context therapeutics

Advancing Medicines for Female Cancers

Corporate Presentation

November 2022

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Context Therapeutics Overview

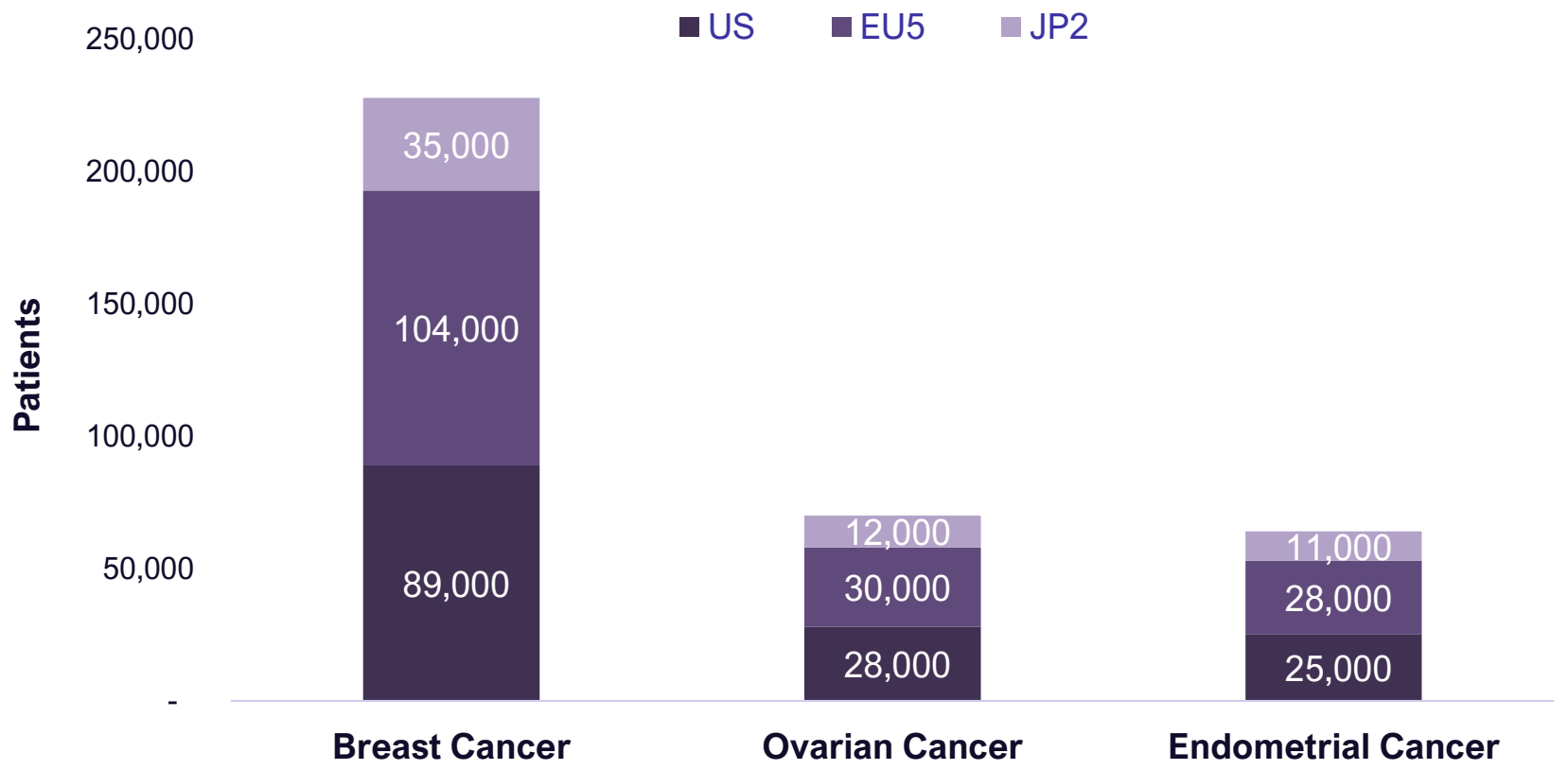
Focus on Women's Oncology	• Unmet clinical need in breast, ovarian, and endometrial cancers
ONA-XR *oral PR antagonist*	• ONA-XR is a novel, potentially first-in-class progesterone receptor (PR) antagonist • Endometrial Phase 2 trial initial data reports 4-month PFS rate of 77%[1] • In November 2022, initiated Phase 1b/2 ELONA trial. On track for Phase 1b data in Q4 2023 • 2L/3L metastatic breast cancer initial data to be presented in December 2022
CLDN6 x CD3 *bispecific antibody*	• Claudin 6 (CLDN6) is uniquely expressed in certain adult and pediatric cancers • Developing a highly selective CLDN6 x CD3 bispecific antibody • On track for Candidate selection in Q4 2022 and IND submission in Q1 2024
Cash Guidance	• Expected cash runway into Q1 2024

1 Data cut off as of September 30, 2022; preliminary raw data

Unmet Need in Female Cancers

Prevalence of Metastatic Female Cancers in EU5, Japan, and US

Within the G7 countries, it is estimated that there are over 355,000 patients living with metastatic breast, ovarian, or endometrial cancer



