
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934**

Date of report (Date of earliest event reported): **October 4, 2019**

ADVAXIS, INC.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-36138
(Commission
File Number)

02-0563870
(IRS Employer
Identification No.)

**305 College Road East
Princeton, New Jersey, 08540**
(Address of Principal Executive Offices)

(609) 452-9813
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act.
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act.
- Pre-commencement communications pursuant to Rule 14d-2b under the Exchange Act.
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act.

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common stock, par value \$0.001 per share	ADXS	Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01 Other Events.

Attached hereto as Exhibit 99.1 and incorporated herein by reference is a PowerPoint presentation, including a corporate overview of the Company, which will be made available on its website at www.advaxis.com.

Forward-Looking Statements

Some of the statements included in this report may be forward-looking statements that involve a number of risks and uncertainties. For those statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. The factors that could cause our actual results to differ materially include: the impact of the discontinuation on relationships related to the Aim2Cerv Study; the success and timing of our clinical trials, including subject accrual; our ability to avoid and quickly resolve any clinical holds; our ability to obtain and maintain regulatory approval and/or reimbursement of our product candidates for marketing; our ability to obtain the appropriate labeling of our products under any regulatory approval; our plans to develop and commercialize our products; the successful development and implementation of our sales and marketing campaigns; the size and growth of the potential markets for our product candidates and our ability to serve those markets; our ability to successfully compete in the potential markets for our product candidates, if commercialized; regulatory developments in the United States and other countries; the rate and degree of market acceptance of any of our product candidates; new products, product candidates or new uses for existing products or technologies introduced or announced by our competitors and the timing of these introductions or announcements; market conditions in the pharmaceutical and biotechnology sectors; our available cash, including to support current and planned clinical activities; the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing; our ability to obtain additional funding; our ability to obtain and maintain intellectual property protection for our product candidates; the success and timing of our preclinical studies including IND-enabling studies; the timing of our IND submissions; our ability to get FDA approval for study amendments; the timing of data read-outs; the ability of our product candidates to successfully perform in clinical trials; our ability to initiate, enroll, and execute pilots and clinical trials; our ability to maintain our existing collaborations; our ability to manufacture and the performance of third-party manufacturers; the performance of our clinical research organizations, clinical trial sponsors and clinical trial investigators; our ability to successfully implement our strategy; and, other risk factors identified from time to time in our reports filed with the SEC. Any forward-looking statements set forth in this press release speak only as of the date of this press release. We do not intend to update any of these forward-looking statements to reflect events or circumstances that occur after the date hereof.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit is furnished as part of this report:

Exhibit Number	Description
99.1	October 2019 Investor Presentation.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: October 4, 2019

ADVAXIS, INC.
(Registrant)

By: /s/ Molly Henderson

Molly Henderson

Executive Vice President and Chief Financial Officer

ADVAXIS
IMMUNOTHERAPIES™

Corporate Presentation

Nasdaq: ADXS

October 2019

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Forward-Looking Statements

This presentation contains forward-looking statements that involve a number of risks and uncertainties. For those statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. The factors that could cause our actual results to differ materially include: the impact of the discontinuation on relationships related to the Aim2Cerv Study; the success and timing of our clinical trials, including subject accrual; our ability to avoid and quickly resolve any clinical holds; our ability to obtain and maintain regulatory approval and/or reimbursement of our product candidates for marketing; our ability to obtain the appropriate labeling of our products under any regulatory approval; our plans to develop and commercialize our products; the successful development and implementation of our sales and marketing campaigns; the size and growth of the potential markets for our product candidates and our ability to serve those markets; our ability to successfully compete in the potential markets for our product candidates, if commercialized; regulatory developments in the United States and other countries; the rate and degree of market acceptance of any of our product candidates; new products, product candidates or new uses for existing products or technologies introduced or announced by our competitors and the timing of these introductions or announcements; market conditions in the pharmaceutical and biotechnology sectors; our available cash, including to support current and planned clinical activities; the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing; our ability to obtain additional funding; our ability to obtain and maintain intellectual property protection for our product candidates; the success and timing of our preclinical studies including IND-enabling studies; the timing of our IND submissions; our ability to get FDA approval for study amendments; the timing of data read-outs; the ability of our product candidates to successfully perform in clinical trials; our ability to initiate, enroll, and execute pilots and clinical trials; our ability to maintain our existing collaborations; our ability to manufacture and the performance of third-party manufacturers; the performance of our clinical research organizations, clinical trial sponsors and clinical trial investigators; our ability to successfully implement our strategy; and, other risk factors identified from time to time in our reports filed with the SEC. Any forward-looking statements set forth in this presentation speak only as of the date of this presentation. We do not intend to update any of these forward-looking statements to reflect events or circumstances that occur after the date hereof. Our fiscal year ends October 31. Throughout this presentation, all references to quarters and years are to the calendar quarters and years unless otherwise noted.

