

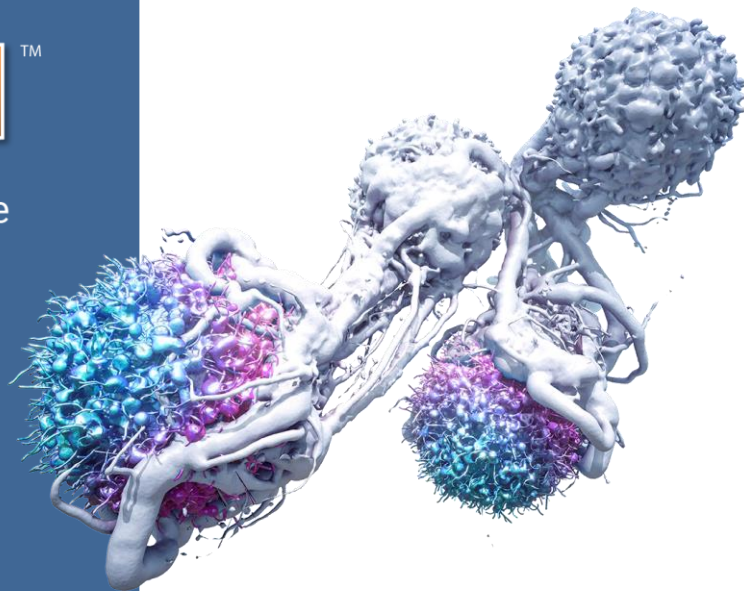
12 TRIALS • 5 CANCERS • MONOTHERAPY • COMBINATION THERAPY • NEO-EPITOPES

# IMMUNITION™

The Intelligent Immune Response

## Aegis Capital 2016 Growth Conference

September 21, 2016



**ADVAXIS**  
IMMUNOTHERAPIES™

This presentation contains forward-looking statements including, but not limited to, statements regarding Advaxis' ability to develop the next generation of cancer immunotherapies, and the safety and efficacy of Advaxis' proprietary immunotherapy, axalimogene filolisbac (AXAL). These forward-looking statements are subject to a number of risks including the risk factors set forth from time to time in Advaxis' SEC filings including, but not limited to, its report on Form 10-K for the fiscal year ended October 31, 2015, which is available at <http://www.sec.gov>.

Advaxis undertakes no obligation to publicly release the result of any revision to these forward-looking statements, which may be made to reflect the events or circumstances after the date hereof, or to reflect the occurrence of unanticipated events, except as required by law. You are cautioned not to place undue reliance on any forward-looking statements.

- *Lm (Listeria Monocytogenes)* Technology has broad applicability
- Partnership with Amgen to develop ADXS-NEO, a neoepitope-based immunotherapy platform
- Promising monotherapy data in multiple tumor types
- Lead asset, axalimogene filolisbac (AXAL), in Phase 3
- 2 additional clinical stage assets: ADXS-PSA and ADXS-HER2
- Potential additive effect with checkpoint inhibitors and activators
- Well capitalized and strong IP
- Experienced management team

# Experienced Management Team

**ADVAXIS**  
IMMUNOTHERAPIES™



**Daniel O'Connor**

President and Chief  
Executive Officer



**PharmaNet**



Ernst & Young  
Entrepreneur  
Of The Year®



**Gregory Mayes**

Executive Vice President  
and Chief Operating Officer

**Dendreon**

**AstraZeneca**



**unigene**



**Robert Petit**

Executive Vice President  
and Chief Scientific Officer

**Bristol-Myers  
Squibb Company**



**PHARMACIA**



**Sara Bonstein**

Senior Vice President and  
Chief Financial Officer

**Lilly**

**Johnson & Johnson**



# Lm Technology™ Overview: Harnessing Unique Life Cycle of *Lm* in APCs

*Lm*-LLO agent taken up only by phagocytic dendritic cells/APCs



*Lm*-LLO stimulates a strong innate multipathway immune response (eg. STING) in APC



