Welcome and Executive Summary

Daniel J. O’Connor, J.D.
President, Chief Executive Officer and Director
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 immunotherapies. 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, 2016, which is available at http://www.sec.gov.

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**Investment Snapshot**

9 Programs Supported by Our Proprietary Lm Technology™ Immunotherapy Platform

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**Lm Technology™ Immunotherapy Platform**

*Creates novel cancer treatments* that overcome legacy immunotherapy barriers

- Worldwide, perpetual, exclusive rights
- Mechanism validated, impact on tumor microenvironment, Tregs demonstrated
- Enables personalized cancer treatments targeting tumor-specific genetic mutations
  - Gains access to the immune system
  - Triggers tumor-specific adaptive immunity
  - Overcomes tumor defenses

---

**5 Product Candidates for 9 Cancers, 3 Orphan**

*Clear Paths to Market with Regulatory Acceleration*

**Axalimogene filolisbac**
- Ph3, *orphan*, in high-risk, locally advanced cervical
- Ph2, *orphan*, metastatic anal

**ADXS-DUAL**
- *Registrational quality study*, combination with BMS’s OPDIVO® (nivolumab) in metastatic cervical

**ADXS-PSA**
- Ph2, combination with Merck’s KEYTRUDA® (pembrolizumab) in metastatic prostate

**ADXS-NEO**
- Ph 1, neoepitope program in collaboration with Amgen

---

**Accomplished Management Team**

- Significant value creation in 2013-2017

---

**$1B+ Value from Collaborations and Partnerships**

[Logos of various companies]
Why Does Advaxis Exist? To Cure Cancer.

Advaxis is a biotechnology company developing immunotherapies that enlist the body’s own immune system to fight cancer. We discover, develop and make better medicines through innovative sciences.

COMMITTED
Committed to the fact that a new approach in cancer care is needed today.

COLLABORATIVE
Collaborative, partnering with major pharmaceutical companies and cancer centers of excellence to speed our therapies to market and save lives.

GRATEFUL
Grateful to bring immunotherapies to market for unmet needs, where no FDA-approved treatment options exist.
The State of Cervical Cancer

HPV is the leading cause of cervical cancer, causing over 90% of cases worldwide.

Nearly half of U.S. adults are infected with HPV.

25% of men and 20% of women are infected with cancer-causing HPV.

Attributing to over 30,000 cases of cancer each year:

- ~13,000 cervical cancer
- ~8,000 anal cancer
- ~12,000 head and neck cancer

1 million women worldwide are believed to be living with cervical cancer.

131.95 million women in the U.S. are at risk of developing cervical cancer.

Over 13,000 cervical cancer cases are diagnosed each year.

High-risk cervical cancer recurs in 50% of women following treatment with chemotherapy.

~5,000 American women have terminal cervical cancer and do not respond to approved treatments.

Due to lack of innovation and new treatment options, an estimated 4,120 women in the U.S. will die of cervical cancer in 2017.

Get screened:

- 93% of cervical cancer cases in the U.S. could be prevented through screening.

Diagnosed with cervical cancer?

Know your options:

- Chemotherapy/radiation
- Surgery
- Clinical trials

Did you know?

In the last 30 years, only one therapeutic for cervical cancer has been approved, with an average benefit of only 3 additional months of survival. Learn more about clinical trials and help drive research for new treatments. Visit clinicaltrials.gov.

References:
- Centers for Disease Control: www.cdc.gov
- American Cancer Society: www.cancer.org
- World Health Organization: www.who.int

Advaxis.com
Axalimogene Filolisbac and ADXS-DUAL Strategic Approach
An Attack on Multiple Fronts, Driving Towards Revenue Generation

_Lm Monotherapy_ Early in Disease Progression

High Risk Locally Advanced Cervical: AIM2CERV

High Risk, Locally Advanced Anal w/ RTOG

End Goal: Regulatory Approvals and Start of Revenue Generation

EU Submission: GOG-0265 metastatic monotherapy

_Lm Combination_ Therapy w/ Checkpoint in Metastatic Disease

Metastatic Cervical combination with OPDIVO® (nivolumab)

Metastatic Anal with checkpoint

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### Cancer Indication

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<th>Phase 1</th>
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### U.S. Treatment Eligible Patients

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Clinical Symposium: Advaxis Clinical Trials Advancing Cancer Treatment and Patient Care - Introduction

Moderated by Dr. Brian Slomovitz, MD
Professor and Chief, Division of Gynecologic Oncology
Sylvester Comprehensive Cancer Center
University of Miami
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. 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, 2016, which is available at http://www.sec.gov.

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**Axalimogene Filolisbac in Cervical and Head & Neck Cancer**

**Phase 2 Study In Combination with Durvalumab**

**Part 1: Dose Escalation, Dose Determination**

**Axalimogene Filolisbac + durvalumab combination**
- n=11 enrolled/treated to date
- Axalimogene Filolisbac: $1 \times 10^9$ (fixed)
- Durvalumab: 3+3 dose-confirmation

Dose Level 1: 3 mg/kg, n=5 cervical cancer
Dose Level 2: 10 mg/kg, n=3; cervical cancer; n=3; HPV+ squamous cell cancer of head and neck

**Part 1 Objectives**
- Safety
- Tolerability
- Randomized phase 2 dose

**Expansion Phase**
- n=20
- Axalimogene filolisbac + durvalumab (randomized phase 2 dose) in **squamous cell cancer of head and neck only**

**Part 2: n=90 Cervical Cancer Only**

- **durvalumab monotherapy**
  - 10mg/kg

- **Axalimogene Filolisbac + durvalumab**
  - $1 \times 10^9$ + randomized phase 2 dose

**Part 2 Objectives:**
- Progression-free survival
- Overall safety
- Tumor response

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Axalimogene Filolisbac in Cervical and Head & Neck Cancer
Phase 2 Study in Combination with Durvalumab

49-Year-old Patient Achieves Complete Response at Dose Level 1

**Diagnosis:** 49 y/o woman - squamous cell carcinoma of the cervix

- Treated three rounds of systemic chemotherapy
- Enrolled study with metastatic cervical cancer refractory to treatments

**Axalimogene Filolisbac -**

- 1 × 10⁹ CFU
- +
- durvalumab - 3 mg/kg

**PET/CT Scan**

- Sep ‘15 – May ‘16
- Partial Response
- May 2016
- Complete Response
- May 2017
- Ongoing

**Clinical Hold**

- Jan 2016
- Clinical Hold

**Preliminary Safety Findings:**

- Grade 1 transient chills, fatigue, fever, nausea, vomiting, headache, hypotension
- Grade 2 rigors

**“It is rare for an immunotherapy to result in a complete response. These early data show encouraging anti-tumor activity of the combination of [axalimogene filolisbac] and durvalumab.”**

Brian Slomovitz, MD
Division Director, Gynecologic Oncology

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ADX-S-PSA: Prostate Cancer Program

Mark Stein, MD
Medical Oncologist
Rutgers Cancer Institute of New Jersey, Rutgers University
Peptide recognition by the αβ T cell receptor (TCR) is mediated by the complementarity-determining region 3 (CDR3) regions of the TCRα and -β chains.

The CDR3 regions of each T cell clone are distinct; therefore, CDR3 sequencing can determine the frequency of individual T cell clones in a biological sample (e.g., blood, tumor tissue).

Sequencing of the CDR3 regions of rearranged TCRβ genes has been used to study the αβ T cell response in metastatic castration-resistant prostate cancer (mCRPC) patients treated with ipilimumab.

- Maintenance of pre-existing high-frequency T cell clones was associated with improved survival in mCRPC patients treated with ipilimumab.