Corporate Overview

Corporate Facts

- Founded 2002; HQ in Princeton, NJ
- ~40 employees
- **Recently financed** raising \$17 million
- 48 million shares outstanding as of September 30, 2019

Platform Technology

- Clinically validated, unique immuno-oncology platform
- Bacterial vector equipped with targeted (neo)antigens

Clinical Pipeline

- ADXS-NEO: personalized, patient-specific
- ADXS-HOT: off-the-shelf, tumor type-specific
- ADXS-PSA: prostate program
- ADXS-HPV (AXAL): HPV+ cancers

Upcoming Milestones

- ADXS-PSA Phase 2: further mOS data in combination arm
- ADXS-NEO Phase 1: further monotherapy data
- ADXS-HOT Phase 1/2: NSCLC monotherapy data; start combination cohort +checkpoint inhibitor
- ADXS-HPV: initiation of IST in head and neck cancer

Investment Highlights

Validated and Versatile I/O Platform

Innovative Platform

- Proprietary bacterial vector/platform can elicit rapid and strong immunological activity
- Nearly 500 patients treated, manageable safety profile⁽¹⁾

Immunogenicity and Clinical Signals

- NEO: 90% CD8+ T cell reactivity and antigen spreading in first MSS CRC patient
- PSA: Phase 2 study in prostate cancer⁽²⁾ showed prolonged survival in combination with checkpoint inhibitor
- HPV⁽³⁾: Phase 2 clinical trials demonstrated improvement in survival in cervical cancer
- HER2: Dramatic responses seen in canine osteosarcoma led to conditional USDA approval and commercial launch by vet partner

Additional Pipeline Opportunities

- HOT: Trial in lung cancer initiated in February 2019, currently enrolling; planned filing of IND in prostate cancer 1H 2020; with another 10 constructs designed that can be moved into the clinic
- HPV: Phase 2 IST in head and neck cancer planned in late 2019/early 2020
- Additional vet product opportunities: Leveraging multiple antigen approach

Clinical Pipeline

Program	Cancer Indication	IND	PHASE 1	PHASE 2	PHASE 3
ADXS - NEO	NSCLC, MSS-CRC, Head & Neck, Melanoma, Bladder				
ADXS - HOT	Non-Small Cell Lung				
	Prostate	★ IND Submission 2H 2019			
	Bladder	★ IND Submission 1H 2020			
ADXS - HPV (AXAL)	HPV+ Head and Neck (Partners to be announced)		★ 2H 2019		
ADXS - PSA	Metastatic Prostate in Combination with KEYTRUDA® (pembrolizumab)				

Advaxis Funded	Investigator Funded
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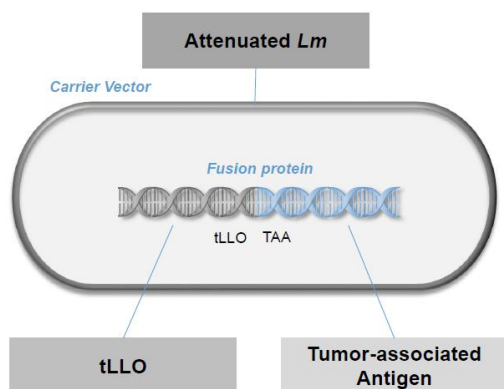
★ = Planned

Lm Platform Technology

Proprietary Antigen Delivery Platform that Activates the Immune System, Naturally