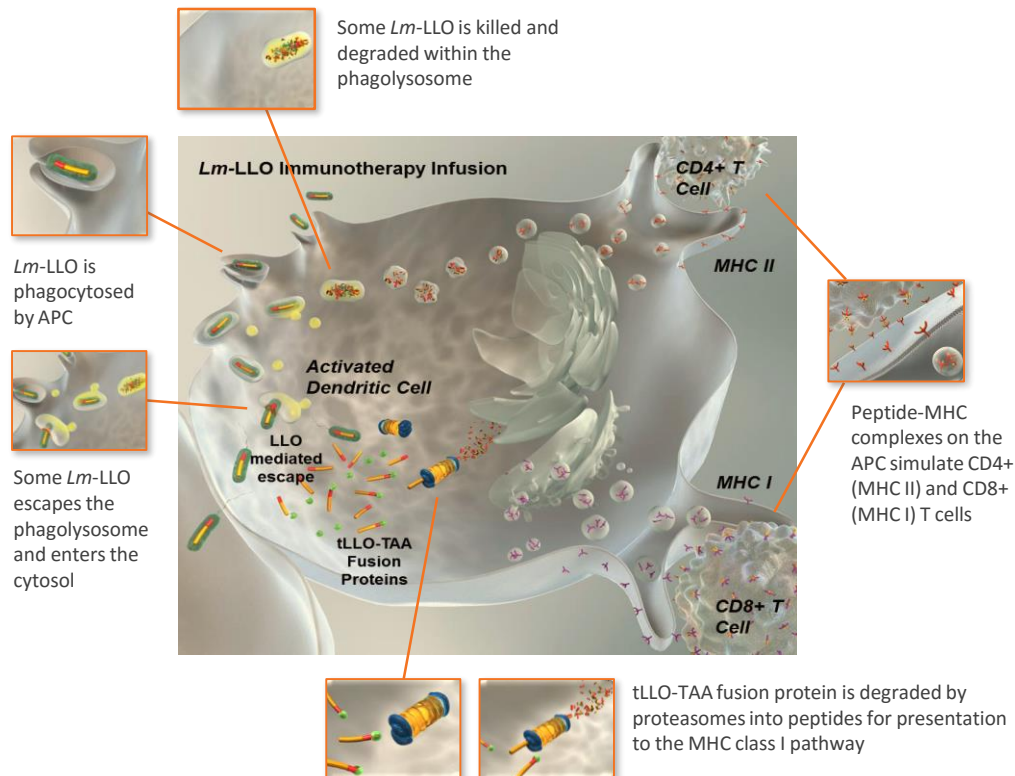
*Lm*-LLO expresses LLO-TAA fusion protein, which is processed by stimulated APC and activates TAA-specific T-cells



Robust T-cell response generated toward TAA, allowing tumor-specific immune response



Immune activation can overcome checkpoint inhibition and negative regulators of cellular immunity



Personalized neoepitope cancer immunotherapies have evolved

- Letting patient's unique cancer mutations tell us how to target the tumor
- ADXS-NEO, a preclinical asset, has demonstrated tumor control in an in vivo model

Ideal platform for activating the immune system against cancer neoepitopes:

- Directly activates APC through an attenuated but specific infection
- Delivers a large payload of neoepitopes for producing a T cell response
- Decreases the number of Tregs and MDSCs in the tumor microenvironment
- Has been shown to be synergistic with checkpoint inhibitors
- Manufacturing process meets requirement for scalability, reasonable turnaround and cost

# Convergence of Complementary Capabilities

**AMGEN®**

- Biotechnology pioneer with more than 35 years of experience
- Global presence
- World-class development capabilities

**ADXS-NEO**

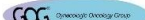






- Targeted immunotherapy
- Innovative science
- Collaboration
- Clinical development

**ADVAXIS**  
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- *Lm* Technology™
- Over 70 employees
- Neoepitope expertise
- Manufacturing capabilities