Inclusion Criteria:

- Pretreated metastatic CRPC
- <3 prior systemic treatment regimens or >1 prior regimen in the metastatic setting

Part A: ADXS-PSA Monotherapy
- n=21
- Dose escalation (3 dose levels)

Endpoints: Safety, RP2D

Part B: ADXS-PSA + pembrolizumab
- n=30 (up to 21 in part B, remainder in expansion)
- Dose determination & confirmation

Endpoints: Safety, RP2D of the combination

Part B Expansion: Endpoints
- Safety
- Efficacy
- Immunologic Activity

Up to PD or 2 years

https://clinicaltrials.gov/ct2/show/NCT02325557  RP2D, recommended Phase 2 dose

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Open-label, Phase 1, non-randomized, dose-determining trial of ADXS-PSA monotherapy in subjects with metastatic castration-resistant prostate cancer

- **Dose 1** (1 x 10^9)
- **Dose 2** (5 x 10^9)
- **Dose 3** (1 x 10^10)

Weeks: 1, 2, 3, 4, 5, 6, 7, 8, 9

- ADXS-PSA infusion
- Blood draw for TCRB sequencing

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Dynamics of the αβ T Cell Response in Part A Patients with Stable Disease Following ADXS-PSA Treatment

- Expansions of new and pre-existing clones occur primarily after the first ADXS-PSA treatment
- These clonal expansions are stable over the entire 9-week time course (i.e., no clones are lost)
- *These dynamics are observed in all 4 patients with stable disease*
Dynamics of the αβ T Cell Response in Part A Patients with Stable Disease Following ADXS-PSA Treatment

- Expansions of new and pre-existing clones occur primarily after the first ADXS-PSA treatment.
- These clonal expansions are stable over the entire 9-week time course (i.e., no clones are lost).
- These dynamics are observed in all 4 patients with stable disease.
Expansions of new and pre-existing clones can occur after each ADXS-PSA treatment.

These clonal expansions are not sustainable over the entire 9-week time course (i.e., clones are lost).

These dynamics are observed in all patients with progressive disease or who died due to progressive disease.
Expansions of new and pre-existing clones can occur after each ADXS-PSA treatment.

These clonal expansions are not sustainable over the entire 9-week time course (i.e., clones are lost).

These dynamics are observed in all patients with progressive disease or who died due to progressive disease.
Dynamics of the αβ T Cell Response in Part A Patients with Progressive Disease Following ADXS-PSA Treatment

- Expansions of new and pre-existing clones can occur after each ADXS-PSA treatment.
- These clonal expansions are *not* sustainable over the entire 9-week time course (i.e., clones are lost).
- *These dynamics are observed in all patients with progressive disease or who died due to progressive disease.*

---

Patient 0101-005 - Age 65

- Pre-existing clones
- New clones
- Lost clones

Week 1: pre-dose
Week 3: 2 wks post-dose 1
Week 6: 2 wks post-dose 2
Week 9: 2 wks post-dose 3
Part B of ADXS142-03: ADXS-PSA + KEYTRUDA® Combination Therapy

Week 1
ADXS-PSA infusion
Blood draw for TCRB sequencing

Week 2
KEYTRUDA® infusion

Week 3, 4, 5, 6, 7, 8, 9, 10
Blood draw for TCRB sequencing
Expansions of new and pre-existing clones can occur after each ADXS-PSA treatment.

- This difference between monotherapy and combination therapy in the timing of clonal expansions may speak to MOA of combination therapy.

- These clonal expansions are sustainable over the entire 9-week time course (i.e., no clones are lost).
Dynamics of the αβ T Cell Response in Part B Patients with Stable Disease Following ADXS-PSA Treatment

- Expansions of new and pre-existing clones can occur after each ADXS-PSA treatment
  - This difference between monotherapy and combination therapy in the timing of clonal expansions may speak to MOA of combination therapy
- These clonal expansions are sustainable over the entire 9-week time course (i.e., no clones are lost)
Expansions of new and pre-existing clones can occur after each ADXS-PSA treatment.

These clonal expansions are not sustainable over the entire 9-week time course (i.e., clones are lost).
Dynamics of the αβ T Cell Response in Part B Patients with *Progressive Disease* Following ADXS-PSA Treatment

- Expansions of new and pre-existing clones can occur after *each* ADXS-PSA treatment.
- These clonal expansions are *not* sustainable over the entire 9-week time course (i.e., clones are lost).
Dynamics of the αβ T Cell Response in Part B Patients with *Progressive Disease* Following ADXS-PSA Treatment

- Expansions of new and pre-existing clones can occur after *each* ADXS-PSA treatment.
- These clonal expansions are *not* sustainable over the entire 9-week time course (i.e., clones are lost).

**Patient 0101-008 - Age 65**
Conclusions: TCR Repertoire Analysis

- New TCRB sequences are observed in all patients after ADXS-PSA treatment.
- A previous study has shown that maintenance of pre-existing high-frequency T cell clones is associated with improved survival in mCRPC patients treated with ipilimumab\(^1\).
- Here, we show that the expansion of new and pre-existing TCRB clones after ADXS-PSA treatment is stable and sustained in patients with stable disease but not in patients with progressive disease.
- Notably, KEYTRUDA monotherapy has been shown to have no effect on the peripheral TCR repertoire\(^2\).
- Stable clonal expansions may identify clinical responders to ADXS-PSA treatment.


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Patient Case

- 68 year old male. November 2006 (age 58); PSA=5. Gleason 3+4; declined local therapy
- October 2007 Gleason 4+4=8; hypertheramia (Europe)
- Fall 2013 – bone metastasis and renal obstruction; PSA=417; androgen deprivation x 1YR
- May 2015- restarted androgen deprivation with PSA – 700
- July 2016 – mild bone pain
- Oct 2016 – bone scan - extensive osteoblastic mets, spine, ribs, humerus
- Dec 2016 – started ADXS-PSA/pembrolizumab; tolerating it well, no rigors, mild fatigue, mild chills 1- 2 days after treatment.
- Restaging Feb and May stable compared to December
- Mood improved and planning trip to Europe
**Inclusion Criteria:**
- Patients with biopsy-confirmed PC and prior RPA or radiotherapy; confirmed biochemical recurrence
- PSA doubling time ≤12 mo; PSA ≤50 ng/mL & lymph nodes <2 cm
- No prior ADT for progressive disease
- No ADT within 6 months of study entry or any prior cytotoxic chemotherapy
- **TARGETED ACCRUAL N=80**

**Primary Endpoint:**
- Relapse defined as: PSA >0.2 ng/mL for RP patients or PSA >2.0 ng/mL for those who received primary RT
- RFS defined as time from random assignment to PSA relapse or death
- Safety and feasibility of ADXS-PSAv2 + ADT

**Secondary endpoints:**
- Percent of patients with PSA <0.2 ng/mL by 6 months
- 1-year RFS
- Time to testosterone recovery

---

**Initiate Together**
- ADT × 6 months
- ADXS-PSAv2 q3 weeks × 6 months

**R (1:1)**
- ADT × 6 months

---

ADXS-PSAv2
ADXS-PSAv2
ADXS-PSAv2

ADXS-PSAv2
Q 8 Weeks

PSA Recurrence Free Survival

Follow-Up

ADXS-PSAv2 for 6 months
Time to Castration Resistant Disease Free Survival at 5 years

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ADXS-HPV: Cervical Cancer Program

Sharad Ghamande, MD
Professor and Director of Gynecologic Oncology
Associate Director for Clinical Trials and Research
Georgia Cancer Center, Augusta University, Augusta, GA
Global Demographics

- **Prevalence**: 2,274,000 women have cervical cancer
- **Incidence**: 510,000 new cases each year; 80% in developing countries
- **Mortality**: Second leading cause of female cancer-related deaths (288,000 annually)
- **Estimated individual loss of life**: 25.9 years (Breast Cancer: 19 years, Ovarian Cancer: 17.4 years)
US Demographics

- **~13,000** cases of invasive cervical cancer diagnosed in 2016\(^2\)
- **~4,000** DEATHS due to cervical cancer in 2016\(^2\)
- **~5,000** patients with recurrent, metastatic cervical cancer who are eligible for treatment\(^3\)

Lethal disease with limited treatment options

- No approved therapy following failure of first-line treatment
- Survival only 4–7 months\(^1\)
- In the last 30 years, only 1 new drug approved, Avastin (bevacizumab) in 2014

---

GOG, Gynecologic Oncology Group, now NRG Oncology; OS, overall survival; SOC, standard of care.

Axalimogene Filolisbac in Recurrent / Metastatic Cervical Cancer
GOG-0265 Open-Label Phase 2 Simon 2-Stage Study

Two-stage Trial Design

Eligibility
Persistent or recurrent squamous or nonsquamous cell carcinoma, adenosquamous carcinoma, or adenocarcinoma of the cervix.

