



A Gene Expression Based Biomarker For Predicting Response To Treatment

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Feb 2024

Nasdaq: ALLR



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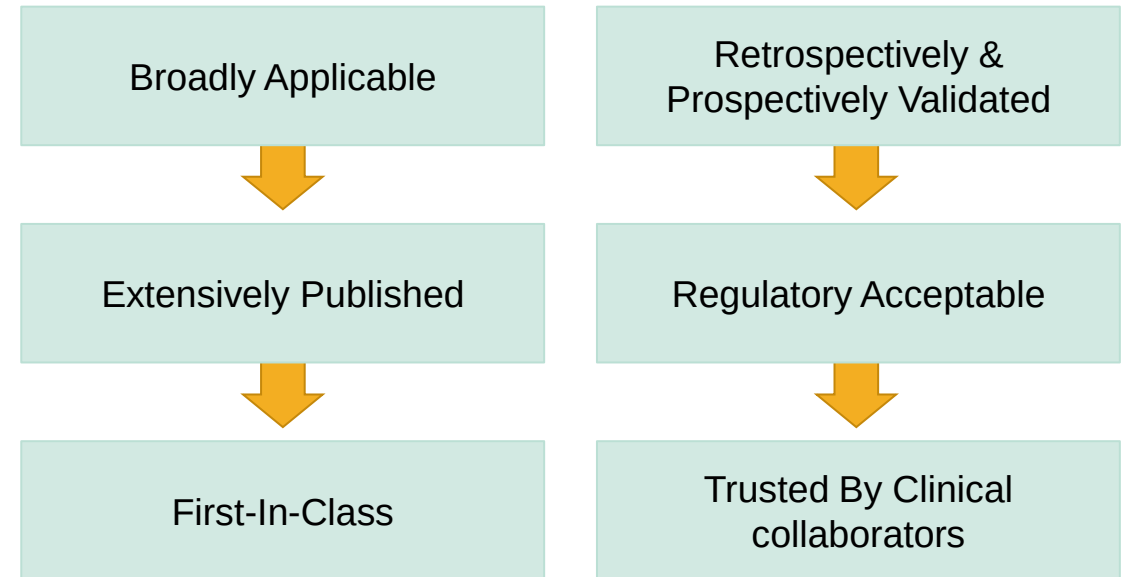
Our DRP[®] Companion Diagnostics Platform

DRP® Supplements Conventional Biomarker Technology

Conventional Biomarker Approaches work for some, but not all oncology drugs



Allarity's DRP® develops predictive biomarkers based upon complex gene expression analysis



* DRP® **is** based on comprehensive, tumor cell transcriptome **data** from actual cancer patients.

* DRP® **is not** based on data mining, AI, or database analysis.



The DRP® Platform Addresses the Complexity of Cancer

Cancer is Very Complex

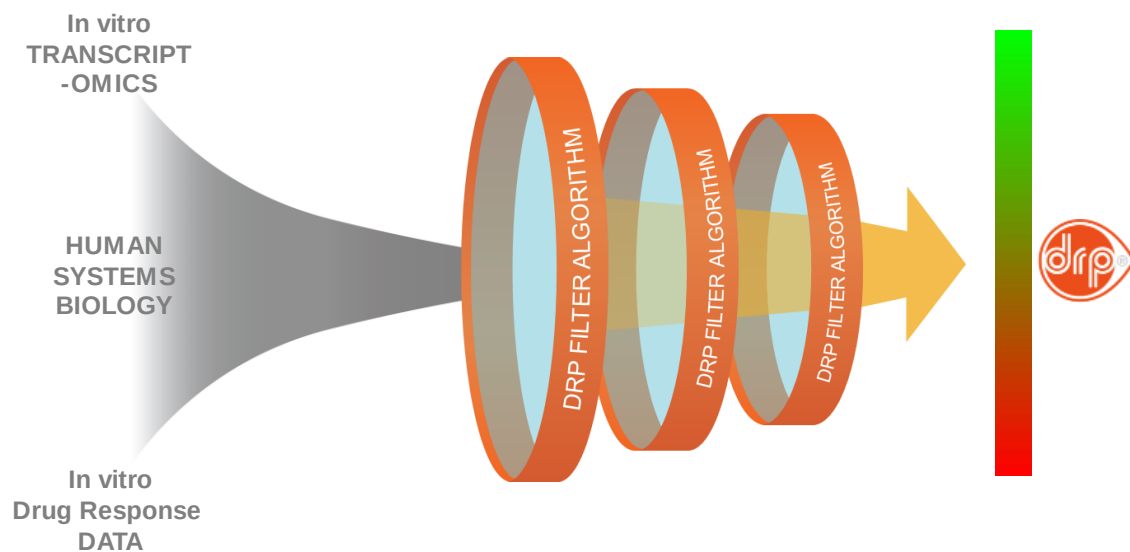
“Systems biology” is used to **analyze all genes** (~25,000) expressed in a cancer cell/tumor, without bias towards current knowledge of relevant drug targets or pathways.