Source: secondary epidemiologic estimates, 2020 estimates

Pipeline

Cancer	Clinical Indication	Preclinical	Phase 1 Clinical	Phase 2 Clinical	Milestones
ONA-XR (PR antagonist)[1]					
Breast Cancer	**2L/3L ER+,PR+,HER2-** Combination w/ elacestrant			**Phase 1b/2 ELONA Trial**	**Initiate Q4 2022** ☑ Phase 1b data Q4 2023
	2L/3L ER+,PR+,HER2- Combination w/ fulvestrant			***Phase 2 SMILE Trial**	Initial data Dec 2022
Endometrial Cancer	**Recurrent PR+ Endometrioid** Combination w/ anastrozole			***Phase 2 Trial**	**Initial data Q4 2022** ☑ Data update mid-2023
Ovarian Cancer	**Recurrent PR+ Granulosa Cell Tumor** Combination w/ anastrozole			***Phase 2 Trial**	**Initial data Q4 2022** ☑ Data update mid-2023
CLDN6xCD3 bispecific antibody					
	CLDN6-positive cancers				Candidate selection Q4 2022 IND submission Q1 2024

1 Tyligand Biosciences Ltd licensed rights to ONA-XR in China, HK, Macau
* Investigator Sponsored Trial

ONA-XR

Progesterone Receptor Antagonist

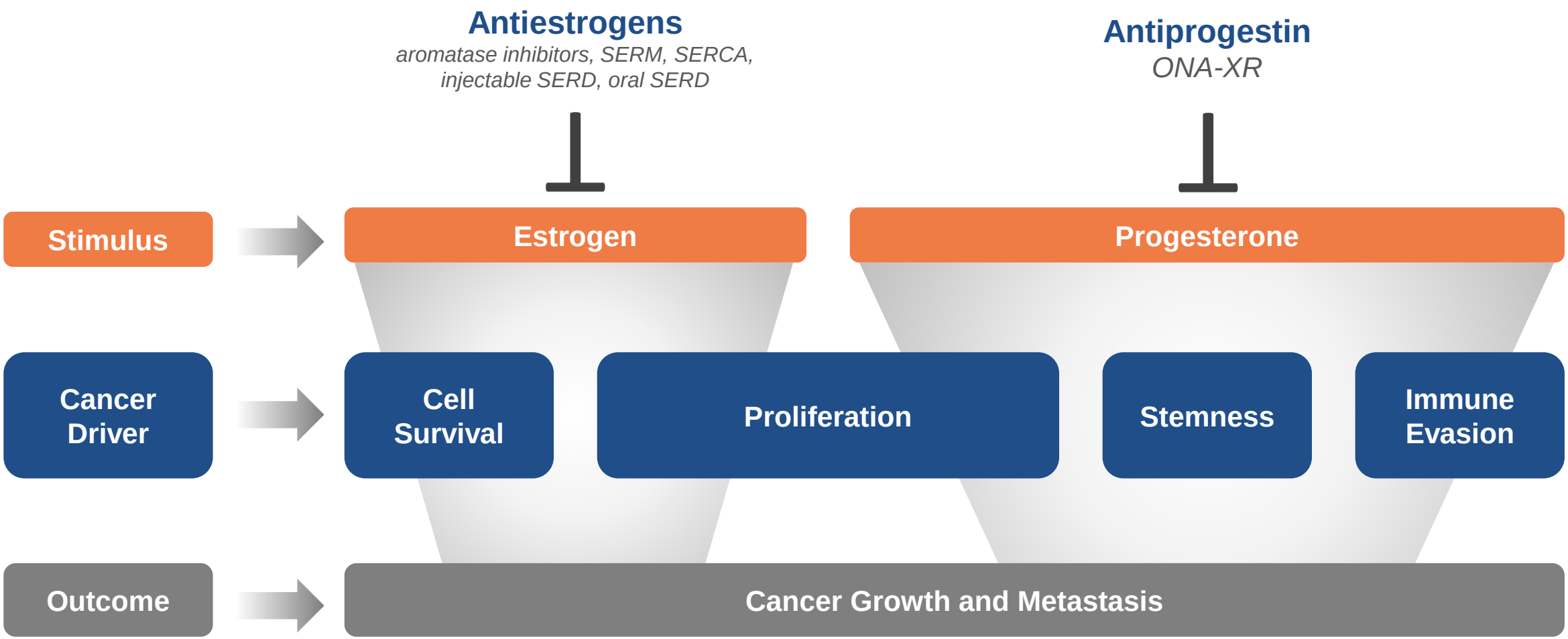
Onapristone Extended Release (ONA-XR)

Mechanism of Action	• Onapristone (ONA) is a progesterone receptor (PR) antagonist that suppresses PR oncogenic signaling • PR oncogenic signaling is associated with breast, ovarian, and endometrial cancer • Onapristone is the only PR antagonist that blocks both ligand-dependent and ligand-independent PR activation[1]
Dosing and Administration	• ONA-XR is an extended-release (XR) tablet form of onapristone (ONA) • 50 mg administered orally twice per day
Clinical Data With Immediate Release Formulation	• 56% overall response rate (ORR) in patients with advanced or metastatic 1L ER+,PR+,HER2- breast cancer[2] • Immediate release formulation associated with liver enzyme elevations[3,4]
Clinical Data With Extended Release Formulation[5,6]	• Extended release formulation mitigates liver enzyme elevations; no treatment-related severe adverse events to date • Preliminary 4-month progression free survival (PFS) rate of 77% in ongoing Phase 2 endometrial cancer trial
Intellectual Property	• IP protection through at least 2034 assuming no additional patent filings or patent term extensions • ONA-XR is a New Chemical Entity (NCE)

1 Huang, Mol Can Res, 2019
2 Robertson et al., J Eur Cancer, 1999
3 Cottu et al., PLOS One, 2019
4 Lewis et al., Drug Safety, 2020
5 Data referenced as of September 30, 2022
6 As assessed by study Investigator