Stage 1
- n=26
- Axalimogene Filolisbac
- q28d X 3

Safety, tolerability and efficacy hurdle met for initiation of Stage 2

Stage 2
- n=37
- Axalimogene Filolisbac
- q28d until progressive disease, unacceptable toxicity, or consent withdrawn

Primary Endpoints:
- 12-month overall survival rate
- Safety & Tolerability

Secondary Endpoints:
- Progression-free survival
- Overall survival
- Objective response rate

Study sponsored by Advaxis and Cancer Therapy Evaluation Program and coordinated by the Gynecologic Oncology Group (GOG) in collaboration with the National Cancer Institute.

Axalimogene Filolisbac in Recurrent / Metastatic Cervical Cancer
52% Improvement in Overall Survival at 12-months In GOG-0265 Phase 2 Study

12-Month Overall Survival for Study GOG-0265

- Represents a 52% improvement vs. logistic model-predicted milestone survival rate of 24.5%
- Primary endpoint met

“The 12-month survival rate of axalimogene filolisbac reached unprecedented levels in this study, which is both impressive and important given the lack of innovation in metastatic cervical cancer.

Warner K. Huh, MD
Director, Division of Gynecologic Oncology
University of Alabama, Birmingham
- Lead Investigator of GOG-0265 Study
Axalimogene Filolisbac in Recurrent / Metastatic Cervical Cancer
GOG-0265 Complete Response, Ongoing, for 55-Year-old Patient

Diagnosis: squamous cell cancer of the cervix

Pelvic recurrence

Radical hysterectomy

Treated with: paclitaxel/carboplatin bevacizumab pelvic radiation

Systemic recurrence

June 2015 Enrolled in GOG-0265

Dose 1 | Dose 2 | Dose 3
Axalimogene Filolisbac

May 2016 Complete response

May 2017 Ongoing

Treatment-related AEs: Grade 1-2 fatigue, chills, fever, nausea and Grade 3 hypotension, cytokine release syndrome; No Grade 4-5 TRAEs reported

Results may not be typical; further study is warranted.

https://clinicaltrials.gov/ct2/show/record/NCT01266460

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Patient Video
Axalimogene Filolisbac in Recurrent / Metastatic Cervical Cancer
GOG-0265 Complete Response, Ongoing, for 55-Year-old Patient
- Investigator assessment of tumor best response was reported in 38 patients (76%)
- Disease Control Rate (DCR) was 32%

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</tr>
<tr>
<td>NE</td>
<td>10 (20)</td>
</tr>
<tr>
<td>Missing post-baseline scan</td>
<td>2 (4)</td>
</tr>
</tbody>
</table>

Note: These are unconfirmed.
CR, complete response; NE, no evaluation; OR, objective response; PD, progressive disease; SD, stable disease.
Primary endpoint 12-month survival rate of 38.5% exceeds all historical data and represents the highest rate achieved within any Gynecologic Oncology Group PRmCC study.

There are 2 patients with >24 months follow up (~31 and 41 months, respectively).

GOG, Gynecologic Oncology Group; OS, overall survival; PRmCC, persistent/recurrent metastatic cervical cancer.
### ADXS-HPV Phase 2 Clinical Trial in Indian Patients

- Randomized, Multi-center Phase 2 trial conducted in India in 110 patients
- Patients with recurrent cervical cancer
  - Disease recurred after receiving primary treatments, ECOG 0-2, 80% with aggressive disease
- Single agent activity with a single cycle (3 doses) of ADXS-HPV

<table>
<thead>
<tr>
<th>Arm A</th>
<th>N = 56</th>
<th>Treatment</th>
<th>Follow-up Phase Scans</th>
</tr>
</thead>
<tbody>
<tr>
<td>N = 56 ADXS-HPV Only</td>
<td></td>
<td>ADXS</td>
<td>3m 6m 9m 12m 18m</td>
</tr>
</tbody>
</table>

ADXS-HPV alone arm: ADXS-HPV 1x10⁸ CFU was infused on days 1, 29, 57

<table>
<thead>
<tr>
<th>Arm B</th>
<th>N = 54</th>
<th>Treatment</th>
<th>Follow-up Phase Scans</th>
</tr>
</thead>
<tbody>
<tr>
<td>N = 54 ADXS-HPV + Cisplatin</td>
<td></td>
<td>ADXS</td>
<td>3m 6m 9m 12m 18m</td>
</tr>
</tbody>
</table>

ADXS-HPV + Cisplatin arm: ADXS-HPV was infused on days 1, 85, 113, 141; and cisplatin 40 mg/m² was infused on days 29, 36, 43, 50, 57

Data Presented at ASCO 2014
LTS included patients with tumor shrinkage and those who experienced increased tumor burden as best tumor response overall.
Landmark Survival

- Overall 24-month survival at time of study closure was 11% (12/109)
- Majority of treatment related adverse events were of mild to moderate intensity; most common (in ≥10% of patients) included chills (33%) and pyrexia (12.8%)

Long-Term Survivors (LTS) in recurrent cervical cancer are rare

<table>
<thead>
<tr>
<th>Patients</th>
<th>Overall (N=109)</th>
<th>ADXS11-001 ALONE (N=55)</th>
<th>ADXS11-001 + CISPLATIN (N=54)</th>
</tr>
</thead>
<tbody>
<tr>
<td>12-Month Survival</td>
<td>34.9% (38 / 109)</td>
<td>30.9% (17 / 55)</td>
<td>38.9% (21 / 54)</td>
</tr>
<tr>
<td>18-Month Survival</td>
<td>24.8% (27 / 109)</td>
<td>23.6% (13 / 55)</td>
<td>25.9% (14 / 54)</td>
</tr>
</tbody>
</table>

• Persistent, metastatic or recurrent cervical cancer

• 67% of patients had <2 prior regimens for metastatic disease; 67% had prior bevacizumab

• Two dose levels were assessed:
  - Dose Level 1: 5×10^9 CFU
  - Dose Level 2: 1×10^{10} CFU

Primary Objective:
• To evaluate the tolerability and safety of AXAL

Secondary Objectives:
• To evaluate tumor response and progression-free survival (PFS)
## Safety

The table below summarizes the treatment-related adverse events (TRAEs) observed in the study, with data categorized by grade and occurrence in at least 10% of patients.

<table>
<thead>
<tr>
<th>TRAEs occurring in ≥10% of patients, n (%)</th>
<th>Grade 1–4</th>
<th>Grade 1</th>
<th>Grade 2</th>
<th>Grade 3</th>
<th>Grade 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total TRAEs</td>
<td>102</td>
<td>67</td>
<td>34</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Chills</td>
<td>4 (44%)</td>
<td>2 (22%)</td>
<td>2 (22%)</td>
<td>1 (11%)</td>
<td>-</td>
</tr>
<tr>
<td>Hypotension*</td>
<td>4 (44%)</td>
<td>-</td>
<td>3 (33%)</td>
<td>1 (11%)</td>
<td>-</td>
</tr>
<tr>
<td>Vomiting</td>
<td>4 (44%)</td>
<td>2 (22%)</td>
<td>2 (22%)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Tachycardia†</td>
<td>4 (44%)</td>
<td>2 (22%)</td>
<td>2 (22%)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Headache‡</td>
<td>3 (33%)</td>
<td>2 (22%)</td>
<td>1 (11%)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Fever</td>
<td>3 (33%)</td>
<td>2 (22%)</td>
<td>1 (11%)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Nausea§</td>
<td>3 (33%)</td>
<td>-</td>
<td>3 (33%)</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

* Hypotension, worsening hypotension.
† Tachycardia, sinus tachycardia.
‡ Headache, worsening headache, intermittent headache.
§ Nausea + intermittent nausea.