- \$40M upfront; \$25M stock purchase
- \$475M in achievement based milestones
- Amgen to fully fund all development and commercial activities
- Tiered royalties on net sales

# Broad Clinical Pipeline Targeting Multiple Tumors

PRODUCT	INDICATION		PHASE 1	PHASE 2	PHASE 3	Partner
AXAL	CERVICAL CANCER†					
	M	AIM2CERV: Adjuvant Randomized vs Placebo			Phase 3*	
		Metastatic: GOG 0265		Phase 2		
	C	Metastatic: Combo with Durvalumab	Phase 1/2			
	HEAD AND NECK CANCER†					
	M	Presurgical: Window of Opportunity – Mount Sinai		Phase 2		
	ANAL CANCER†					
		RTOG: Adjuvant Randomized vs Control		Phase 2/3		
	M	Adjuvant: Single Arm High Risk – Brown University (BrUOG)	Phase 1/2			
		Metastatic (FAWCETT)		Phase 2		
ADX-PSA	PROSTATE CANCER					
	C	Metastatic: Combo with KEYTRUDA (pembrolizumab)	Phase 1/2			
ADX-HER2	HER2-POSITIVE SOLID TUMORS (INCLUDING OSTEOSARCOMA†)					
	M	Metastatic: Single Arm	Phase 1			
Osteosarcoma			Phase 2			

\*Under FDA Special Protocol Assessment.  
†Orphan Drug Designation.

C

Combination

M

Monotherapy

Active

Planned



# AXAL: Lead HPV Targeted Cancer Immunotherapy

## PRODUCT

AXAL is a live attenuated *Listeria monocytogenes* (Lm) vector system that secretes an antigen-adjuvant protein (Lm-LLO) targeting HPV

## PROFILE

AXAL is designed to improve clinical outcomes in HPV-associated tumors such as Cervical, Anal, and Head & Neck Cancers through a highly-targeted, generally well-tolerated immune-mediated response warranting further study.

## DEVELOPMENT STATUS

Phase 3 in cervical cancer

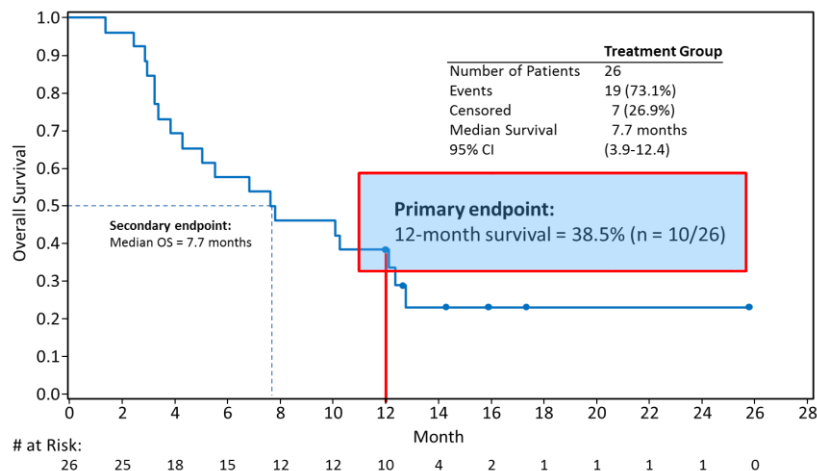
- FDA SPA and Fast-Track designation as adjuvant therapy for high-risk cervical cancer
- Has been well tolerated with established adverse event management in earlier phase trials

Studies in other cancers settings: Head and neck and anal cancers

- Head and neck cancer in combination with durvalumab
- Anal cancer Phase 1/2 adjuvant study (RTOG; Orphan indication) and Phase 2 in metastatic (FAWCETT)

