

- See supplement for endpoint definitions and statistical analysis.
- PROpel included a unique analysis of symptom burden in mCRPC, which was previously unexplored.
- PROpel was the first mCRPC trial to evaluate symptom burden as a primary endpoint.
- Additional endpoints of importance to patients with metastatic castration-resistant prostate cancer (mCRPC) are also reported.

Statistical analysis

- Analysis of time to cytotoxic chemotherapy was post hoc. See supplement for endpoint definitions and statistical analysis.

Reference


Trial registration

- NCT03724720

Acknowledgments

- The authors thank all the PROpel investigators, patients, and staff.
- The authors thank all the PROpel investigators, patients, and staff.
- The authors thank all the PROpel investigators, patients, and staff.

Methods

- PROpel was randomized, double-blind trial in first-line mCRPC.
- Patients received either olaparib plus abiraterone, placebo plus abiraterone, or placebo plus abiraterone.
- Patients were randomized 2:1:1 to receive olaparib plus abiraterone, placebo plus abiraterone, or placebo plus abiraterone.
- Patients were randomized 2:1:1 to receive olaparib plus abiraterone, placebo plus abiraterone, or placebo plus abiraterone.

Objectives

- To investigate patient-reported outcomes in the PROpel trial, including health-related quality of life (HRQoL) and pain outcomes.
- Additional endpoints of importance to patients with metastatic castration-resistant prostate cancer (mCRPC) are also reported.
- PROpel included a unique analysis of symptom burden in mCRPC, which was previously unexplored.
- PROpel was the first mCRPC trial to evaluate symptom burden as a primary endpoint.
- Additional endpoints of importance to patients with metastatic castration-resistant prostate cancer (mCRPC) are also reported.

Conclusions

- Additional endpoints of importance to patients with metastatic castration-resistant prostate cancer (mCRPC) are also reported.
- PROpel included a unique analysis of symptom burden in mCRPC, which was previously unexplored.
- PROpel was the first mCRPC trial to evaluate symptom burden as a primary endpoint.
- Additional endpoints of importance to patients with metastatic castration-resistant prostate cancer (mCRPC) are also reported.

Results

Baseline characteristics

- Table 1: Baseline characteristics of patients with a BPI-SF Item 3 pain score of 4–<6 (moderate pain) were similar between arms throughout the treatment period.
- No meaningful difference in time to first SSRE was observed in the ITT population (median time to first SSRE 12.3 months in both arms).
- Os (final prespecified) (n=397)

FACT-P

- Table 4: LS mean changes from baseline in FACT-P total score was similar in both arms.
- Table 3: FACT-P total score was similar between the arms throughout the treatment period.
- No meaningful difference in time to first SSRE was observed in the ITT population (median time to first SSRE 12.3 months in both arms).

Compliance

- Table 2: Questionnaire compliance was in line with what is typically observed for randomized trials.
- No meaningful difference in time to first SSRE was observed in the ITT population (median time to first SSRE 12.3 months in both arms).
- Os (final prespecified) (n=397)

Pain

- Table 5: Pain: LS mean changes from baseline in BPISF Item 3 pain scores at post, pain severity, and pain interference showed no overall difference between the arms.
- No meaningful difference in time to first SSRE was observed in the ITT population (median time to first SSRE 12.3 months in both arms).
- Os (final prespecified) (n=397)

Supporting information

- See supplement for endpoint definitions and statistical analysis.
- PROpel included a unique analysis of symptom burden in mCRPC, which was previously unexplored.
- PROpel was the first mCRPC trial to evaluate symptom burden as a primary endpoint.
- Additional endpoints of importance to patients with metastatic castration-resistant prostate cancer (mCRPC) are also reported.

Statistical analysis

- Analysis of time to cytotoxic chemotherapy was post hoc. See supplement for endpoint definitions and statistical analysis.

Reference


Trial registration

- NCT03724720

Acknowledgments

- The authors thank all the PROpel investigators, patients, and staff.
- The authors thank all the PROpel investigators, patients, and staff.
- The authors thank all the PROpel investigators, patients, and staff.

Methods

- PROpel was randomized, double-blind trial in first-line mCRPC.
- Patients received either olaparib plus abiraterone, placebo plus abiraterone, or placebo plus abiraterone.
- Patients were randomized 2:1:1 to receive olaparib plus abiraterone, placebo plus abiraterone, or placebo plus abiraterone.
- Patients were randomized 2:1:1 to receive olaparib plus abiraterone, placebo plus abiraterone, or placebo plus abiraterone.