TRAE, treatment-related adverse event
53 year-old African American woman, Stage 3B squamous cell carcinoma of the cervix diagnosed Jan 2014
• Concurrent chemoradiation completed May 2014
• Chest CT with enlarging pulmonary lesion in left upper lobe July 2014 → Platinum/Paclitaxel and Avastin Total of 9 cycles. PET/CT February 2015 → CR.Consolidation bevacizumab x 6 cycles completed June 2015
• Chest CT with recurrent pulmonary lesion (2 x 1.4 cm) in left upper lobe August 2015

Survival to date – pre-treated metastatic squamous cell cervical cancer (post-bevacizumab): 12 months

AXAL well tolerated:
• Grade 1 transient chills/rigors, nausea, vomiting, diarrhea, tachycardia, rash, headache, body ache
• Grade 2 nausea (x 2) and one episode of listeria-positive blood culture requiring a single dose delay

AUC, area under the curve; CFU, colony-forming units; cGY, centigray; CT, computed tomography; CR, complete response; HDR, high-dose radiation; PET, positron emission tomography; PR, partial response; qwk, every week; SD, stable disease.
Patient Video
PR to AXAL Following Prolonged SD
Axalimogene Filolisbac in High-Risk, Locally Advanced Cervical Cancer
AIM2CERV Phase 3 Study as Adjuvant Monotherapy to Prevent Recurrence in High-Risk Cervical Cancer

Trial Design

Eligibility
- HRLACC
- FIGO stage I–II with positive pelvic nodes
- FIGO stage III–IVA
- Any FIGO stage with para-aortic nodes

Treatment with Cisplatin
- Treatment with cisplatin (at least 4-weeks exposure) and radiation (minimum 40-Gy external beam radiation therapy)

Treatment with Axalimogene Filolisbac
- n=300
- 1 X 10⁹ CFU
- Up to 1 year

Placebo IV
- n=150
- Up to 1 year

Primary Endpoint:
- Disease-free survival

Secondary Outcome Measures:
- Safety & Tolerability
- Overall survival

Baseline tumor imaging must be performed within 28 days prior to the first study treatment infusion.

“I just as we need options to prevent HPV-related cancers, there is a significant need for more therapeutic options to treat those with cancer. No woman should die from cervical cancer.”

Deborah Arrindell
Vice President, Health Policy

AIM2CERV – Axalimogene Filolisbac Immunotherapy Following Chemo/Radiation in Patients who have High Risk Locally Advanced Cervical Cancer (HRLACC)

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Axalimogene Filolisbac in High-Risk, Locally Advanced Cervical Cancer
AIM2CERV Phase 3 Study – Estimated Timeline

**Event Driven Study**
184 events (recurrence or death due to any cause) required prior to efficacy analysis

<table>
<thead>
<tr>
<th>FDA Special Protocol Assessment</th>
<th>Initiate Study Start-up</th>
<th>Ex-US Sites to Open</th>
<th>First Patient Enrolled</th>
<th>50% Patient Enrollment</th>
<th>Last Patient Enrolled</th>
<th>Study Completed</th>
</tr>
</thead>
<tbody>
<tr>
<td>July</td>
<td>Q3</td>
<td>Q1</td>
<td>2016</td>
<td>2017</td>
<td>2018</td>
<td>2019</td>
</tr>
</tbody>
</table>

450 Patients

≈170 Global Sites

≈25 Countries

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https://clinicaltrials.gov/ct2/show/NCT02853604
Timeline is based on current estimates. FDA, US Food and Drug Administration.

SPA, Special Protocol Assessment
ADXS-HPV: Anal Cancer Program

Cathy Eng, MD, FACP
Professor, Department of Gastrointestinal (GI) Medical Oncology,
Division of Cancer Medicine

Director, Department of Gastrointestinal (GI) Medical Oncology, Network
Clinical Research

Associate Medical Director, Colorectal Center, Division of Cancer Medicine
The University of Texas MD Anderson Cancer Center

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Axalimogene Filolisbac in Anal Cancer
Significant Need for Therapies to Treat Metastatic Anal Cancer, Prevent Recurrence

8,200 U.S. CASES of Anal Cancer expected to be diagnosed in 2017¹

≈2,400 Recurrent / Metastatic Anal Cancer total U.S. treatment eligible patients

≈4,100 High-Risk, Locally Advanced Anal Cancer total U.S. treatment eligible patients

1,100 DEATHS from anal cancer are expected in U.S. in 2017¹

No FDA Approved Anal Cancer Chemotherapy

Limited therapies under development

92% Anal cancer cases caused by HPV

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Axalimogene Filolisbac in Anal Cancer
Monotherapy: Phase 2 FAWCETT Study (Fighting Anal Cancer With CTL-Enhancing Tumor Therapy)

Two-stage Trial Design

Eligibility
- Persistent/recurrent, loco-regional metastatic anal cancer
- Received at least one line of therapy for their metastatic disease or progressed after platinum-based therapy

Stage 1
- n=31
- Axalimogene Filolisbac monotherapy
- Every 3 weeks, for...
- Up to 2 years

Interim Analysis
If ≥10% ORR or ≥20% 6-month PFS

Stage 2
- n=24 additional patients
- Axalimogene Filolisbac monotherapy
- Every 3 weeks, for...
- Up to 2 years or discontinuation criteria met

Endpoints:
Primary
- 6-month PFS
- Best overall response

Other
- Safety and tolerability
- Duration of response
- Overall survival
Data from 29 of the planned 31 evaluable patients
Median age 60 years (range 43-77 years); 27 F/2 M; median follow-up time 191 days
Durable partial response lasting > 6 months (after progression on prior anti-PD-1 therapy) observed in 1 patient
Stable disease reported in 7 patients (24%)
Disease control rate of 28%
Current KM 6-month PFS estimate is 22%
Treatment was well tolerated with mostly grade 1-2 infusion related AEs that resolved successfully with standard care; common (≥ 30%) treatment related AEs (TRAEs) included grade 1-2 chills/rigors, fever, hypotension and vomiting

ADXS monotherapy showed promising activity and met the predefined 6-month PFS rate, enabling progressing in to Stage 2
• Registrational quality study planned in 2018

• *Lm* combination therapy w/ checkpoint in metastatic anal cancer

• Study design under development
Axalimogene Filolisbac + Mitomycin, 5-FU and Radiation in High Risk, Advanced Anal Cancer Phase 1/2 BrUOG* Study

Eligibility
- Primary Stage II–III anal cancer
- High risk of recurrence
- HPV positive

- 11 patients enrolled, 10 were treated (median age 62.5 years, range 37-71), including 5 with pelvic adenopathy
- 9 patients completed treatment and achieved complete responses

Total n≈25

Primary Efficacy Endpoint:
- 6-month CR rate

Axalimogene filolisbac
1 × 10⁹ CFU × 4 (1 prior to chemoRT and 3 after, q28 days) as a 500-mL infusion over 30 min

Intensity-modulated Radiation Therapy + chemo

Axalimogene Filolisbac #1
Day -10 to 14

Axalimogene Filolisbac #2
Day +10 post-IMRT

Axalimogene Filolisbac #3

Axalimogene Filolisbac #4

Follow-up

Axalimogene Filolisbac + Mitomycin, 5-FU and Radiation in High Risk, Advanced Anal Cancer Phase 1/2 BrUOG* Study

Treatment Completed

Median Follow-up 1034 Days IQR 725-1268

Relapse Free Survival (Days)*

Ongoing

- Patient 2 Day 1,327
- Patient 3 Day 1,310
- Patient 4 Day 1,260
- Patient 5 Day 1,095
- Patient 6 Day 1,025
- Patient 7 Day 960
- Patient 8 expired unrelated to study treatment. Day 12
- Patient 9 progressed systemically. Day 395
- Patient 10 Day 772
- Patient 11 Day 720

 Relapse Free Survival (Days)*

At 6 months 100% of patients who completed RT and received treatment achieved complete remission

- No evidence of recurrence
- Historical 3-year recurrence rate in similar patient population is ≈45%
- 8 (89%) are disease free at a median follow-up of 34 months
- Well tolerated safety profile

Adverse Event Grade 2 Grade 3

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>Grade 2</th>
<th>Grade 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flu-like symptoms</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Migraine</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Hypotension</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Hyponatemia</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Chills/rigors</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Nausea</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Back Pain</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Fever</td>
<td>2</td>
<td></td>
</tr>
</tbody>
</table>

No Grade 4 AEs

• Phase 2/3 Study in high risk, locally advanced anal cancer
• In collaboration with *Radiation Therapy Oncology Group* (RTOG)
• Study protocol under development
• Study start-up planned for 2018
Axalimogene Filolisbac in Head & Neck Cancer

Brian Slomovitz, MD
US Head and Neck Cancers

- ~70% of oropharynx cancers are HPV-associated
- Age >50 diagnosed more often
- 16,400 new cases annually diagnosed
- Men 3x more likely than woman to develop HPV-associated head and neck cancer
  - Epidemiological imbalance expected to become more pronounced in the next 20 years
Study Design
- Patients with newly diagnosed HPV+ squamous cell carcinoma of the oropharynx
- Patients receive ADXS-HPV treatment before SOC transoral surgical resection
- Tumor specimens analyzed for immunological changes
- 8 treated patients, 3 control patients

Results
- Detection of E6- and/or E7-specific T-cell response in peripheral blood in 5 of 8 treated patients
- Potential Axalimogene Filolisbac-induced changes in the tumor microenvironment with regard to T-cell infiltration and immune checkpoint molecule expression
- Decrease in tumor-infiltrating FOXP3+ Tregs observed in 3 out of 8 treated patients

Axalimogene Filolisbac - Induced Changes in T-cell infiltration and Checkpoint Expression in Tumor Microenvironment

“The fact that we are seeing increased T-cell response, evidence of epitope spreading, and signs of increased immune activation consistent with expansion and infiltration of activated T cells into the tumor at this preliminary point in the study suggests that AXAL has the potential to generate beneficial immunologic responses in patients with HPV+ head and neck cancer.”