Lm Platform Designed to Trigger Strong Immune Responses with Targeted Antigens

Three Core Components

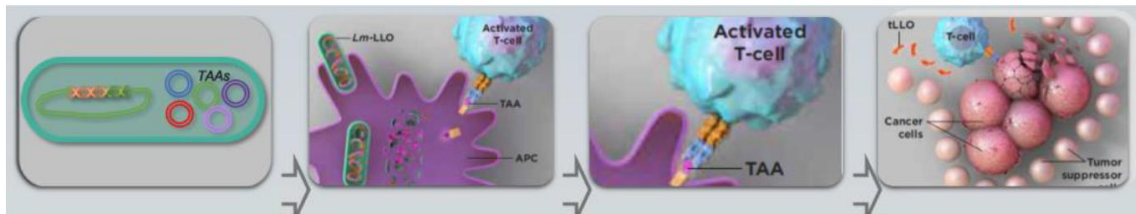


Comprehensive Immune Activity

- *Listeria monocytogenes* (*Lm*) bacteria
 - Carrier vector; irreversibly attenuated⁽¹⁾
 - Mimic infection and redirect immune response against cancer
 - Well understood and manageable safety profile, to date
- tLLO
 - Adjuvant properties
 - Powerful CD8+ T cell response
 - Neutralize Tregs & MDSCs protecting the tumor
- Diverse tumor associated antigens
 - Cancer type-specific (HOT, PSA)
 - Patient-specific neoantigens (NEO)
 - Viral (HPV+)

Using the Body's Own Immune System to Fight Cancer

Harnessing the Unique Life Cycle of *Lm* in APCs



Live attenuated strains of *Lm* are bioengineered to secrete antigen-adjuvant fusion proteins

Upon infusion, Bioengineered *Lm* are phagocytosed by APCs where fusion protein is secreted and processed – presented to MHC class I and II

Target peptides presented on APC surface stimulate tumor associated antigen (TAA) specific CD4+ and CD8+ T cells

Activated CD8+ T cells seek out and kill TAA-expressing cancer cells and modulated tumor microenvironment to overcome immune suppression

Advaxis Technology Evolution: Higher Payloads, New Targets

ADX-HPV (AXAL)

Prolonged survival and **complete responses** in cervical and anal cancer patients and **antigen spreading** observed

ADX-PSA

In combination with KEYTRUDA® **prolonged survival** in metastatic castration-resistant prostate cancer

ADX-NEO

Personalized, patient-specific candidates based on sequencing of each patient's tumor; early data suggest **rapid and strong immunogenicity and antigen spreading**

ADX-HOT

Cancer type-specific candidates based on commonly expressed public hotspot mutations and proprietary cancer antigens with **proof-of-mechanism for hotspot mutations identified in NEO program**

Single antigen delivery platform

Multiple neoantigen delivery platform

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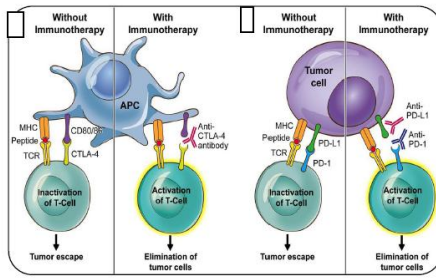
KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA.

ADXS-NEO

Our Personalized Neoantigen-Directed Therapy

*In Phase 1 for Non-Small Cell Lung, MSS-Colorectal, Head & Neck, Melanoma
and Bladder Cancers*

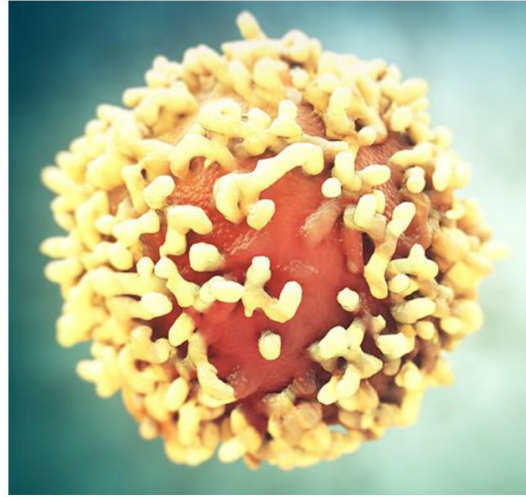
Neoantigen-Directed Immunotherapies Can Transform Cancer Treatment