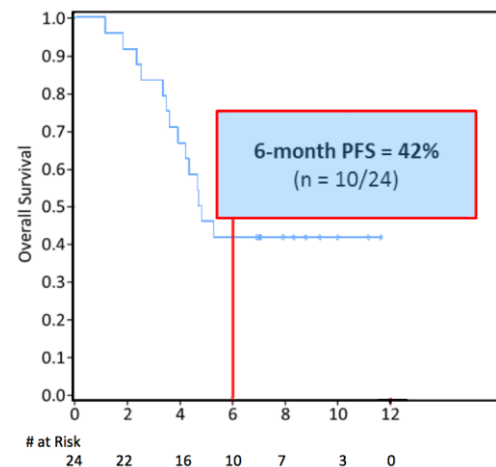
# AXAL - GOG 0265: Phase 2 Study In Recurrent Cervical Cancer Demonstrated Unprecedented Survival in Preliminary Findings

## Stage 1 Data Presented at American Gynecological & Obstetrical Society 2015



- Previously 12-month overall survival never >30%<sup>1</sup>
- Median OS >1 year and 12-month survival of 55.6% in 69% patients given all 3 doses

## Stage 2 Preliminary Results\* Survival Benefits Are Consistent with Stage 1 Results

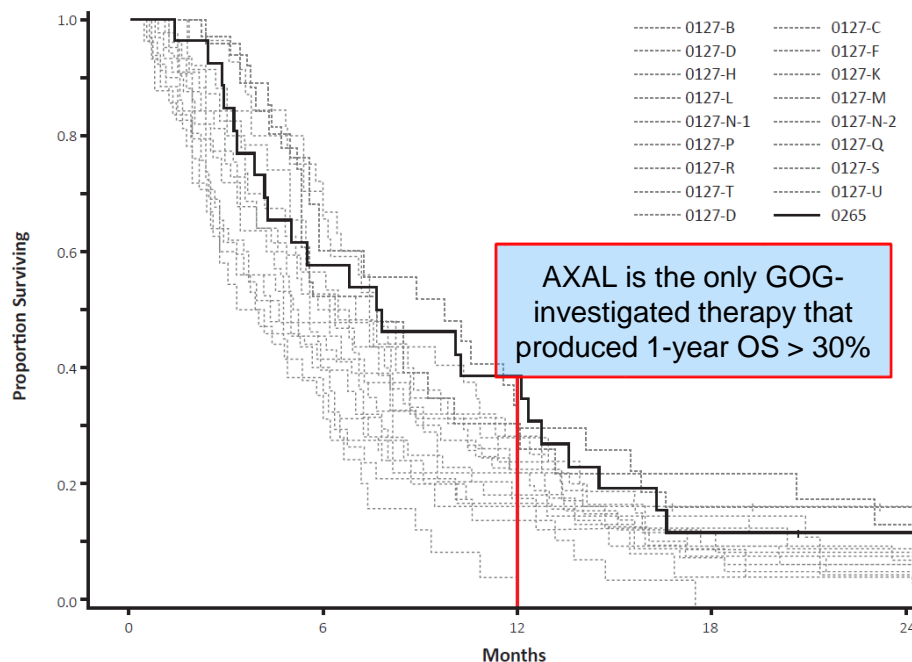


- Median PFS 2.6 mos similar to 3.1 mos in Stage 1
- Primary endpoint of 12-mo OS not calculated due to limited median follow-up of 8.7 mos
- Most common AEs Grade 1–2 fatigue, chills - similar to Stage 1

<sup>1</sup>Monk BJ, et al. *J Clin Oncol*. 2009;27(7):1069-74.

\*These data represent initial Stage 2 results; Stage 2 was re-enrolled after a clinical hold halted dosing in the first group of Stage 2 enrollees. Huh W, et al. ASCO 2016. Abstract 5516.