Andrew Sikora, MD, PhD
Associate Professor of Otolaryngology
Principal Investigator
Patient Video
Axalimogene Filolisbac in Head & Neck Cancer – FIOS Interview
Metastatic Cervical Cancer Combination Study

Sharad Ghamande, MD
Professor and Director of Gynecologic Oncology
Associate Director For Clinical Trials and Research
Georgia Cancer Center, Augusta University, Augusta, GA
ADXS-DUAL in Recurrent Metastatic Cervical Cancer

Limited Treatment Options for Invasive Forms

- In the last 30-years, only 1 new drug approved, Avastin (bevacizumab) in 2014
- Surgery and/or chemoradiation
- Very few therapies under development

Highly Lethal

- 5-year Survival Rates in late stage cervical cancer are very poor

### Baseline Demographics and Disease Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>N = 82</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years, median (range)</td>
<td>45.5 (27-73)</td>
</tr>
<tr>
<td>&lt;65 years, n (%)</td>
<td>77 (94)</td>
</tr>
<tr>
<td>ECOG performance status 1, n (%)</td>
<td>55 (67)</td>
</tr>
<tr>
<td>Stage M1 disease, n (%)</td>
<td>68 (83)</td>
</tr>
<tr>
<td>PD-L1-positive tumor, n (%)</td>
<td>71 (87)</td>
</tr>
<tr>
<td>Baseline tumor size, mm, median (range)</td>
<td>48.8 (10.2-305.1)</td>
</tr>
<tr>
<td>Prior (neo)adjuvant therapy, n (%)</td>
<td>29 (35)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>No. prior therapies for recurrent/metastatic disease, n (%)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>9 (11)</td>
</tr>
<tr>
<td>1</td>
<td>25 (30)</td>
</tr>
<tr>
<td>2</td>
<td>23 (28)</td>
</tr>
<tr>
<td>3</td>
<td>15 (18)</td>
</tr>
<tr>
<td>≥4</td>
<td>10 (12)</td>
</tr>
</tbody>
</table>

### Summary of Response Assessed (RECIST v1.1)

<table>
<thead>
<tr>
<th>Total population</th>
<th>Overalla</th>
<th>PD-L1 Positive</th>
<th>PD-L1 Negative</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N = 82</td>
<td>n = 71</td>
<td>n = 9</td>
</tr>
<tr>
<td>ORR, b % (95% CI)</td>
<td>12 (6-21)</td>
<td>14 (7-24)</td>
<td>0 (0-34)</td>
</tr>
<tr>
<td>Best overall response, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Complete responseb</td>
<td>3 (4)</td>
<td>3 (4)</td>
<td>0</td>
</tr>
<tr>
<td>Partial responseb</td>
<td>7 (9)</td>
<td>7 (10)</td>
<td>0</td>
</tr>
<tr>
<td>Stable disease</td>
<td>17 (21)</td>
<td>14 (20)</td>
<td>2 (22)</td>
</tr>
<tr>
<td>Progressive disease</td>
<td>44 (54)</td>
<td>37 (52)</td>
<td>6 (67)</td>
</tr>
<tr>
<td>Nonevaluablec</td>
<td>3 (4)</td>
<td>3 (4)</td>
<td>0</td>
</tr>
<tr>
<td>No assessmentd</td>
<td>8 (10)</td>
<td>7 (10)</td>
<td>1 (11)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Patients who responded</th>
<th>n = 10</th>
<th>n = 10</th>
<th>n = 0</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time to response, months, median (range)</td>
<td>2.1 (1.6 to 4.2)</td>
<td>2.1 (1.6 to 4.2)</td>
<td>—</td>
</tr>
<tr>
<td>Responders without subsequent disease progression, n (%)</td>
<td>10 (100)</td>
<td>10 (100)</td>
<td>—</td>
</tr>
<tr>
<td>Duration of response, months, median (range)</td>
<td>NR (4.2+ to 8.7+)</td>
<td>NR (4.2+ to 8.7+)</td>
<td>—</td>
</tr>
</tbody>
</table>

NR, not reached.

bIncludes patients with unknown tumor PD-L1 expression level.

cAt the time of analysis, all responses were confirmed.

dPatients for whom not all target lesions were captured on ≥1 postbaseline imaging assessment.

ePatients for whom no postbaseline tumor assessment was performed.
# Demographics and Disease Characteristics

<table>
<thead>
<tr>
<th>Patients (N = 24)</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age, median (range), years</strong></td>
<td>51 (28–78)</td>
<td></td>
</tr>
<tr>
<td><strong>Region, n (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>North America</td>
<td>1 (4.2)</td>
<td></td>
</tr>
<tr>
<td>Europe</td>
<td>23 (95.8)</td>
<td></td>
</tr>
<tr>
<td><strong>ECOG PS, n (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>11 (45.8)</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>12 (50.0)</td>
<td></td>
</tr>
<tr>
<td><strong>Tumor type, n (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cervical</td>
<td>19 (79.2)</td>
<td></td>
</tr>
<tr>
<td>Vaginal/vulvar</td>
<td>5 (20.8)</td>
<td></td>
</tr>
<tr>
<td><strong>Number of prior systemic therapies in R/M setting, n (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>7 (29.2)</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>10 (41.7)</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>7 (29.2)</td>
<td></td>
</tr>
<tr>
<td><strong>HPV status, n (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive</td>
<td>14 (58.3)</td>
<td></td>
</tr>
<tr>
<td>Not reported</td>
<td>10 (41.7)</td>
<td></td>
</tr>
<tr>
<td><strong>Tumor PD-L1 expression, n (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥1%</td>
<td>10 (41.7)</td>
<td></td>
</tr>
<tr>
<td>&lt;1%</td>
<td>3 (12.8)</td>
<td></td>
</tr>
<tr>
<td>Not tested</td>
<td>10 (41.7)</td>
<td></td>
</tr>
<tr>
<td>Not evaluable</td>
<td>1 (4.2)</td>
<td></td>
</tr>
</tbody>
</table>

# Best Overall Response

<table>
<thead>
<tr>
<th>All patients (N = 24)</th>
<th>Cervical (n = 19)</th>
<th>Vaginal/Vulvar (n = 5)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Best overall response, n (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Complete response</td>
<td>1 (4.2)</td>
<td>1 (5.3)</td>
</tr>
<tr>
<td>Partial response</td>
<td>4 (16.7)</td>
<td>4 (21.1)</td>
</tr>
<tr>
<td>Stable disease</td>
<td>12 (50.0)</td>
<td>8 (42.1)</td>
</tr>
<tr>
<td>Progressive disease</td>
<td>7 (29.2)</td>
<td>6 (31.6)</td>
</tr>
<tr>
<td><strong>ORR, n (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>[95% CI]</td>
<td>5 (20.8) [7.1, 42.2]</td>
<td>5 (26.3) [9.1, 51.2]</td>
</tr>
<tr>
<td><strong>Disease control rate, n (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>17 (70.8)</td>
<td>13 (68.4)</td>
</tr>
<tr>
<td><strong>Duration of response, median (range), months</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NR</td>
<td>NR</td>
<td>NA</td>
</tr>
</tbody>
</table>

*NR responses ongoing as of the data cutoff.
+ Ongoing response; CI = confidence interval; NA = not applicable; NR = not reached
Why ADXS-DUAL?

