FOUNDATIONONE® CDx

Clinical Data Summary

PROfound for Prostate Cancer Patients

PROfound is the first phase III biomarker-selected study to evaluate a molecularly-targeted treatment in patients with metastatic castrate-resistant prostate cancer (mCRPC) with positive outcomes.

The PROfound trial is the largest prospective study to date performing central tissue testing for homologous recombination repair (HRR) gene mutations in mCRPC patients.

The clinical trial assay (CTA) is an NGS assay based on FoundationOne®CDx.

Results from PROfound Trial Cohort A

Patients tested positive for HRR gene mutations (specifically in *BRCA1*, *BRCA2* and *ATM*) using their tumor tissue to determine eligibility for olaparib (PARP inhibitor)

The patients eligible and enrolled in the trial were first line mCRPC patients who had previously received treatment with a new hormonal agent.

2,792 patients
were successfully sequenced using FoundationOne CDx based CTA

↓

245 patients
who tested positive for *BRCA1/2* or *ATM* were included in the cohort*

Median Progression-Free Survival

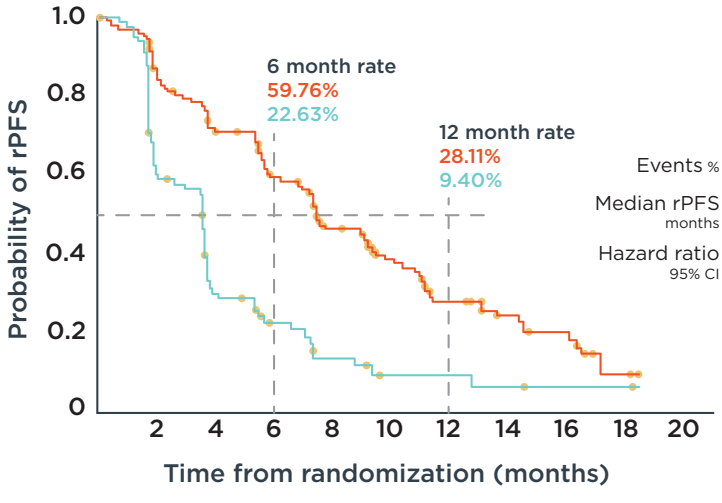
Retreatment with a new hormonal agent arm: **3.55 months**

olaparib arm: **7.39 months**

66%
reduction of risk of progression.

Study met its primary endpoint!*
The primary endpoint of the trial was radiological PFS (rPFS) in Cohort A.

rPFS by BICR in patients with tumors harboring alterations in *BRCA1*, *BRCA2*, or *ATM* from Cohort A



	Olaparib N=162	pcNHA N=83
Events %	106 (65.4)	68 (81.9)
Median rPFS months	7.39	3.55
Hazard ratio 95% CI	0.34 (0.25, 0.47) P<0.0001	

Frequency of gene mutations from the patients screened for PROfound by FoundationOne CDx based CTA

FoundationOne CDx covers all HRR pathway genes recommended by professional guidelines, which include *BRCA1/2* and *ATM*†.

33% objective response rate

for HRR-positive patients treated with olaparib

vs 2.3% in the retreatment with a new hormonal agent arm*

FoundationOne CDx is part of Foundation Medicine's proven portfolio of tests and services and has demonstrated clinical utility in metastatic pre-treated castrate-resistant prostate cancer.

Global Trial

Europe | *North America*
South America | *Asia* | *Australia*

Fast results in less than two weeks‡

FoundationOne CDx detects professional guideline recommended genes for mCRPC

BRCA1 | *BRCA2* | *ATM* | *CHEK2*
FANCA | *PALB2* | *RAD51D*

Simplified and expertly curated reports to help inform clinical decision making

References

*Hussain M, Mateo J, Fizazi K, et al. PROfound: Phase III study of olaparib versus enzalutamide or abiraterone for metastatic castration-resistant prostate cancer (mCRPC) with homologous recombination repair (HRR) gene alterations. Presented at ESMO Congress 2019; September 27-October 1, 2019; Barcelona, Spain. Abstract LBA12_PR.
†https://onlinelibrary.wiley.com/doi/full/10.3322/caac.21560
‡From receipt of specimen

Olaparib is not currently FDA approved for mCRPC.

FoundationOne®CDx is a next-generation sequencing based in vitro test intended for use by healthcare professionals for advanced cancer patients with solid tumors. The test analyzes 324 genes as well as genomic signatures including microsatellite instability (MSI) and tumor mutational burden (TMB) and is FDA-approved as a companion diagnostic to identify patients who may benefit from treatment with a specific list of therapies (listed in Table 1 in the Technical Information at www.foundationmedicine.com/f1cdx) in accordance with the approved therapeutic product labeling. Additional genomic findings, other than those listed in Table 1, may be reported and are not prescriptive or conclusive for labeled use of any specific therapeutic product. Use of the test does not guarantee a patient will be matched to a treatment or clinical trial option, or that all relevant alterations will be detected. Some patients may require a biopsy. For the complete label, including important risk information, please visit www.foundationmedicine.com/f1cdx.

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