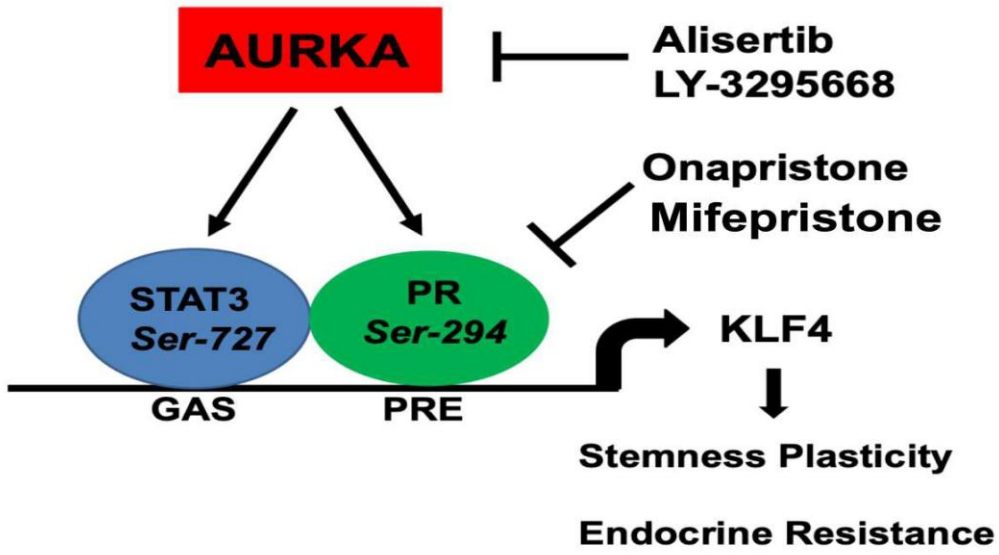
Mechanism of Action

Blocking cancer growth by combining antiestrogen and antiprogestin therapies



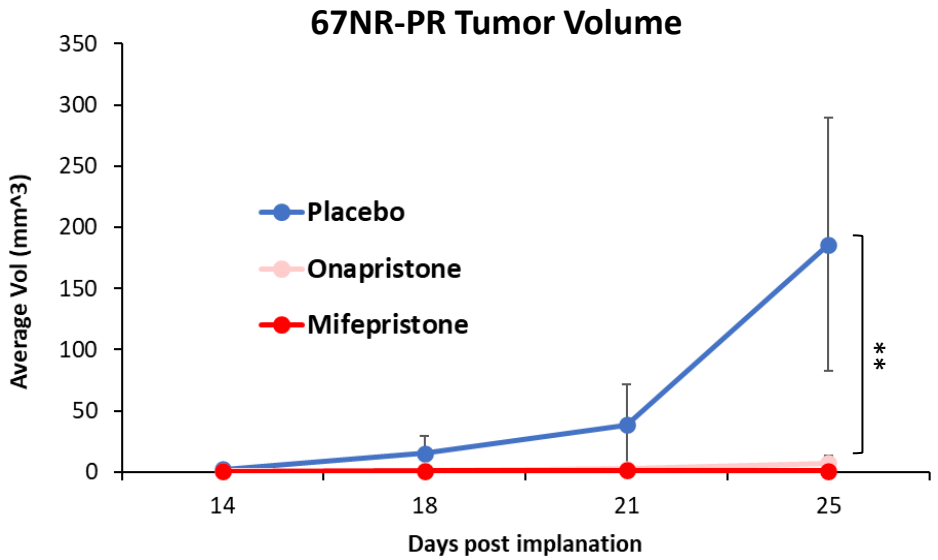
PR Regulates Cancer Drivers of Stemness and Immune Evasion

PR Promotes Cancer Cell Stemness and Metasteses[1]



- Cancer plasticity and endocrine therapy resistance is mediated through AURKA phosphorylation of S727-STAT3 and S294-PR transcription factors that favors their co-recruitment in the promoter region of KLF4 stemness reprogramming gene

PR Restricts Immune Recognition of Cancer Cells[2]



- Antiprogestins onapristone and mifepristone inhibited tumor growth in syngeneic (67NR-PR) tumor model in BALB/C mice
- Antiprogestins had limited tumor growth inhibition in immune-deficient (NOD/SCID) mice (data not shown)

1 D'Assoro, AACR Annual Meeting 2022
2 Werner, AACR Annual Meeting 2022

Completed Clinical Trials

Summary of select clinical trials evaluating onapristone with IR or XR formulation

Onapristone Treatment	Stage	Patients (n)	Clinical Indication	Prior Treatments Median (range)	Biomarker	Data
IR (100 mg QD)	Ph 2	19	Breast Cancer First line (1L) advanced or metastatic	Hormone naïve		**56% ORR[1]** **67% CBR** **14.0 month PFS**
IR (100 mg QD)	Ph 2	101	Breast Cancer Second line (2L) advanced or metastatic	1 (1-2)		**10% ORR[2]** **48% CBR** **4.0 month PFS**
XR (50 mg BID)	Ph 2	14	Granulosa Cell Tumor of Ovary Advanced or Metastatic	4 (2-17)	PR+	**35% CBR[3]** **12 month PFS rate of 20%**
XR (10-50 mg BID)	Ph 1	13	Ovarian Cancer Advanced or Metastatic	4 (2-10)	PR+	**8% ORR[4]** **6 month PFS rate of 31%**
XR (10-50 mg BID)	Ph 1	20	Breast Cancer Advanced or Metastatic	9 (2-14)	PR+	**25% DCR[4]** **6 month PFS rate of 15%**