# AXAL Monotherapy Study GOG-0265: Survival in the Context of Historical 12-month Survival in GOG Trials



1. Tewari KS, Monk BJ. *Curr Oncol Rep.* 2005;7(6):419-434; 2. Muggia F, et al. *Gynecol Oncol.* 2004;92(2):639-643; 3. Plaxe SC, et al. *Cancer Chemother Pharmacol.* 2002;50(2):151-154; 4. Armstrong DK, et al. *Invest New Drugs.* 2003;21(4):453-457; 5. Fracasso PM, et al. *Gynecol Oncol.* 2003;90(1):177-180; 6. Brewer CA, et al. *Gynecol Oncol.* 2006;100(2):385-388; 7. Rose P, et al. *Gynecol Oncol.* 2006;102(2):210-213; 8. Garcia AA, et al. *Am J Clin Oncol.* 2007;30(4):428-431; 9. Miller DS, et al. *Gynecol Oncol.* 2008;110(1):65-70; 10. Fiorica JV, et al. *Gynecol Oncol.* 2009;115(2):285-289; 11. Monk BJ, et al. *J Clin Oncol.* 2009;27(7):1069-1074; 12. Schilder RJ, et al. *Int J Gynecol Cancer.* 2009;19(5):929-933; 13. National Cancer Institute. Vaccine therapy in treating patients with persistent or recurrent cervical cancer. <http://www.cancer.gov/about-cancer/treatment/clinical-trials/search/view?cdrid=691288>. Accessed May 25, 2016; 14. Gynecologic Oncology Group/NRG Oncology. Data on file, 2016.

# GOG-0265: Safety/Tolerability – Stage 1

Adverse Event Summary (n=26)			
Adverse event (AE)	Grade 1-4	Grade 3	Grade 4
<b>Patients with ≥ 1 treatment-related AE (TRAE), n (%)</b>	24 (92)	4 (15)	1 (4)*
TRAEs occurring in ≥ 10% of patients			
Fatigue	15 (58)	-	-
Chills	14 (54)	-	-
Fever	11 (42)	-	-
Nausea	10 (39)	-	-
Headache	9 (35)	-	-
Hypotension	7 (27)	2 (8)	-
Vomiting	6 (23)	-	-
Cytokine release syndrome	5 (19)	3 (12)	-
Myalgia	5 (19)	-	-
Abdominal pain	4 (15)	-	-
General pain	4 (15)	-	-
Flu-like symptoms	3 (11)	-	-
AST elevation	3 (11)	-	-

\*The observed grade 4 TRAE recorded in one patient (lung infection and sepsis) was considered possibly related to treatment.  
AE, adverse event;; AST, aspartate aminotransferase; TRAE, treatment-related AE.

# AXAL Adjuvant Monotherapy (AIM2CERV)

## Phase 3 Study to Prevent Recurrence in High-Risk Cervical Cancer

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Randomization 1:2 Between Reference and Treatment Groups

### High-risk locally advanced cervical cancer

- FIGO Stage IB2–II with positive pelvic nodes
- FIGO Stage III–IV
- Any FIGO stage with para-aortic nodes

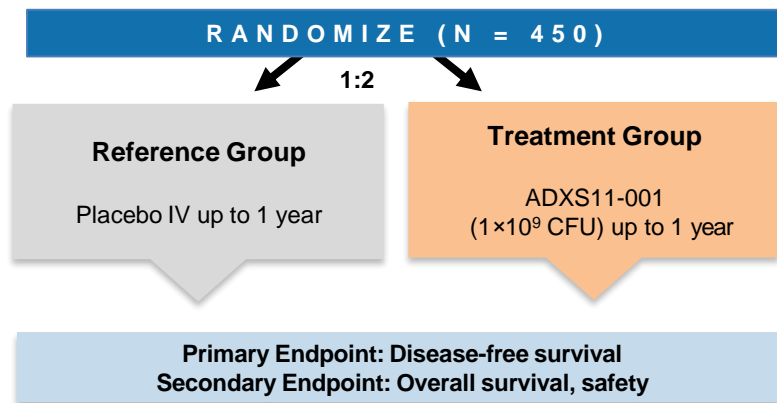
### Total sites: 150 in 20 countries

- GOG is supporting AIM2CERV by acting as a Site Management Organization

### Trial timeline (estimated)

- First patient enrollment: 3Q16
- Last patient enrollment: 1Q18
- Final data readout: 3Q19