Graph of all 680 non-redundant proteins

The Tumor Tells us What is Important

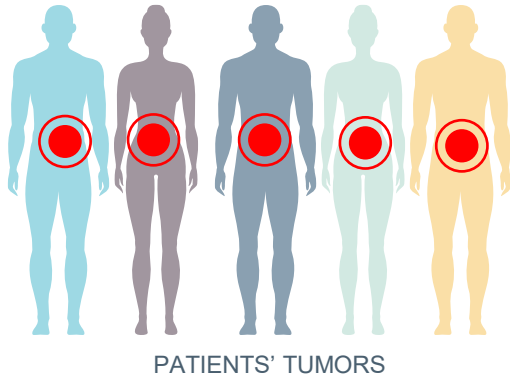
Input is generated by taking drug testing data from cancer cell lines. Our **DRP® engine then applies the system biology analysis** as a “filter” of human tumor biopsy data, to yield a 50 to 400 gene DRP® signature for that specific drug.



DRP[®] CDx: Predicting a Cancer Patient's Drug Response

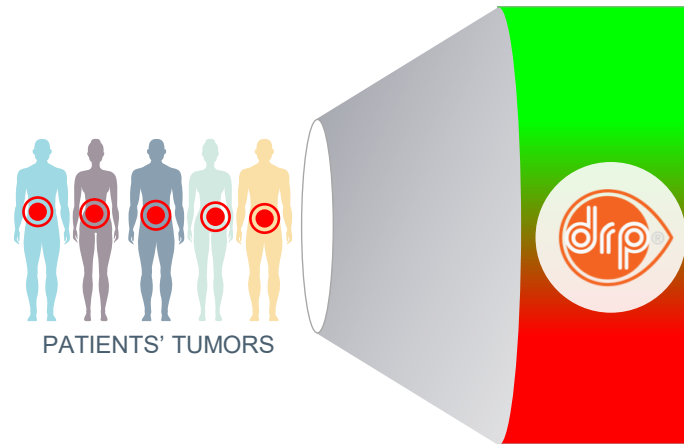
Step 1

Patients' biopsy samples



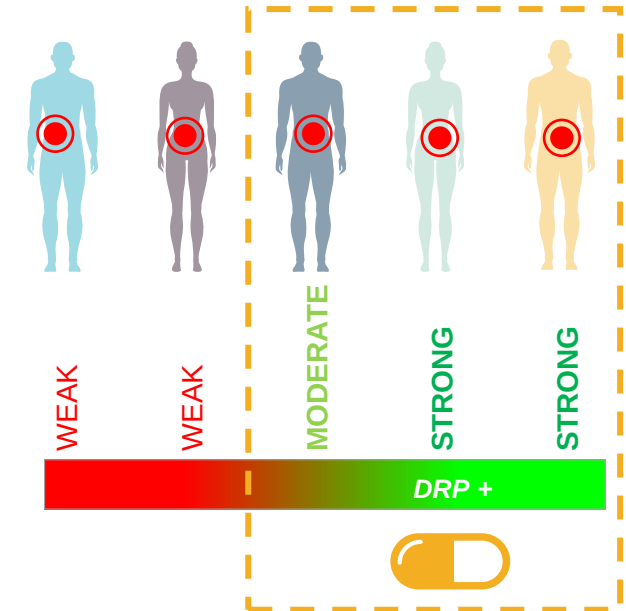
Step 2

Compare patients' tumor gene expression to DRP[®] signature



Step 3

Identify patients with high DRP[®] score for a given drug



DRP® Platform: Extensively Proven in 47 Clinical Trials



PROSPECTIVE CLINICAL TRIALS – PHASE 2

DRP® Clinical Impact

Cisplatin/LiPlaCis®	Phase 2 study (n=37) completed – late-stage metastatic BC
Stenoparib	Phase 2 study (n=30) underway – 3 rd line ovarian cancer
IXEMPRA®	Phase 2 study (n=60) underway – 2 nd line metastatic BC

More than 50%
increase in response
or time to
progression between
predicted sensitive and
predicted resistant

RETROSPECTIVE (BLINDED) CLINICAL TRIALS – PHASE 2/3

Dovitinib	RCC – metastatic	Lung
Fulvestrant	AML	Lung – NSCLC
Belinostat	Breast	Ovarian
5-FU	Breast – Metastatic	Renal
Epirubicin	Breast – Neoadjuvant	Solid Tumors
Exemestane	Colon	
(+ dozens of other validations*)		

More than 50%
increase in
response or time to
progression between
predicted sensitive and
predicted resistant



Publications of Clinical/Method Validation for Drug-Specific DRP®'s

1. Chen J, et al. **A 71-gene signature of TRAIL sensitivity in cancer cells.** (October 25, 2011); *Mol Cancer Ther*, 10.1158/1535-7163.
2. Wang W, et al. **Independent validation of a model using cell line chemosensitivity to predict response to therapy.** *J Natl Cancer Inst.* 2013 Sep 4;105(17):1284-91
3. Knudsen S, et al. **Development and validation of a gene expression score that predicts response to fulvestrant in breast cancer patients.** *PLoS One.* 2014 Feb 5;9(2):e87415
4. Knudsen S, et al. **Development and blind clinical validation of a microRNA based predictor of response to treatment with R-CHO(E)P in DLBCL.** *PLoS One.* 2015 Feb 18;10(2):e0115538