IR = immediate release; XR = extended release

1 Robertson, Eur J Cancer, 1999
2 Jonat, Endocrine Therapy of Breast Cancer, 2002
3 Grisham, ASCO Annual Meeting 2022
4 Cottu, PLoS One, 2018

Key Ongoing Clinical Trials

Treatment	Stage	Patients (n)	Clinical Indication	Biomarker	Key Inclusion and Exclusion Criteria	Collaborator	Data Update[1]
ONA-XR + Anastrozole	Ph 2	25	Endometrial Cancer	PR+	• Must have received at least one prior treatment with a platinum/taxane chemotherapy	Jefferson HOME OF SIDNEY KIMMEL MEDICAL COLLEGE	• **12 patients enrolled** • **4-month PFS rate of 77%** • **No treatment-related SAE**
ONA-XR + Anastrozole	Ph 2	25	Granulosa Cell Tumor of the Ovary	PR+	• Must have received at least one prior chemotherapy regimen	Memorial Sloan Kettering Cancer Center	• **14 patients enrolled** • **No treatment-related SAE**
ONA-XR + Fulvestrant	Ph 2	39	Breast Cancer (2L/3L) SMILE Trial	PR+	• Must have received prior CDK4/6 inhibitor therapy • One line of prior chemotherapy in metastatic setting allowed	Carbone Cancer Center UNIVERSITY OF WISCONSIN SCHOOL OF MEDICINE AND PUBLIC HEALTH	
ONA-XR + Elacestrant	Ph 1b/2	67	Breast Cancer (2L/3L) ELONA Trial	PR+	• Must have received prior CDK4/6 inhibitor therapy • ≥50% patients with ESR1 mutant • No prior chemotherapy in metastatic setting	MENARINI group	

1 Data cut off as of September 30, 2022; preliminary raw data

ONA-XR

Recurrent PR+ Endometrial Cancer

Endometrial Cancer

- **Endometrial cancer is the 4th most common cancer in women**
  - Endometrial cancer is on the rise and is linked to obestiy[1,2]
  - ~13,000 patient deaths per year in the US[3]
  - Market is projected to grow from $1.5bn in 2020 to $5.1bn in 2029[5]
- **Hormone signaling is a driver of endometrial cancer**
  - Endometrial cancer is thought to be caused by excess hormone production that leads to endometrial hyperplasia and cancer
- **Chemotherapy and surgery remain first line treatments**
  - Primary treatment includes surgical removal of uterus, ovaries, and fallopian tubes followed by platinum/taxane chemotherapy
  - PD-1 antibodies (Keytruda, Jemperli) were recently approved in MSI-H and dMMR genetic subpopulations post-chemotherapy (~13-30% of population)[5]
  - Lenvima + Keytruda combination therapy is approved post-chemotherapy, however, tolerability can be challenging for patients[6]
- **Antiestrogen therapy is currently used off-label**
  - Hormonal therapy is an alternative treatment for patients who wish to preserve their fertility, and for those with metastatic or recurrent disease without curative options

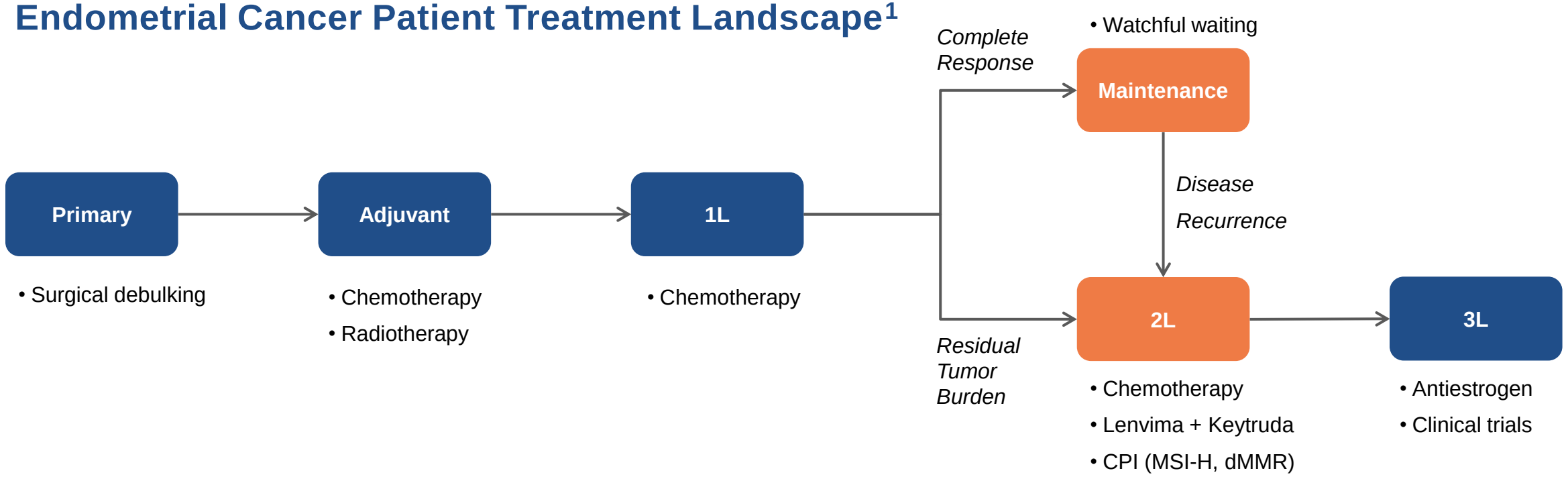
~14,000 patients have recurrent endometrial cancer that cannot be fully removed via surgery[2]