Cisplatin (at least 4 weeks of exposure) and  
radiation (minimum 40 Gy external beam radiation therapy)



FDA SPA issued July 2016  
Fast-Track Designation for FDA Review  
Advanced-Therapy Medicinal Product (ATMP) from EMA CAT

# AXAL ± Durvalumab (PD-L1)

## Phase 1/2 Study in Metastatic Cervical or Head and Neck Cancers

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### Main Patient Characteristics

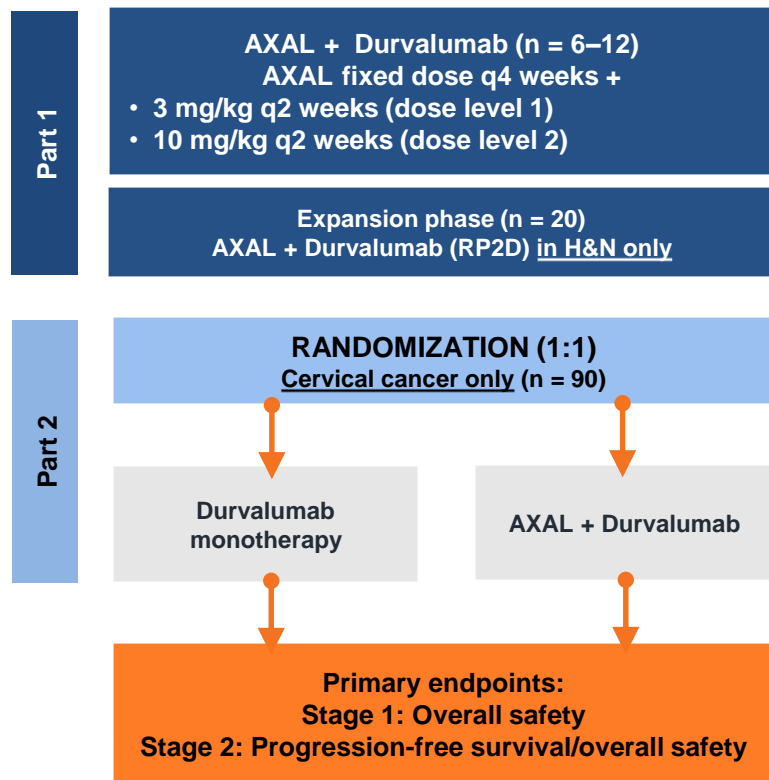
- Cervical cancer or HPV+ head/neck cancer
- Measurable and/or evaluable disease

### Targeted Accrual

- 6–12 in Part 1 (dose finding)
- 20 in Part 1 expansion (H&N only)
- 90 in Part 2, phase 2 (cervical only)

### Trial Timeline (estimated)

- Part 1 first and second patient cohort enrollment are complete
- Part 1 expansion initiated: 3Q16
- Part 2 first patient enrolled: 3Q16
- Study completion: 2018



# AXAL Monotherapy

## Initial Phase 2 Study in Anal Cancer: FAWCETT

### Two-part Study of AXAL Monotherapy

- Primary and secondary endpoints ORR by RECIST (primary) and irRECIST (secondary); 6-month PFS
- Other endpoints: safety and tolerability, duration of response, PFS, and overall survival
- **Note: Stage 2 may include PD-1 / PD-L1 combination**

### Main Patient Characteristics

- Persistent/recurrent, locoregional, or metastatic anal cancer
- Stage 1 enrollment: 31 patients
- Stage 2 enrollment: 24 additional patients