5. Buhl IK, et al. **Cell Line Derived 5-FU and Irinotecan Drug-Sensitivity Profiles Evaluated in Adjuvant Colon Cancer Trial Data.** *PLoS One.* 2016; 11(5): e0155123.
6. Winther M, et al. **Clinical Impact of a Novel MicroRNA Chemo-Sensitivity Predictor in Gastroesophageal Cancer.** *PLoS One.* 2016; 11(2): e0148070.
7. Rücker FG, et al. **Molecular dissection of valproic acid effects in acute myeloid leukemia identifies predictive networks.** *Epigenetics.* 2016 Jul 2;11(7):517-25.
8. Prahm KP, et al. **Clinical validation of chemotherapy predictors developed on global microRNA expression in the NCI60 cell line panel tested in ovarian cancer.** *PLoS ONE* 12(3): e0174300.
9. Bohl SR, et al. **Gene expression analysis of decitabine treated AML: high impact of tumor suppressor gene expression changes.** *Leukemia & Lymphoma* Vol. 58 , Iss. 9, 2264-2267 (2017).
10. Vangsted AJ, et al. **Drug response prediction in high-risk multiple myeloma.** *Gene* 644 80-86 (2018).
11. Buhl IK, et al. **Molecular prediction of adjuvant cisplatin efficacy in Non-Small Cell Lung Cancer (NSCLC)—Validation in two independent cohorts.** *PLoS ONE* 13(3): e0194609 (2018).
12. Buhl ASK, et al. **Predicting efficacy of epirubicin by a multigene assay in advanced breast cancer within a Danish Breast Cancer Cooperative Group (DBCG) cohort: a retrospective-prospective blinded study.** *Breast Cancer Res Treat.* 2018 Aug 11.
13. Christensen TD, et al. **Prediction of fulvestrant efficacy in patients with advanced breast cancer: retrospective-prospective evaluation of the predictive potential of a multigene expression assay.** *Breast Cancer.* 2019 Oct 25. doi: 10.1007/s12282-019-01017-7 (2019).
14. Plummer R, et al. **First-in-human study of the PARP/tankyrase inhibitor E7449 in patients with advanced solid tumours and evaluation of a novel drug-response predictor.** *Br J Cancer* (2020) 123(4):525-533.
<https://doi.org/10.1038/s41416-020-0916-5>
15. Knudsen S, et al. **A novel drug specific mRNA biomarker predictor for selection of patients responding to dovitinib treatment of advanced renal cell carcinoma and other solid tumors.** *PLOS ONE.* 18(8): e0290681
<https://doi.org/10.1371/journal.pone.0290681> (2023)