34%

Of endometrial cancer patients are PR+[4]

1 American Cancer Society, Endometrial Cancer Risk Factors. (accessed Nov. 4, 2022)
2 Epic Oncology (Incidence, 1st/ 2nd line treated); epic Oncology physician survey 2019
3 Nation Cancer Institute, Endometrial Cancer Incidence Rising in the US and Worldwide (accessed Nov. 4, 2022)
4 Høgdall, Oncol Rep, 2007
5 Vinuesa and Webster, Nat Rev Drug Disc, 2022
6 Makker, NEJM, 2022

Endometrial Cancer Patient Treatment Landscape[1]



1L First Line (1L)

- Standard of Care (SOC) is carboplatin + paclitaxel
- mPFS of ~12 months

2L Second Line (2L)

- Treatment goal is disease stabilization for 4-6 months
- Lenvima + Keytruda poor tolerability associated with high discontinuation rate in patients

M Maintenance Line

- No approved therapies
- Treatment goal is disease stabilization for ≥4 months and to provide a high quality of life

3L Third Line (3L)

- Limited treatment options

Potential Target Indications for ONA-XR

1 National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology. Uterine Neoplasms. v4.2021

ONA-XR + Anastrozole in PR+ Endometrial Cancer[1]

- **Ongoing Phase 2 Trial**
  - Investigator-initiated, open label, multi-center, trial evaluating ONA-XR 50 mg BID in combination with the antiestrogen anastrozole 1 mg QD administered orally to treat women with ER+/PR+ endometrial adenocarcinoma who have received at least one prior platinum/taxane-based chemotherapy regimen
  - Co-primary endpoints: 4-month PFS and ORR
  - Secondary endpoints: DCR, DoR, safety, and quality of life

- **Efficacy**
  - The study has enrolled 12 of 25 planned patients
  - 9 patients have completed at least one month of treatment
  - 4-month PFS rate was 77%
  - 12-month PFS rate was 33%
  - 7 patients remain on the trial

- **Safety**
  - There have been no treatment-related serious adverse events reported

- **Updated data anticipated in mid-2023**

1 Data cut off as of September 30, 2022; preliminary raw data

All statements contained in this presentation are based on preclinical and clinical trial data related to an investigational molecule, ONA-XR. Development of this molecule is ongoing and, therefore, statements relating to study data to date should not be regarded as definitive reflections of safety, efficacy or the risk-benefit profile of the molecule

Benchmarking Against Single Agents

	ONA-XR + Anastrozole	ONA-XR	Anastrozole
Trial	Schilder (ongoing)[1]	Cottu 2018[2]	PARAGON 2019[3]
Patients (n)	12 (9 evaluable)	12	54
Lines of Prior Chemotherapy, n (%) **1** **≥2**	 8 (66) 4 (33)	 4 (33) 8 (66)	 50 (93) 4 (7)
Treatment free interval (TFI) ≥6 months, n (%)	4 (33)	1 (8)	36 (70)
4-month PFS rate, n (%)	7 (77)	4 (33)	ND
12-month PFS rate, n (%)	3 (33)	1 (8)	4 (7)
mPFS (95% CI), months	NE	2.0 (1.7-5.3)	2.7 (1.9-4.5)
Side Effects	Well tolerated	Well tolerated	Well tolerated

1 Data cut off as of September 30, 2022; preliminary raw data
2 Cottu, PLoS One, 2018
3 Mileshkin, Gyn Onc, 2019

CLDN6xCD3
Bispecific Antibody Program

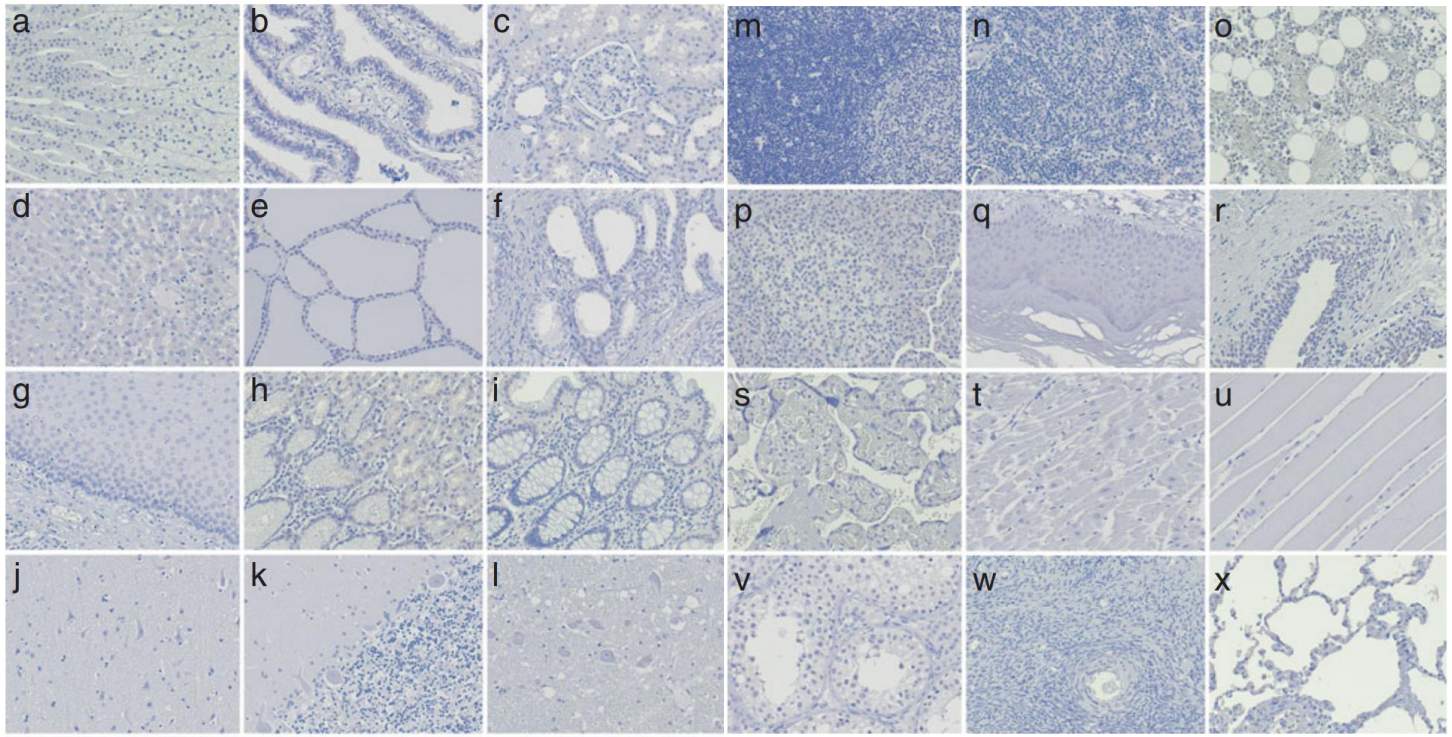
Claudin 6 (CLDN6) is an Emerging Oncology Target