- Developed from the learnings from axalimogene filolisbac, ADXS-DUAL includes additional HPV antigens intended to provide even stronger coverage against certain HPV types which are more frequent in metastatic cervical cancer.

- In evaluating the data from GOG-265, Advaxis observed that there was a significantly higher representation of patients with the alpha 7 family (HPV 18) viruses than are typically seen at the initial diagnosis of cervical cancer.

- ADXS-DUAL, which contains antigen for both alpha 7 (HPV18) and alpha 9 (HPV 16) families, has the potential to promote more potent T-cell responses for patients with metastatic cervical cancer, where patients may have a greater disease burden.

Women with alpha 7 family viruses are 5x more likely to recur vs. alpha 9.

Alpha 7 (18) Family Representation at Disease Stage

- Disease Onset: 20%
- Metastatic: 52%
Expected to start by the end of this year, the study will evaluate this combination regimen in women with persistent, recurrent or metastatic (squamous or non-squamous cell) carcinoma of the cervix who have failed at least one prior line of systemic chemotherapy.

Anticipated study design: Global, randomized, SOC controlled, registrational-quality study.

Co-primary endpoints: Survival and ORR.
Update on the use of ADXS31-164 in canine and pediatric osteosarcoma

Nicola Mason, BVetMed, PhD, DACVIM
Associate Professor of Medicine & Pathobiology,
University of Pennsylvania,
School of Veterinary Medicine
ADXS31-164 prolongs disease free interval and overall survival in dogs with spontaneous osteosarcoma

Survival curve updated since CCR 2016 publication

Results presented at AACR and ACVIM 2015/2016
Open-label, multicenter, prospective study in dogs with appendicular OSA following SOC amputation and carboplatin. Enrolled dogs will be compared to SOC arm (COTC022) already enrolled.

Objectives
- Primary
  - To determine whether ADXS31-164 prolongs disease free interval over SOC alone
  - To expand safety profile of ADXS31-164
- Secondary
  - To identify factors associated with clinical efficacy (early innate immune response, adaptive immune response)

Canine patients must have no evidence of metastatic disease at the time of enrollment.

Treatment regimen: 3 treatments with ADXS31-164 given once every 3 weeks following carboplatin. Additional treatments given once every 6-8 month intervals until disease progression.

Thoracic radiographs and abdominal ultrasound will be performed at baseline, and thoracic radiographs repeated at the third carboplatin tx (Week 9) and then at Weeks 15, 23 and every 8 weeks thereafter.

Exploratory Arm: to evaluate effects of ADXS31-164 in the setting of established metastatic disease (second arm).
Effects of ADXS31-164 on Metastatic OSA

Prevention of metastatic disease

Control of metastatic disease

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Effects of ADXS31-164 on Metastatic OSA

Baseline

Third ADXS31-164 treatment

3 months post metastectomy

Inflammation surrounding metastatic nodule

H&E

CD3

CD3

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Effects of ADXS31-164 on Metastatic OSA

Baseline 3.21.2014

Inflammatory foci in resected lung lobe

Third ADXS31-164 treatment 5.2.2014

3 months post metastectomy 8.18.2014

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Phase 2, open-label, multicenter, single arm study in patients between 12 and 39 years of age with HER2-expressing, recurrent, completely resected osteosarcoma

Patients will be in surgical remission upon enrollment

Objectives

- **Primary**
  - To determine whether ADXS31-164 increases the disease control rate at 12 months compared to historical COG experience
  - To assess safety and tolerability of ADXS31-164

- **Secondary**
  - To evaluate overall survival

- **Exploratory**
  - To identify correlates of immune response to ADXS31-164

Treatment regimen: ADXS31-164 every 3 weeks for 48 weeks or until disease progression or unacceptable toxicity

Disease surveillance imaging to be performed at baseline and at Weeks 12, 24, 36 and 52
ADXS31-164 Pediatric Osteosarcoma Trial - Study Design

Safety Phase at $1 \times 10^9$ CFU
- 3-6 patients enrolled in a rolling 6 design
- Treatment administered every 3 weeks for 48 weeks
- DLT assessed over the first 3 weeks of treatment

Expansion Phase at $1 \times 10^9$ CFU
- Up to an additional 36 patients enrolled
- Treatment administered every 3 weeks for 48 weeks

Study begins

Safety Phase at $0.5 \times 10^9$ CFU
- 3-6 patients enrolled in a rolling 6 design
- Treatment administered every 3 weeks for 48 weeks
- DLT assessed over the first 3 weeks of treatment

Expansion Phase at $0.5 \times 10^9$ CFU
- Up to an additional 36 patients enrolled
- Treatment administered every 3 weeks for 48 weeks

Anticipated start date: End of 2017
Clinical Symposium: Advaxis Clinical Trials Advancing Cancer Treatment and Patient Care - Introduction

Moderated by Dr. Brian Slomovitz, MD
Professor of Clinical Obstetrics And Gynecology
University of Miami Health System
The GOG/NRG-0265 trial: Potential Prognostic Biomarkers Correlated with Survival:
axalimogene filolisbac (AXAL)-treated metastatic cervical cancer

Sandra M. Hayes, David Balli, Quan Hong, and Robert G. Petit
>50 candidate markers and factors evaluated from blood, tumor tissue, and medical history

Bioinformatic machine learning and modeling employed to establish regression and survival relatedness analyses by growing multiple deep decision trees and overlaying variable importance

Subsets data (bootstrapping) - 2/3 of data, randomly assign predictor variables at each tree node, takes the split that best classifies the control variable (Survival)

Ranks variables based on importance and minimal depth of decision tree

For GOG study – constructed random forest plot models to identify candidate markers predictive of 12-month survival status
Results: High baseline levels of 4 markers negatively correlate with OS in PRmCC patients participating in the GOG/NRG-0265 trial

12-month survivor status
- NO
- YES

Previous bevacizumab treatment
- TRUE
- FALSE

Figure 1
Results: Patients who survived ≥12 months have significantly lower baseline levels of the 4 markers than patients who survived <12 months

Figure 2
Results: Two dimensional hierarchical clustering identifies two patient clusters, distinguishable by low (cluster 1) or high (cluster 2) baseline levels of the 4 markers.

Figure 3
Results: Kaplan-Meier estimates of OS for patient clusters 1 and 2

Figure 4
Study GOG-0265: Overall survival by Marker #1 Status

Median OS = 6.2 mo
12-mo OS% = 38%

<table>
<thead>
<tr>
<th>Marker</th>
<th>Median OS</th>
<th>12-mo OS%</th>
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<tbody>
<tr>
<td>Low</td>
<td>10.3 mo</td>
<td>49%</td>
</tr>
<tr>
<td>High</td>
<td>3.6 mo</td>
<td>0%</td>
</tr>
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</table>
• Evaluate Marker #1 Expression in Other Trials Constructs and Diseases

• Conduct Nonclinical Investigations to Further Characterize Its Impact on Lm Construct Activity

• Prospectively Evaluate and Validate Its Potential as a Biomarker in Clinical Trials
Evidence Generation and Publication Planning

**Primary Manuscripts in Progress**

- Target Peer Reviewed Journals
  - Journal of Clinical Oncology
  - Gynecologic Oncology
  - International Journal of Clinical Oncology

**Reviews**
- Safety review of cervical cancer trials
- Mechanism of Action of AXAL
  
  *PUBLISHED June 2017 in Gynecological Oncology Research Practice*

**Collaborative Trials and ISTs**
- IMPAIR-PC in Prostate Cancer
- Head and Neck

**Clinical Trials**

- P2 GOG/NRG 0265
- P1 High Dose
- P2 Study in Indian Patients
- P2 ADXS HER2 Ped Osteosarcoma
- P2 FAWCETT Study
- BrUOG IST

**Journals**
- ADXS DUAL + Nivolumab
- ADXS NEO
- ADXS PSA + Pembrolizumab
- ADXS PSAv2 IMPAIR-PC

**Tumor Types**
- Cervical Cancer
- Pediatric Osteosarcoma
- Multiple Tumor Types
- Prostate Cancer
NEO IND “FDA Allowed” – A Monumental Achievement!