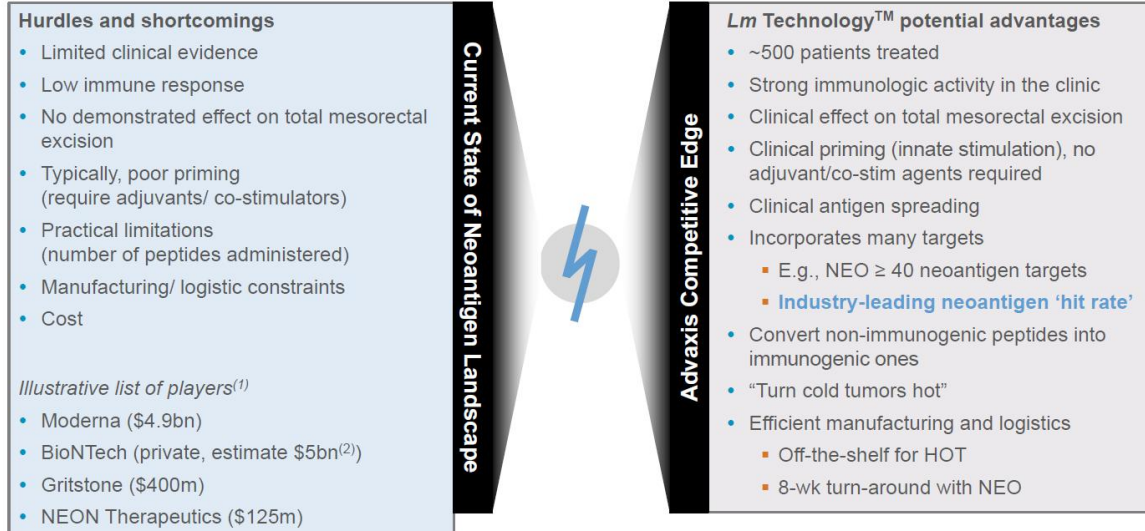
- I/O treatments work to harness the power of individuals' immune system
- Immune Checkpoint Inhibitors (ICIs) have dramatically altered the cancer treatment landscape but still **only a minority of patients treated with ICIs have durable responses** and improved outcomes leading to long-term survival
- Emerging data from studies of patients who successfully respond to ICIs show that most have pre-existing T cells against neoantigens
- Neoantigen-directed immunotherapies can build upon the success of ICIs, leading to durable outcomes with long-term survival to further transform cancer treatment paradigms

Unlocking the Potential of Neoantigens

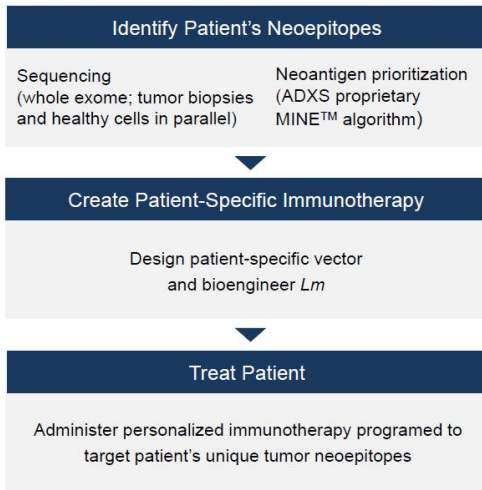
- Neoantigens are only found in cancer cells - making them good targets for therapies
- T cells that target neoantigens are the common link among successful immunotherapies developed to date (e.g., checkpoint inhibitors, Tumor Infiltrating Lymphocytes or TILs)
- Our *Lm* platform is able to generate broad and rapid T cell responses against neoantigens¹
- Preliminary clinical data suggest industry leading hit rate with CD8+ T cell responses generated or maintained against 90% of the neoantigens in an ADXS-NEO drug construct



Lm Technology: Overcoming Challenges in the Neoantigen Landscape

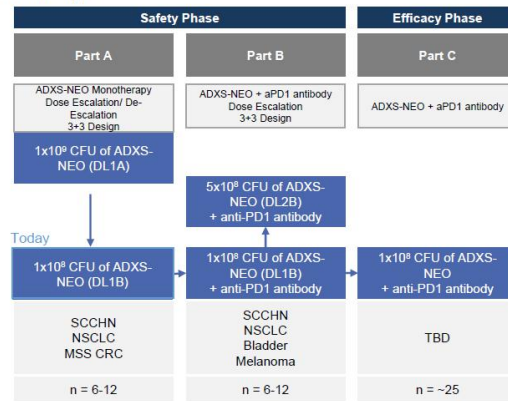


NEO Manufacturing and Trial Design



Title: A Phase 1 Dose-Escalation Study of ADXS NEO Expressing Personalized Tumor Antigens, Alone and in Combination with Pembrolizumab in Subjects with Advanced or Metastatic Solid Tumors