Opportunity	• CLDN6 is a **tumor-specific protein** that is present at high surface density across adult and pediatric cancers[1] • CLDN6 is expressed at **very low levels or absent** from normal adult tissue
Challenge	• CLDN6 antigen is **conformationally-dependent**, which limits the utility of traditional antibody discovery approaches • Antigen binding region is **highly conserved** with CLDN3, CLDN4, and CLDN9 • CLDN6 **selectivity is required** to avoid off-target liabilities identified in murine knockout studies with CLDN3 (pancreas), CLDN4 (kidney, pancreas), and CLDN9 (ear, gut)
Target Validation	• BNT211 CAR-T establishes **Proof of Concept**[2]: – Novel CAR-T + mRNA vaccine evaluated in Phase 1 dose-escalation study in CLDN6+ solid tumors – **50% response rate** (ORR) in second dosing cohort
Unmet Need	• **Selectivity:** preferentially target CLDN6 over other CLDN proteins • **Potency:** specific lysis of CLDN6+ cancer cells over normal cells • **Safety:** activation of cytotoxic T cells without concomitant activation of free cytokines • **Manufacturability:** scalable process

1 Faber MS, et al. Bispecific claudin-6 x CD3 antibodies AACR Annual Meeting; 2021; Virtual. Abstract 1860
2 Haanen JB, et al. BNT211: A Phase I trial. ESMO Annual Meeting; 2022; Paris, France. LBA38

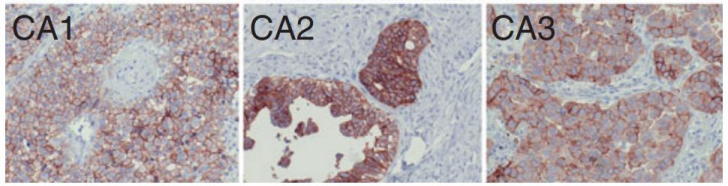
CLDN6 is Selectively Expressed on Cancer Cells

Normal Tissue



(a) adrenal gland, (b) fallopian tube, (c) kidney, (d) liver, (e) thyroid, (f) prostate, (g) esophagus, (h) stomach, (i) colon, (j) cerebrum, (k) cerebellum, (l) spinal cord. (m) thymus, (n) spleen, (o) bone marrow, (p) pancreas, (q) skin, (r) bladder, (s) placenta, (t) heart muscle, (u) striated muscle, (v) testis, (w) ovary, (x) lung

Cancer Tissue



(CA1) testicular cancer, (CA2) ovarian cancer, and (CA3) lung cancer

Reinhard, Science, 2020

CLDN6 Has the Potential to Reach a Large Patient Population

~62,500 patients per year in the US only in Relapse/Refractory Setting

Initial indications of interest based on:

