

DEVELOPMENT SCIENCES: Innovation & Technology

TITLE

Ipatasertib CDx Development

SUMMARY

Ipatasertib inhibits the active form of AKT. There are multiple mechanisms of PI3K/AKT pathway activation in cancer, which can vary based on tumor type; flexible diagnostic development strategies are dependent on early biomarker insights to identify patients with active AKT due to:

- AKT1 activating mutations
- PIK3CA activating mutations
- PTEN loss of function alterations

IMPACT

- DBI queries helped refine the Ipatasertib biomarker signature for clinical trial assay Dx development and evaluate the prevalence of DX+ patients in other tumor types

2015

Single analyte assays have limitations around capturing relevant biologies at the complex AKT signaling node

- IHC-based PTEN status not predictive in TNBC (LOTUS)
- PIK3CA qPCR kit captures only ~12-15% of TNBC biomarker population
- Additional 2 year development time for hypothesized biomarkers estimated at \$10M

2016

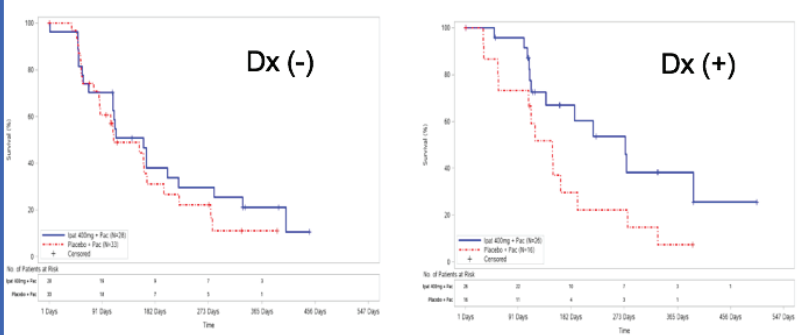


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A. MARTIN & LOTUS ph II retrospective study data

Real-world database insights from FoundationCORE

Unique NGS-based signature associated with efficacy^{1,2}



2017-2019



- Ph III study selecting Dx+ breast cancer patients
- Only \$1.5M & 6 months for additional development work in time for FPI
- Dx+ FPI achieved in Q4 2017

FoundationOne CDx is lead clinical diagnostic for breast cancer

3-gene biomarker signature is critical to the success of the study

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