- NEO represents a breakthrough innovation in personalized immunotherapies
  - Unique bioinformatics, 100’s of neoantigens, rapid manufacturing and testing, and just-in-time logistics
- Current FDA guidelines primarily designed for standard / traditional products
  - Advaxis developed compliant alternatives to address many key obstacles encountered with personalized products and opened a dialogue with FDA to evolve current expectations
- Robust data supported a complex IND package
  - Solid pre-clinical data provided the foundational science behind NEO
  - Advaxis also manufactured numerous mock batches to prove that the NEO concept was feasible and repeatable
  - INDs from other Lm programs were cross-referenced to provide additional supporting data
- Patient product chain of custody addressed via custom IT solution vs. paper-based system
  - “NORM”
    NEO Operational Resource Management
- Collaboration with Amgen and key suppliers was instrumental in ensuring efficient IND review and approval
  - Team anticipated potential questions and was able to quickly provide responses
  - FDA was able to review and approve a comprehensive and complex IND in <30 days
- Experience gained with NEO paving the way for other unique upcoming INDs like ADXS-HOT
Highly Personalized Neoepitope-Based Cancer Immunotherapy

Robert Petit, PhD
Convergence of Complementary Capabilities

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

MINE™
- Targeted immunotherapy
- Innovative science
- Collaboration
- Clinical development

ADVAXIS IMMUNOTHERAPIES™
- Lm Technology™
- Over 60 employees
- Neoepitope expertise
- Manufacturing capabilities
Targeting Neoepitopes with *Lm Technology™* Advantages for Personalized Immunotherapy

- **tLLO—TAA fusion protein** is a synthetic peptide presenting multiple neoepitopes secreted into the cytoplasm of the APC
- Numerous plasmid copies per bacteria
- Payload for multiple neoepitopes per construct—up to \(~2k+\) amino acids
- All or Most Neoantigens can be included
- Activates multiple innate immune pathways (TLRs, PAMP, STING, DAMP, NOD1, NOD2, CpG)
- Treatments can be given without neutralizing antibodies
- Decreases Tregs and MDSCs in the tumor microenvironment
- Eliminates need for restrictive algorithms
- Selected to participate in the TESLA neoepitope research initiative
- Biopsy to first treatment in 6-8 weeks
- 1 manufacturing run provides 2 years of treatment

---

*Lm Technology™* has advantages for targeting neoepitopes

- **Bandwidth** - All or Most Neoepitopes Covered (more is better)
- **Feasibility** - Low COGs and easy to manufacture in-time for patient treatment
- No requirement to manipulate a patients cells or expose to a virus

---

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TAA, tumor-associated antigen
MINE™: How does it work?

Parallel DNA Sequencing
ADXS-NEO: Lm bacteria with neoepitope
ADXS-NEO into antigen-presenting cells
tLLO-NEO secreted in cytoplasm

Neoepitopes presented
T cells activated
T cells find, destroy tumor
Tregs, MDSCs reduced
Treat patient with personalized immunotherapy vector programmed to his/her neoepitopes

Advaxis designs vector based on neoepitopes and bioengineers Lm

Identify neoepitopes

Massive Parallel Sequencing of tumor biopsies

Patient-specific Immunotherapies

Patient’s Hospital or Treating Institution

Time from biopsy to initial infusion administration ~6-8 weeks
Additional doses available for up to two years
**Experimental Design**

- B16F10 tumors were implanted
- Mice (C57BL/6) received three doses of ADXS-Neo vectors expressing neoepitopes
- Control mice received either PBS or Listeria without neoantigen (LmddA274)

---

**B16F10 Tumor Regression**

- PBS
- LmddA274
- Lm Neo 12
- Lm Neo 20

---

• ADXS-NEO is a revolutionary approach to cancer treatment
• Required state of the are innovations in Technology, Manufacturing, and Regulatory Strategy
• 2nd Fully Commercial, Multi-patient IND allowed by FDA for personalized Neoepitope Immunotherapy
  ▪ Not an academic investigator IND or just for a single patient, or single disease
• IND allowed within first 30 days with no delays
• Protocol is complete, Investigators identified
• Multiple sites are being activated and we will initiate enrollment shortly (Q4 2017)
• First study will focus on safety and deep immunologic correlative investigations
  ▪ Exact Clinical Indications and Clinical Settings are Undisclosed
• Advaxis and Amgen are participating in the TESLA initiative
  ▪ TESLA (the Tumor neoantigEn SeLection Alliance)
  ▪ Leading neoantigen groups from around the world, evaluate, test, improve methods, algorithms, and vector systems
Shared Hotspot-Mutation Cancer Immunotherapy ADXS-HOT

Robert Petit, PhD
ADXS-HOT leverages \( Lm \) technology to target public (shared) acquired mutations ("hotspots") in tumor driver genes

- A ‘hotspot’ is a region of DNA with an unusually high propensity to mutate
- Hotspot mutations in human cancers are considered recurrent, shared or ‘public’ mutations and confer fitness advantage (i.e. drivers) to tumor growth

Proteins encoded by genes with tumor-specific mutational hotspots, such as KRAS, NRAS, BRAF, KIT and EGF are considered therapeutic targets in human cancers

Advaxis is able to create a “library” of constructs directed to “hotspots”

Personalized approach:

- Identify shared mutations with rapid diagnostic kit – No DNA Sequencing required
- Treat patient with “off the shelf” construct(s) directed to their mutations IMMEDIATELY

Advantages vs. patient-specific approaches (e.g. CAR-T, neoantigens):

- Available for immediate treatment
- Applicable to a broader set of patients (shared mutations)
- Lower cost to manufacture

• Many ADXS-HOT constructs have been developed preclinically
• Preclinical evaluations and data generation is under way
• On-track for having the ADXS-HOT IND(s) ready to file by end of 2017
• Clinical program and Hot-Spot gene targets – UNDISCLOSED
WT1

Robert Petit, PhD
Lm WT1: WT1 Highly Expressed in Most Cancers

- Rational WT1 identified as the #1 most important cancer antigen by NCI
- Sellas has validated activity in a subcutaneous peptide vaccine platform
- Incorporation into the Advaxis Lm-platform confers the inherent advantages of our platform to their peptides
- The combined product is more likely to have activity in solid tumors and can be administered without adjuvant, GM-CSF or DTH
• Approached by Sellas to incorporate their proprietary WT-1 peptides into the Advaxis Lm-platform

• Agreement announced Feb 27, 2017

• JSC has been formed and the WT-1 LM is under development

• IND planned for early 2018

• Validation of modified peptides to improve immunogenicity – will be applied to other high value TAA targets
Regulatory Update: European Union

- Scientific Advice from Paul Ehrlich Institute (Germany) and Medical Products Agency (Sweden)
- Axalimogene filolisbac designation as Advanced Therapy Medicinal Product (ATMP)
- Certification of Quality and Non-Clinical Data by Committee for Advanced Therapies (CAT)
- Committee for Medicinal Products for Human Use (CHMP) Confirmation of Eligibility for Union Marketing Authorization (Centralized Procedure)
- Rapporteurs Assigned
- Pre-Submission Meetings Scheduled
### Program Scope - medicinal products for:

- Seriously debilitating or life-threatening diseases
- Emergency threats (WHO, EU Commission)
- Orphan medicinal products

### Program Requirements - a Conditional MA may be granted when, although comprehensive clinical data have not been provided, all of the following requirements are met:

- Benefit/Risk balance is positive
- It is likely that comprehensive clinical data will be provided
- Unmet medical needs will be fulfilled
- Benefit to public health of immediate availability outweighs risks that additional data are still required

---

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<thead>
<tr>
<th>Requirement</th>
<th>Qualification</th>
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<tbody>
<tr>
<td>Benefit/Risk balance is positive</td>
<td>GOG-0265 risk balance is positive</td>
</tr>
<tr>
<td>It is likely that comprehensive clinical data will be provided</td>
<td>Follow-up Registrational Study Planned (AIM2CERV)</td>
</tr>
<tr>
<td>Unmet medical needs will be fulfilled</td>
<td>These women have exhausted all available treatment options and are terminal; 24,000 women die annually in EU from cervical cancer¹</td>
</tr>
<tr>
<td>Benefit to public health of immediate availability outweighs risks that additional data are still required</td>
<td>No other treatments for these women, and there has only been one approved treatment in the past 30 years (Avastin)</td>
</tr>
</tbody>
</table>

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Estimated Timeline: EU Submission