Revitalizing Former Big Pharma Therapeutics with Our DRP[®] CDx

Classical Drug Development

Treat all of the patients



Low Average
Patient Benefit



Companion
Diagnostics

Allarity Approach

Treat only patients sensitive to therapy



High Average
Patient Benefit

Lead Program	PHASE 1/1b		PHASE 2	PHASE 3	INDICATION	RIGHTS
	Stenoparib	PARP & tankyrase inhibitor			3 rd + line Ovarian Cancer	Global

Each program is advancing with a drug-specific DRP[®] companion diagnostic (CDx) to select and treat patients most likely to benefit from treatment.



Prior validation example: Dovitinib

Knudsen S, et al. *PLOS ONE*. 18(8): 2023

Dovitinib: A Unique Pan-Tyrosine Kinase Inhibitor (TKI)

Dovitinib Has Shown Therapeutic Equivalence to Sorafenib in Prior Phase 3 mRCC Study. It is no longer in clinical development, but was used to validate DRP

- Pan-Tyrosine Kinase Inhibitor (TKI), small molecule, targeted inhibitor of FGFR, VEGFR, and other RTKs. **Unique, inhibitory profile.**
- **Clinical activity demonstrated in monotherapy** Phase 3 Renal Cell Carcinoma (mRCC) trial², and in Phase 2 studies for gastrointestinal stromal tumors (GIST)³, liver (HCC)⁴, breast⁵, and endometrial cancers⁶
- **Dovitinib-DRP[®] CDx evaluated** in 5 different cancers including mRCC, GIST, liver, metastatic breast, and endometrial.