### Trial Timeline (projected)

- First patient enrollment: 2Q16
- Study completion: 2021

Treatment naive in metastatic setting or progressed after platinum-based therapy



**AXAL Monotherapy**  
Every 3 weeks for up to 2 years



**Key Endpoints:**  
Overall response rate  
6-month PFS



**Interim Analysis and Stage 2 Enrollment**  
Additional 24 patients if  $\geq 10\%$  ORR or  $\geq 20\%$  6-month PFS

# AXAL + Mitomycin, 5-FU, and Radiation Open-Label Phase 1/2 Study in Anal Cancer (BrUOG\*)

## BrUOG Phase 1/2 Anal Cancer Study Design and Preliminary Data

*Early response rates and lack of recurrence suggest AXAL signal*

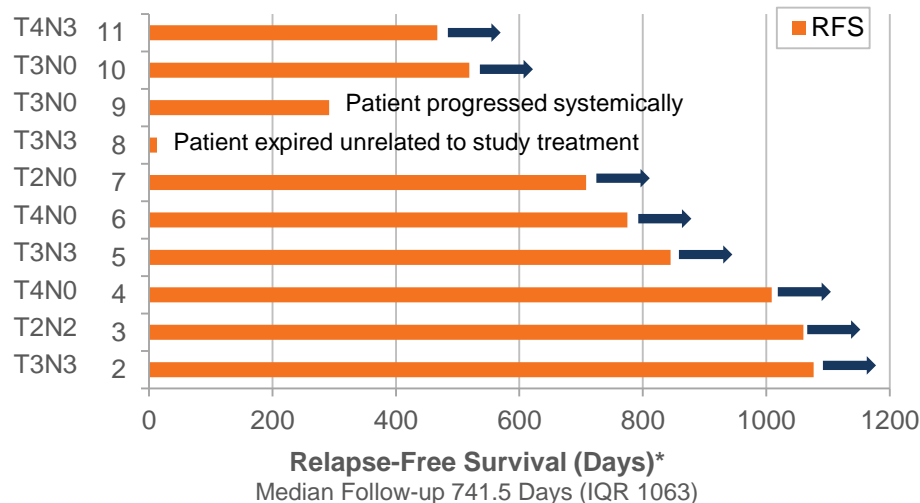
### Study Design

- Study open: April 2013
- Primary endpoint: 6-month CR rate
- N = 25 (10 enrolled w/ preliminary data)
- Patients: Primary stage II-III anal cancer, high risk of recurrence, HPV-positive

### Summary

- All patients who have completed treatment achieved CR (N = 9)
- No evidence of recurrence
- Historical 3-year recurrence rate in similar patient population = ~45%
- Follow-up duration: 0.5 months – 33 months
- Well tolerated safety profile

### Preliminary Relapse Free Survival Data



\*As of Mar 27, 2016.

Personal communication: L. Kachnic, MD.

Note: Patient #1 enrolled but was never treated on study



# AXAL BrUOG Study: Safety/Tolerability

Adverse Event	Grade 2	Grade 3	Grade 4
Flu-like symptoms	1		
Migraine	1		
Hypotension	1		
Hypokalemia*		1	
Chills/rigors	3	2	
Nausea	2		
Back Pain	1	1	
Fever	2		

Acute Grade 3 toxicities related to ADXS11-011:

- Chills/rigors (N=2)
- Back Pain (N=1)
- All toxicities were within 24 hours of dosing

\*These AEs occurred during dosing time point but are also included with overall AEs