Day 1
Advaxis submission to CHMP

Day 120
CHMP provides first set of questions to Advaxis

Day 180
CHMP provides second set of questions to Advaxis

Day 210
CHMP makes final recommendation

Day 270
EMA finalizes CHMP recommendation

Estimated Submission Date: Q4 2017

Clock Stop: Advaxis has 90 days to provide answers to CHMP

Clock Stop: Advaxis has 30 days to provide answers to CHMP

Update to be provided at EMA Finalization
AIM2CERV Phase 3 Clinical Trial & EU Commercial Readiness

Chris Duke
Chief Operating Officer
Axalimogene Filolisbac in High-Risk, Locally Advanced Cervical Cancer
AIM2CERV Phase 3 Study – Estimated Timeline

### Event Driven Study
184 events (recurrence or death due to any cause) required prior to efficacy analysis

### 450 Patients

<table>
<thead>
<tr>
<th>First Patient Enrolled</th>
<th>50% Patient Enrollment</th>
<th>Last Patient Enrolled</th>
<th>Study Completed</th>
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<tr>
<td>July</td>
<td>1H</td>
<td>2Q</td>
<td>2016</td>
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<td></td>
<td></td>
<td>2Q</td>
<td>2020</td>
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</table>

≈170 Global Sites
≈25 Countries

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https://clinicaltrials.gov/ct2/show/NCT02853604
Timeline is based on current estimates. FDA, US Food and Drug Administration.

SPA, Special Protocol Assessment
Significant Commercial Opportunity for axalimogene filolisbac in the EU in Metastatic Cervical Cancer

- Significant unmet needs continue within cervical cancer community
- Vaccination and screening rates extremely low
- Little to no drug development in cervical with exception of bevacizumab (April '15)
- Current treatment options are untargeted and have high toxicity profile
- Cervical patients in the metastatic setting typically considered to be chemorefractory
- Poor prognosis for patients with recurrent metastatic disease
  - 5-Yr OS: ~15%
  - Median OS: ~17 mos (w/ bev)

Strong support from medical community for additional treatment options

---

Cervical Cancer Incidence (EU5)

“… The outlook for recurrent / metastatic cervical cancer patients is very bleak as the five-year survival rates are extremely low. The unmet need rests with this particular patient population. If you really have the stated PFS and OS benefits, no one would hesitate granting Product X conditional approval for use after Avastin …”

Oncologist, Marienhospital Bottrop gGmbH, DE

“… No treatment options exist to shrink the risk of relapse for recurrent / metastatic patients. This is where the unmet need lies. We need treatments that will significantly improve the quality of life. All of the safety and tolerability data sounds very promising, and I would be likely to employ this as a second line treatment after Avastin. I would be willing to use this as a conditionally approved product after I have gone through my first line of treatment …”

Oncologist, Paris Hospital, FR
Achieve a successful regulatory filing with EMEA

1. Evaluate all commercial model options and select the approach that maximizes the long-term value.

2. Develop a strong global value dossier to support the value proposition and establish a robust pricing strategy.

3. Conduct additional targeted market research with a strong focus on P&R, physician landscape and diagnostic & treatment pathway.

4. Continue identification, mapping and engagement of key stakeholders including HCPs and patient organizations.

5. Optimize the end-to-end supply chain to maximize patient access and ease of use.
**Commercial Models Under Consideration**

**Stand Alone**
- Build out is costly and time consuming
- More appropriate for companies with multiple filings within a short timeframe
- Can be a distraction to small companies

**Out-Licensing Partnership**
- Multiple options to consider within the partnering front
- Key considerations include overall oncology experience (particularly gynecological oncology), strength of commercial capabilities, extent of geographic reach, immuno-oncology experience, strategic vision

**Hybrid**
- Risk-sharing model which leverages partner’s existing infrastructure and expertise
- Low upfront cost structure
- Provides an Advaxis-branded business unit dedicated to axalimogene
- Opportunity to buy back the asset
<table>
<thead>
<tr>
<th>FUNCTION</th>
<th>ACTIVITY</th>
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<tbody>
<tr>
<td>Regulatory</td>
<td>• Preparation of full regulatory filing</td>
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<td></td>
<td>• Development of SmPC</td>
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<tr>
<td>Marketing</td>
<td>• Development of a global brand plan</td>
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<td></td>
<td>• Conduct analysis of KOL landscape including diagnostic and treatment pathway</td>
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<td>Market Access</td>
<td>• Development of global value dossier</td>
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<td>• Conduct pricing research and establish framework for global pricing strategy</td>
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<td></td>
<td>• Evaluate expanded access opportunities globally</td>
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<tr>
<td>Medical</td>
<td>• Relationship management with key opinion leaders</td>
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<td></td>
<td>• Ongoing support of data generation activities including clinical trials and ISTs</td>
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<td></td>
<td>• Data dissemination at key meetings and congresses</td>
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<td></td>
<td>• Advisory Boards as needed to support overall program strategy</td>
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<tr>
<td>Tech Ops</td>
<td>• Full mapping of supply chain requirements</td>
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<td></td>
<td>• Continued refinement of end-to-end product delivery</td>
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<tr>
<td>Patient Advocacy</td>
<td>• Build relationships with international patient organizations</td>
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<td></td>
<td>• Focus on patient centricity, understanding the patient journey, barriers, etc.</td>
</tr>
</tbody>
</table>
Summation & Q&A

Daniel J. O’Connor, J.D.
President, Chief Executive Officer and Director
<table>
<thead>
<tr>
<th>Product Candidate</th>
<th>Cancer Indication</th>
<th>Partner</th>
<th>IND</th>
<th>Phase 1</th>
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<td>AXALIMOGENE FILOISBAC</td>
<td>High-Risk, Locally Advanced Cervical</td>
<td>AJM2CERV</td>
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<td>Metastatic Anal</td>
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<td>Metastatic Cervical, Metastatic Head &amp; Neck</td>
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<td>Combination with IMFINZI™ (durvalumab)</td>
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<td>Combination with KEYTRUDA® (pembrolizumab)</td>
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<td>ADXS-HER2</td>
<td>HER2-positive Metastatic Solid Tumors</td>
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<td>ADXS-NEO</td>
<td>Multiple Cancers by Targeting Neoantigens</td>
<td>AMGEN</td>
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<td>ADXS-HOT</td>
<td>Multiple Cancers by Targeting Hotspot Mutations</td>
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= Ongoing
= Planned
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<th>Indication / Candidate</th>
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<tr>
<td>EU Filing H2 2017*</td>
<td>Recurrent / Metastatic Cervical Cancer GOG-0265 Open-Label Phase 2 Simon 2-Stage Study</td>
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<tr>
<td>Status Update H1 2017*</td>
<td>Prevent Recurrence in High-Risk Cervical Cancer AIM2CERV Phase 3 Study as Adjuvant Monotherapy</td>
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<tr>
<td>Updated Data H2 2017*</td>
<td>Axalimogene Filolisbac</td>
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<tr>
<td>Updated Data ASCO 2017</td>
<td>Metastatic Cervical and Head &amp; Neck Cancer Phase 2 Study In Combination with Durvalumab</td>
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<tr>
<td>Stage 1 Data &amp; Start Stage 2 2017*</td>
<td>High Risk Advanced Anal Cancer Phase 1/2 BrUOG Study Axalimogene Filolisbac + Mitomycin, 5-FU and Radiation</td>
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<td>Trial to Launch H2 2017*</td>
<td>ADXS-DUAL Recurrent / Metastatic Cervical Cancer Registralional quality study in combination with Nivolumab</td>
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<td>Prelim Phase 1 Data H2 2017*</td>
<td>HER2-positive Metastatic Solid Tumors ADXS-PSA Phase 1B Monotherapy in Multiple HER2-Expressing Tumors</td>
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<td>Trial to Launch H2 2017*</td>
<td>Pediatric Osteosarcoma Phase 2 Children’s Oncology Group</td>
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<tr>
<td>Trial to Launch In H2 2017*</td>
<td>MINE™ Program My Immunotherapy Neo-Epitopes ADXS-NEO Clinical Trials</td>
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<tr>
<td>IND Filing 2017*</td>
<td>ADXS-HOT Multiple Cancers by Targeting Hotspot Mutations</td>
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2017

- **February**
  - First patient dosed in Phase 3 AIM2CERV trial, HRLA cervical cancer
- **March**
  - FDA accept IND for ADXS-NEO
- **ASCO 2017**
  - Updated data on BrUOG study

*Expected.