1) 2. NCT01223027 3. NCT01478373 4. NCT01232296 5. NCT01528345 and NCT00958971 6. NCT01379534

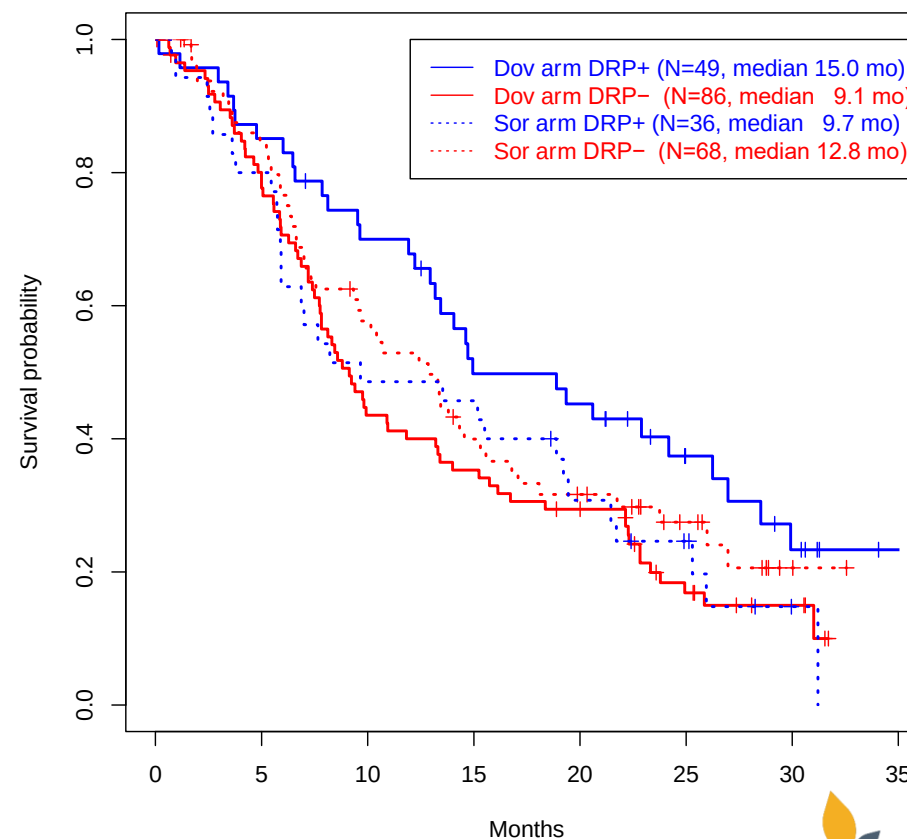
Dovitinib-DRP[®] CDx Identifies Dovitinib-Responsive Patients

Dovitinib-DRP[®] CDx (58 mRNAs) Identified Patients with Overall Survival (OS) Benefit in Novartis Phase 3 in 3rd line RCC¹



- Dovitinib-DRP[®] positive:
 - median **15.0 mo.** OS
(95%CI 12.9-26.3)
- Dovitinib-DRP[®] negative:
 - median **9.1 mo.** OS
(95% CI 7.6-13,2)
- Dovitinib-DRP[®] CDx does not select Sorafenib responders.

DRP selects survivors in dovitinib arm but not in sorafenib arm





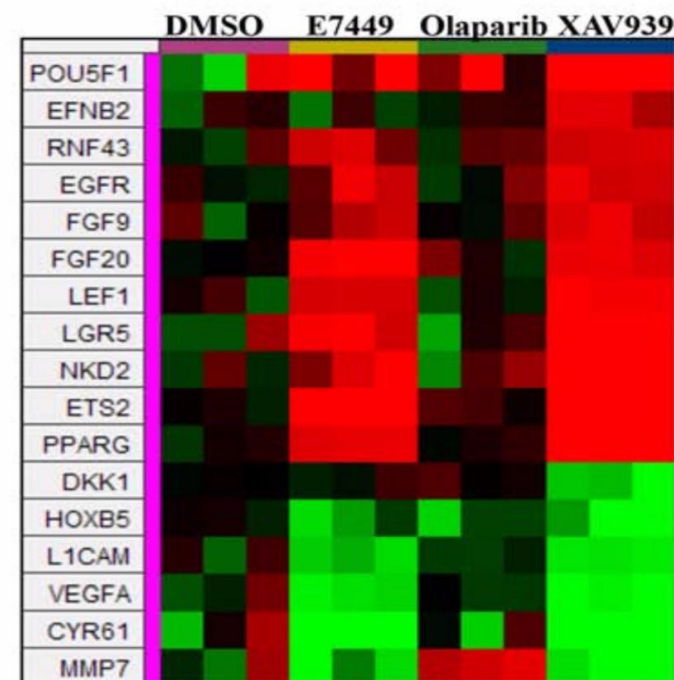
Ongoing Phase 2 Prospective trial: Stenoparib

Stenoparib: A Unique Dual PARP and Tankyrase Inhibitor

Ongoing Phase 2 Monotherapy Study in 3rd Line Ovarian Cancer (OC) All patients screened with Stenoparib DRP to identify patients for inclusion