# ADXS-HER2: Phase 1B Monotherapy in Multiple HER2-Expressing Tumors

## PRIMARY EFFICACY ENDPOINT: SAFETY AND RP2D

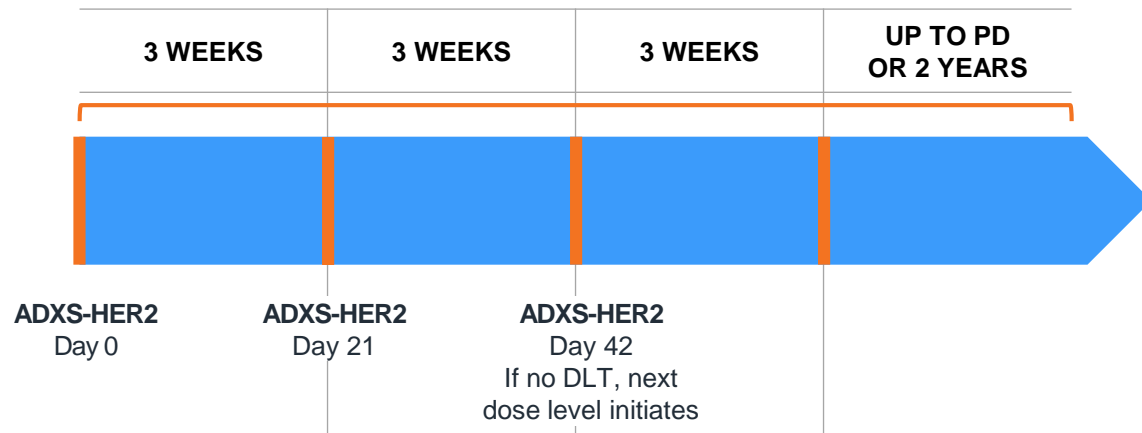
Tumors to include: osteosarcoma, breast, gastric, and other cancers

### ADXS-HER2 Monotherapy

Total N ~100

Primary endpoints: Safety and RP2D

- N ≤18 (dose finding); N ≤80 (expansion phase in tumor-specific subgroups)
- HER2-positive solid tumor
- Disease progressed or intolerant to standard therapy
- ECOG performance status 0–1
- 3+3 phase 1 design with possible expansion phase in up to 4 different indications



**Market Cap:** \$468mm

**Headquarters:** Princeton, NJ

**Employees:** 70+

**New state-of-the-art  
manufacturing facility**

## Cash Summary

Cash on hand as of August 31, 2016	\$162.8M
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**No Debt**

## Equity Summary

Basic Shares Outstanding	39.7mm
Warrants and Options	3.1mm/3.4mm
Fully Diluted Shares Outstanding*	46.2mm

# Near-Term Milestones

	<b>MILESTONE</b>	<b>ANTICIPATED DATE</b>
<b>AXAL: AIM2CERV</b>	First Patient Dosed	Q3 2016
	Committee for Advanced Therapeutics Filing (EU)	Q4 2016
	Complete Enrollment	Q1 2018
<b>ADX-NEO</b>	Initiate Phase 1 Trial	H1 2017
<b>AXAL / Durvalumab</b>	Initial Dose Escalation Data Planned for SITC	Q4 2016
	Complete Enrollment of Part 1 Expansion (Head & Neck) and Part 2 (Cervical)	H2 2017
<b>ADX-PSA / Pembro</b>	Complete Enrollment of Dose Escalation	End 2016

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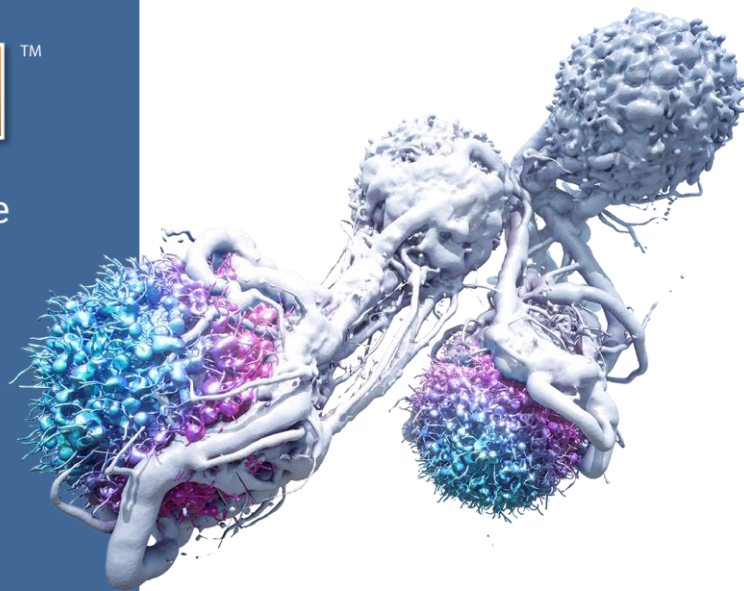
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