Trial design:



Endpoints:

- Primary:** Tolerability/ Safety
- Secondary:** Clinical activity RP2D
- Exploratory:** Immunological

Early Data From ADXS-NEO¹ Program

- Emerging data suggest potential for rapid, strong and broad CD8⁺ T cell response to targeted neoantigens
 - 100% patients (n=3) had CD8⁺ T cell responses to at least 1 peptide within 1 week after first dose
 - CD8⁺ T cells generated against 90% of peptides in first CRC patient
 - Antigen spreading observed in 100% of patients (n=3), consistent with our other constructs and clinical data
- Early clinical signals in metastatic colorectal cancer (CRC) patients who have microsatellite stable (MSS) disease
 - True unmet need: 80% of patients with CRC are MSS and typically do not respond to I/O treatments
 - CD8⁺ T cells generated against KRAS mutation (key driver mutation in CRC)
 - IHC data suggest ability to turn “cold” tumors “hot” in 100% of patients (n=2)
- Combination of strong immunogenicity and early clinical signals from ADXS-NEO suggestive of promise in our ADXS-HOT programs
 - CD8⁺ T cells generated against EGFR (key driver mutation in NSCLC) and KRAS mutations
 - Proof-of-mechanism demonstrated with CD8⁺ T cells generated against patient hotspot mutations
 - Hotspots included in ADXS-503 (HOT Lung) and ADXS-508 (HOT CRC) constructs

Strong Competitive Position within Neoantigen Landscape

	% CD8+ Ex-vivo (direct Elispot)	% CD8+ IVS Assay (In-Vitro Stimulation, Central memory)	Capacity	Antigen Spreading	T cell Generation Against Hotspot Mutations	Demonstration of Clinical Impact in Late-Stage Setting
Peer Data ¹	47%	33%	10-30	Unknown	Unknown	Most studies done in adjuvant setting
ADXS-NEO	~92% (Initial pool data)	90% (n=1, first CRC patient)	ADXS-NEO, 40 MINE™ selected neoantigens	Clinically Observed	Clinically Observed	Stable Disease (SD) in 2 of first 4 patients per RECIST 1.1

- ✓ Proven activity in pre-clinical models
- ✓ Observed effect on the TME (MDSCs, Tregs)
- ✓ Immunogenic proprietary targets
- ✓ Priming via innate immune stimulation; adjuvant/co-stims not required
- ✓ Ability to “convert” non-immunogenic peptides into immunogenic peptides and potential to “turn cold tumors hot”

ADXS-HOT

Off-the-Shelf Hotspot Neoantigen-Directed Therapy

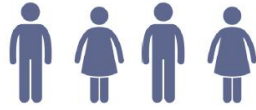
Phase 1/2 in Non-Small Cell Lung Cancer

ADX5-HOT

Targeting Multiple Hotspots, OFAs and CTAs Increases Patient Applicability and Clinical Activity Potential



Hotspot mutations have demonstrated pre-clinical activity in Advaxis' Lm Technology¹



ADX5-HOT constructs target both public, or shared, hotspot neoantigens and multiple proprietary tumor associated antigen targets, including oncofetal antigens (OFAs) and cancer testis antigens (CTAs)

Over 10 drug candidates designed using this approach

coverage of nearly

100%

ADX5-HOT constructs can include over 30 antigen targets and are designed to allow for multiple shots on goal to control the tumor in nearly all patients

Antigen spreading could further increase the potential number of targets

Can be used as monotherapy and/or in combination with other cancer treatments like checkpoint inhibitors



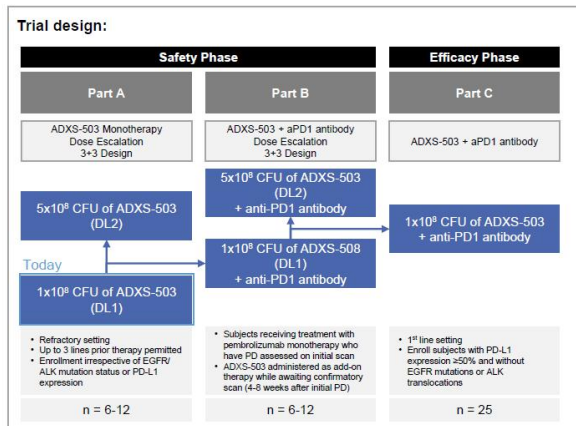
Off-the-shelf and available for patients to start treatment immediately