- First-in-class small molecule targeted inhibitor of DNA damage repair enzymes (**PARP**) with **dual Tankyrase inhibitor activity**:
 - Tankyrases are involved in **telomerase maintenance** during tumor cell division and are active in the **Wnt signaling pathway** in tumor cells.
 - Dual inhibition of PARP & Tankyrase potentially yields **improved anti-tumor activity**, including in tumors that develop PARPi resistance.
- Stenoparib has shown **promising monotherapy activity against OC and pancreatic cancer** in prior Phase 1 clinical trial.
 - **Stenoparib-DRP[®]** companion diagnostic showed ability to identify patients that benefited in Phase I study.
- Global rights, exclusively in-licensed from **Eisai**. GMP drug manufacturing contract in place with LONZA.
- PARPi's approved for use in **ovarian, breast, prostate, pancreatic, fallopian tube and peritoneal cancers**.

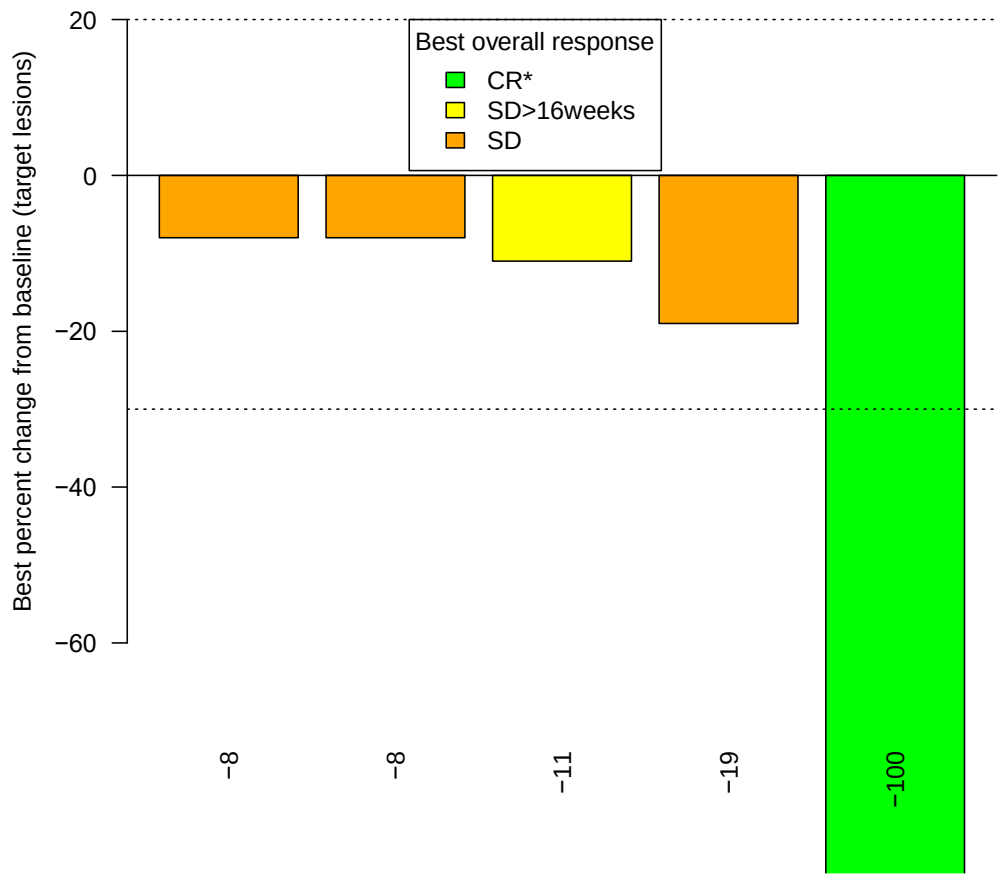
Stenoparib (E7449) targets Wnt/ β -catenin related genes like selective tankyrase inhibitor XAV939¹



1. McGonicle et al, OncoTarget vol 6 no 38, 2016.

At first interim analysis, *all* patients selected by DRP showed benefit (i.e. reduction in tumor size. This is better than what other PARP inhibitors have shown without DRP)

Second interim analysis planned for H1 2024 at N=18



Unpublished preliminary data. Not yet fully source data verified.



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