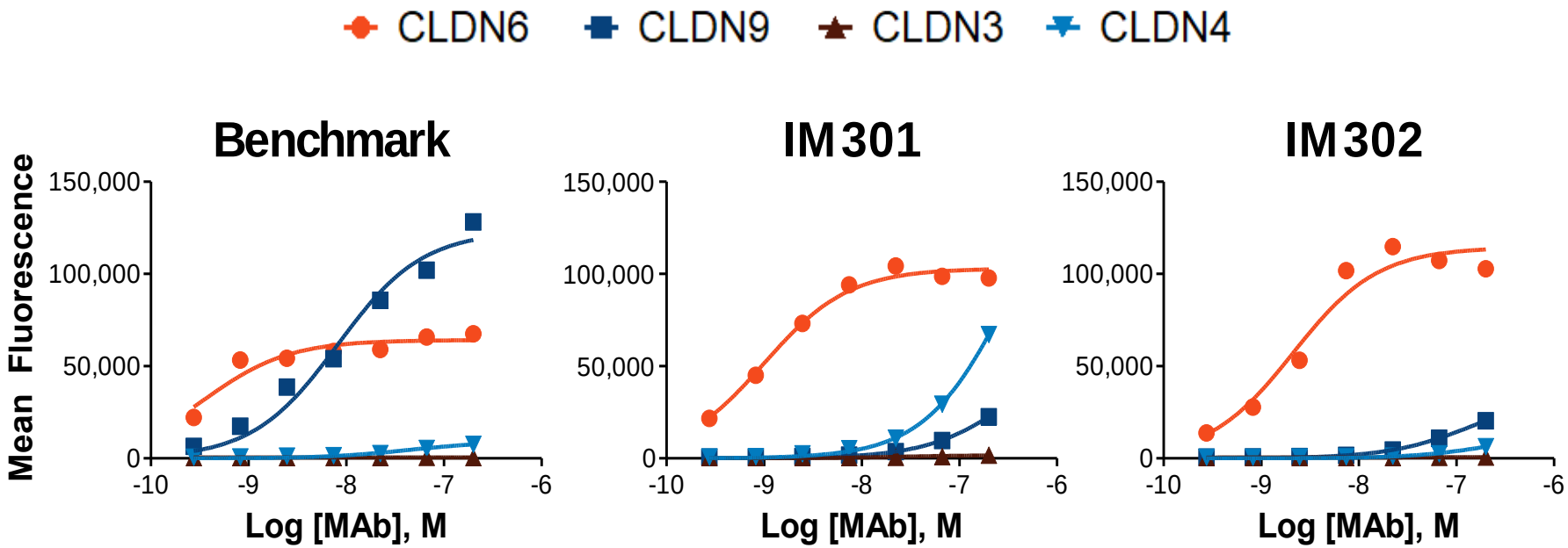
- CLDN6 prevalence
- Patient population size
- Observed clinical responses
- Eligibility for Orphan or Rare Pediatric Designation

Selected Cancer indications	Incidence	R/R Incidence	CLDN6 Positive	Patient Population Based on R/R Incidence
Testicular	9,910	400	95%[1]	**380**
Ovarian	19,900	12,800	54-55%[1,2]	**6,982**
NSCLC	201,229	110,653	6-50%[3,4,5]	**35,221**
Malignant Rhabdoid	50	500	29-44%[1,2,6,7]	**183**
Gastric	26,380	11,090	13-55%[8,9]	3,771
Breast	290,600	43,800	2-41%[1,10,11]	9,417
Endometrial	65,900	12,500	20-31%[1,12,13]	3,188
Glioma	19,000	10,000	21%[8]	2,100
Bladder	81,180	17,100	2-8%[1,13]	855
SCLC	35,511	19,527	2%[1]	391

1 Reinhard, Science, 2020; 2 Wang, Diagn Pathol., 2013; 3 Gao, Oncol Lett., 2013; 4 Kohmoto, Gastric Cancer, 2020; 5 Lin, Diagn Pathol., 2013; 6 Micke, Intl J Cancer, 2014; 7 Soini, Pol J Path, 2022; 8 Antonelli, Brain Pathol., 2011; 9 Sullivan, Am J Surg Pathol., 2012; 10 Jia, Intl J Clin Exp Pathol., 2019; 11 Yafang, J Breast Cancer, 2011; 12 Kojima, Cancers, 2020; 13 Ushiku, Histopath., 2012

Incidences based on public estimates; Relapsed/refractory (R/R) or last-line patient population approximated by annual mortality; CLDN6 target prevalence is based on IHC or RNAseq from published reports. Patient population derived from midpoint of CLDN6 positive population multiplied by R/R incident population.

Context Antibodies Display High Selectivity for CLDN6[1]



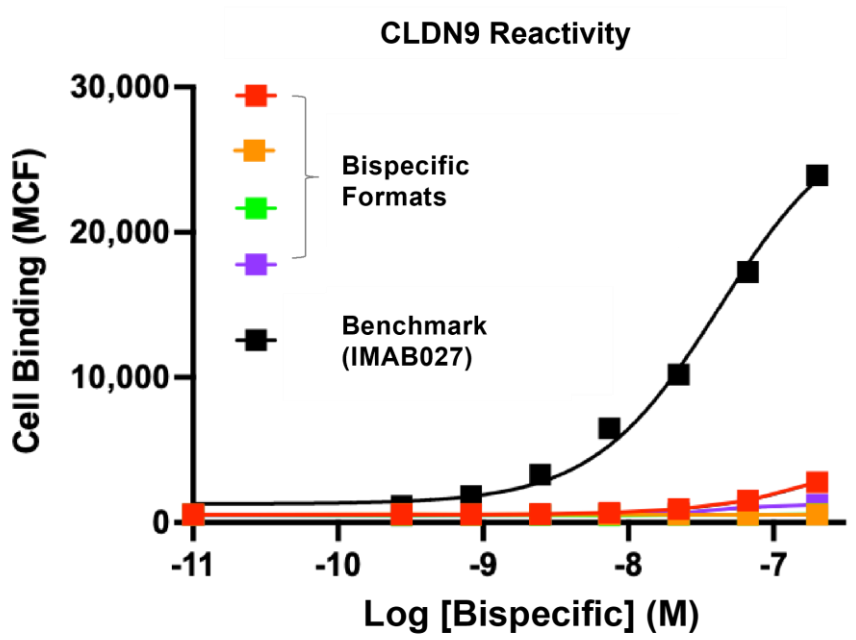
Key Takeaways

- Benchmark (IMAB027/ASP1650; Astellas/Ganymed) exhibits off-target binding to CLDN9
- 1st generation Context mAb (IM301, IM302) exhibit high CLDN6 selectivity
- 2nd generation Context mAb exhibit even greater CLDN6 selectivity than IM301 and IM302 (data not shown)