Manufactured in bulk with good stability keeping cost of goods low vs. "individualized" products

HOT Development Overview – Lung Phase 1/2 Clinical Trial

ClinicalTrials.gov Identifier: NCT03847519

Title: A Phase 1/2, Open-Label Study of ADXS-503 Alone and in Combination with Pembrolizumab in Subjects with Metastatic Squamous or Non-Squamous Non-Small Cell Lung Cancer



Endpoints:

Primary
Tolerability/ Safety

Secondary
Clinical activity
RP2D

Exploratory
Immunological

Highlights*

- Part A in monotherapy in non-small cell lung cancer
 - Currently enrolling
 - Safety and immunogenicity data in 2H 2019
 - Part B in combination with checkpoint open for enrollment
- Broad pipeline of latest generation *Lm* products
 - Constructs for ≥10 cancer types readily designed
- HOT Prostate (ADXS-504) IND to be filed in late 2019

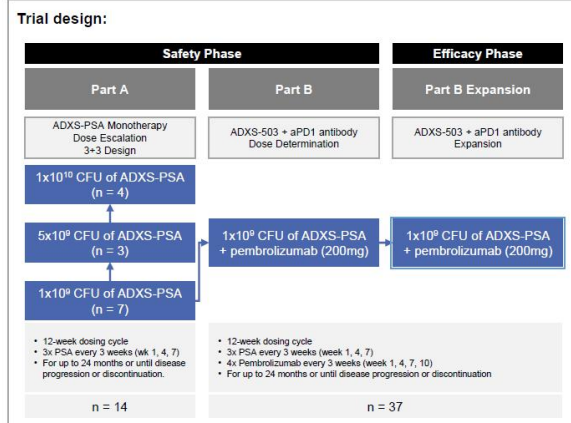
ADX-PSA

Prostate Cancer Therapy

PSA Development Overview – Phase 1-2 Clinical Trial

ClinicalTrials.gov Identifier: NCT02325557

Title: A Phase 1/2 Dose-Escalation and Safety Study of ADXS31-142 Alone and in Combination With Pembrolizumab in Patients With Previously Treated Metastatic Castration-Resistant Prostate Cancer



Endpoints:

Primary
Tolerability/ Safety
RP2D

Secondary
Anti-tumor activity
Progression-free survival
Effects on serum PSA
Peripheral immunogenic response
Biomarkers
Patient reported outcomes

Highlights*

- Currently monitoring the expansion arm (Part B)
 - Part A completed
 - 1x10⁹ +/- 200mg pembrolizumab established as R2PD
- Combination prolonged survival
 - Despite MSI-H negative status and presence of visceral metastases
 - Median OS=21.1 months (16.0–NR) in patients who had failed chemotherapy or were chemotherapy-naïve
 - [Reference: Stein et al., AACR 2019](#)
- Collaboration with Merck & Co.

Clinical History

Demonstration of Safety and Efficacy

Lm Safety

Summary of ADXS-HPV (AXAL) Treatment-Related Adverse Events

Treatment-Related Adverse Events Reported $\geq 5\%$ with ADXS11-001 (AXAL)
 Monotherapy: n (%) Adverse Events (N=192)

Preferred Term	Any Grade	Grade 3/4
Chills	91 (47.4%)	0
Pyrexia	70 (36.5%)	3 (1.6%)
Nausea	54 (28.1%)	0
Vomiting	48 (25.0%)	1 (0.5%)
Hypotension	46 (24.0%)	12 (6.3%)
Headache	41 (21.4%)	0
Tachycardia	15 (7.8%)	0
Cytokine release syndrome	15 (7.8%)	7 (3.6%)
Gamma-glutamyltransferase increased	15 (7.8%)	3 (1.6%)
Dizziness	14 (7.3%)	0
Aspartate aminotransferase increased	13 (6.8%)	0
Back pain	12 (6.3%)	0
Myalgia	12 (6.3%)	0
Influenza like illness	11 (5.7%)	0
Blood alkaline phosphatase increased	11 (5.7%)	2 (1.0%)
Diarrhea	10 (5.2%)	1 (0.5%)
Pain	10 (5.2%)	0
Decreased appetite	10 (5.2%)	0

- The largest source of *Lm* safety data is from patients treated with AXAL monotherapy at 1×10^9 CFU¹
- Treatment-related adverse events across AXAL trials were primarily Grade 1 and 2²
- Adverse Events generally occurred within hours and were transient in nature
 - manageable and reversible
- Standard premedication regimen has appeared to be adequate (diphenhydramine, NSAID, etc.)

HPV Scientific Summary

Extensive Clinical Experience with Demonstrated Clinical Benefit

Phase	Cancer	Setting	Line	NCT	IIT	Combo	Start	On Drug	Status
3	CC	HRLA	Adjuvant after chemoradiation	NCT 02853604	-	-	Sep 2016	TBR/Late 2019	Terminated
2	CC / HN	PR/m	≥ 2L	NCT 02291055	-	Durvalumab	Sep 2015	47 / 66	Suspended
2	CC	PR	2L/3L	NCT 01266460 GOG-0265	✓	-	May 2011	50	Complete
2	CC	PR	2L	N/A (India)	-	Cisplatin	Nov 2010	55 AXAL 54 AXAL + CIS	Complete
1-2	AN	Stage II/III	1L	NCT 01671488 BRUG-278	✓	5-FU + IMRT	Apr 2013	11	Complete
2	AN	PR/LR/m	≥ 2L	NCT 02399813	-	-	Sep 2015	36	Terminated
2	HN	all	1L	NCT 02002182	✓	Before robotic surgery	Dec 2013	8 / up to 30	Complete
2	HN	LA	Adjuvant after chemoradiation	N/A	✓	TBA	2H 2019	-	Planned
1-2	CC	PR/m	2L/3L	NCT 02164461	-	N/A	Mar 2015	12	Complete
Total: >400									

- 38% 12-month survival rate (19/50)
- **Highest 12m OS rate achieved to-date at GOG**
- Compared to expected 1-year survival of 15%
- 1 CR, 1 PR, 5 SD

- 35% & 25% 12-month & 18-month survival rates
- Compared to typical 1-year survival of 15%
- 3 CR, 3 PR, 16 SD

- All 9 patients who completed treatment had CR
- **8 of 9 patients (89%) were progression-free** at a median follow-up of **42 months**
- Compared to expected 1-year survival of 50%

Key Financial Information

Balance Sheet

Cash, Cash Equivalents and Marketable Securities, as of July 31, 2019	\$41.8MM
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Shares Outstanding, as of September 30, 2019	48.0MM
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Fully Diluted Shares Outstanding, as of September 30, 2019	51.0MM
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Operating Expenses for Nine Months Ended July 31, 2019

Research and Development Expenses	\$19.7MM
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General and Administrative Expenses	\$8.8MM
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*Reduced operating expenses by nearly 50% compared to nine months ended July 31, 2018
Targeted cash burn for August 2019-July 2020 approximates \$33MM-\$37MM, includes ~\$6MM in non-recurring program costs

Anticipated Catalysts Over the Next 12 Months

PROGRAM	COMPLETED/ANTICIPATED MILESTONES	TARGET
ADXS-PSA	<ul style="list-style-type: none"> Metastatic Prostate Ph1/2 Combination with pembrolizumab--Part B Combination Therapy Data (updated survival and preliminary biomarker data) presented at AACR Updated survival data from Part B 	Q1 2019* 2H 2019
ADXS-NEO	<ul style="list-style-type: none"> Data from initial clinical cohort (safety, immune response) presented at AACR and I/O 360 Additional immunogenicity and clinical data Initiate Part B in combination with checkpoint inhibitor 	1H 2019* 2H 2019 2H 2019
ADXS-503 HOT NSCLC	<ul style="list-style-type: none"> Immunogenicity data from initial clinical cohort (safety, immune response) Initiate Part B in combination with checkpoint inhibitor 	2H 2019 2H 2019
ADXS-504 HOT Prostate	<ul style="list-style-type: none"> IND Submission 	2H 2019
ADXS-HPV (axalimogene filolisbac)	<ul style="list-style-type: none"> Announce planned Investigator-Sponsored Trials in Head and Neck Cancer Data from unblinding of terminated Phase 3 Study (AIM2CERV) 	2H 2019 1H 2020

*Completed

Advaxis Management

Seasoned Management Team Transaction Oriented

Chief Executive Officer



Kenneth A. Berlin



Chief Financial Officer



Molly Henderson



Chief Medical Officer



Dr. Andres Gutierrez



Head of Scientific Advisory Board



Dr. Robert Petit



Thank You