1 Rucker, AACR Annual Meeting 2022

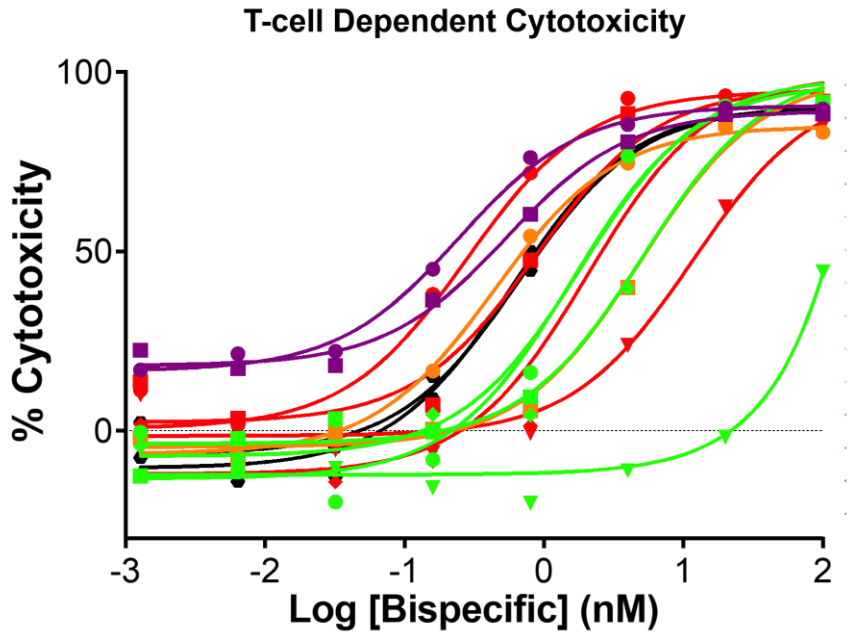
Development of Selective and Potent CLDN6 Bispecific Antibodies

Bispecific antibodies retain high CLDN6 specificity[1]



- A diverse set of bispecific formats were evaluated, represented by a different color (red, orange, green, purple)
- Binding to CLDN9 was not affected by Context bispecific format and was markedly lower compared to IMAB027 (black)

Bispecifics induce robust T-cell dependent cytotoxicity[1]



- A diverse set of bispecific formats and derivatives thereof effectively induced T-cell dependent cell killing in OV90 ovarian tumor cells
- Certain bispecific formats (green) and derivatives thereof were less potent (purple) than others

1 Rucker, AACR Annual Meeting 2022

Corporate

Experienced Leadership Team

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CEO and Director

Praesidia BIOLOGICS
Cure Duchenne
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Chief Medical Officer

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Celgene

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VP Clinical Operations

Spark THERAPEUTICS
teva
PRA Health Sciences

Focus on Execution

Experienced team with deep oncology experience

Our CMO led the clinical development of multiple blockbuster drugs for female cancers, including Kisqali, Arimidex, and Afinitor

Our management team is supported by a Board with strong public company operating and governance experience

Recent and Key Anticipated Milestones

ONA-XR	1H 2022	2H 2022	2023	2024
Breast – AACR preclinical update	✓			
Breast – ELONA trial initiation		✓		
Endometrial – Phase 2 initial data		✓		
Granulosa Cell – Phase 2 initial data		✓		
Breast – SMILE trial initial Phase 2 data		●		
Breast – ELONA trial Phase 1b data			●	

Claudin 6	1H 2022	2H 2022	2023	2024
Candidate selection		●		
IND submission				●

Investment Highlights

Large Unmet Need

Female Cancers

High-Value Targets

Progesterone Receptor and Claudin 6

Near-Term Milestones

Multiple Data Readouts in Q4 2022

Strong Team

Deep Domain Experience, Track Record of Success

Financial Strength

Expected Cash Runway into Q1 2024

context therapeutics

ADVANCING MEDICINES FOR FEMALE CANCERS

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Abbreviations

Clinical Trial Efficacy	
CBR (CR+PR+ SD ≥6 mos)	Clinical benefit rate
CR	Complete response
DCR (CR+PR+ SD)	Disease control rate
DoR	Duration of response
mPFS	Median PFS
ORR (CR+PR)	Overall response rate
PFS	Progression free survival
SD	Stable disease
95% CI	95% confidence interval

Clinical Trial Safety	
AE	Adverse event
DLT	Dose-limiting toxicity
TRAE	Treatment-related adverse event
SAE	Serious adverse event

Diseases	
BC	Breast cancer
GCT	Granulosa cell tumor
NSCLC	Non-small cell lung cancer
SCLC	Small cell lung cancer

Other Terms	
1L	First Line
2L	Second Line
BID	Twice per day
CPI	Checkpoint inhibitor
dMMR	DNA mismatch repair
ER	Estrogen receptor
mAb	Monoclonal antibody
MSI-H	Microsatellite instability high
ND	Not determined
NE	Not evaluable
PK	Pharmacokinetics
PR	Progesterone receptor
QD	Once per day
QOL	Quality of life
SOC	Standard of care
TFI	Treatment free interval

Approved Drugs Mentioned	
Jemperli	Dostarlimab-gxly (GSK)
Lenvima	Lenvatinib (Eisai)
Keytruda	Pembrolizumab (Merck)

Medical Organizations / Conferences	
AACR	American Association for Cancer Research
ASCO	American Society of Clinical Oncology
ESMO	European Society for Medical Oncology
SABCS	San Antonio Breast Cancer Symposium