Advaxis (ADXS)

New Data Presented from Advaxis's Phase II GOG Study with AXAL for PRmCC

Advaxis (NasdaqCM: ADXS) announced new data at the Society of Gynecologic Oncology's (SGO) Annual Meeting on Women's Cancer from the Phase II GOG-0265 study using axalimogene filolisbac (AXAL) in patients with persistent or recurrent metastatic cervical cancer (PRmCC). As previously reported, the 12-month overall survival (OS) rate for 50 enrolled patients was 38%, which is the highest 12-month survival rate seen in any GOG study for PRmCC. The updated results contain response and survival analyses showing encouraging activity with AXAL monotherapy. One patient has had an ongoing complete response for 18.5 months, and 8 patients are alive as of January 31st. Based on these data, Advaxis plans to file for European approval with AXAL in PRmCC during the second half of 2017.

- **New PRmCC Data Highlight Survival Benefit with AXAL.** Of the 50 patients enrolled in the Phase II GOG study, 8 were alive as of January 31st, ranging from 12.02 to 40.6 months. This includes one patient who was previously treated with radiation, chemotherapy and Roche's (VTX: ROG.VX) *Avastin* (bevacizumab), and has had an ongoing complete response (CR) for 18.5 months. Overall, the 12-month survival rate in the GOG study was 38%. Dr. Charles Leath was a PI on the study, and presented the AXAL data. He noted that between 1998 and 2015, the GOG has conducted more than 20 Phase II studies in PRmCC, and the highest 12-month OS rate seen was 30% with *Avastin*, which received approval for cervical cancer based on an overall survival advantage. Notably, the GOG studies contain very similar protocols, participating centers, and statistical analysis methods, increasing our confidence in these results with AXAL monotherapy.

- **Potential Activity Seen in Multiple HPV Genotypes.** AXAL consists of a modified *Listeria monocytogenes* (*Lm*) bacteria, which is designed to stimulate a T-cell immune response against tumor-associated antigens (TAAs). The HPV virus is a common cause of cervical cancer, and so the antigen used in this study was the HPV-16 E7 protein. HPV-18 is another common cervical cancer antigen, and has a similar coding sequence to HPV 16. Because of this, AXAL may also stimulate an immune response against this antigen. Within the GOG study, 16 evaluable patients had HPV-16 and 17 had HPV-18. The survival data was slightly skewed in favor of HPV-16, but also showed promise in HPV-18 patients compared to historical control. The 12-month OS rate was 44% (7/16) for patients with HPV-16, and 41% (7/17) for patients with HPV-18. The one patient who experienced a CR had HPV-16. Potential signs of activity were previously seen with AXAL in additional HPV genotypes during the Phase II study conducted in India.

- **Promising Disease Control Rate with AXAL.** The patient population enrolled in the GOG study had late stage cervical cancer, and 52% of patients had received 2 or more prior lines of therapy. 1 patient experienced a CR following treatment with AXAL, and 39% (15/38) of evaluable patients had stable disease. As shown in **Figure 1**, there is a plateau in the survival curve for patients who lived beyond 16 months, indicating that AXAL could provide a long-term clinical benefit. Notably, only 4 patients who progressed on AXAL went on to receive a subsequent treatment, meaning the survival benefit derived from treatment was likely due to AXAL and not subsequent treatments. The small number was likely due to the patients being too sick to receive additional care, or death.

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Market Data

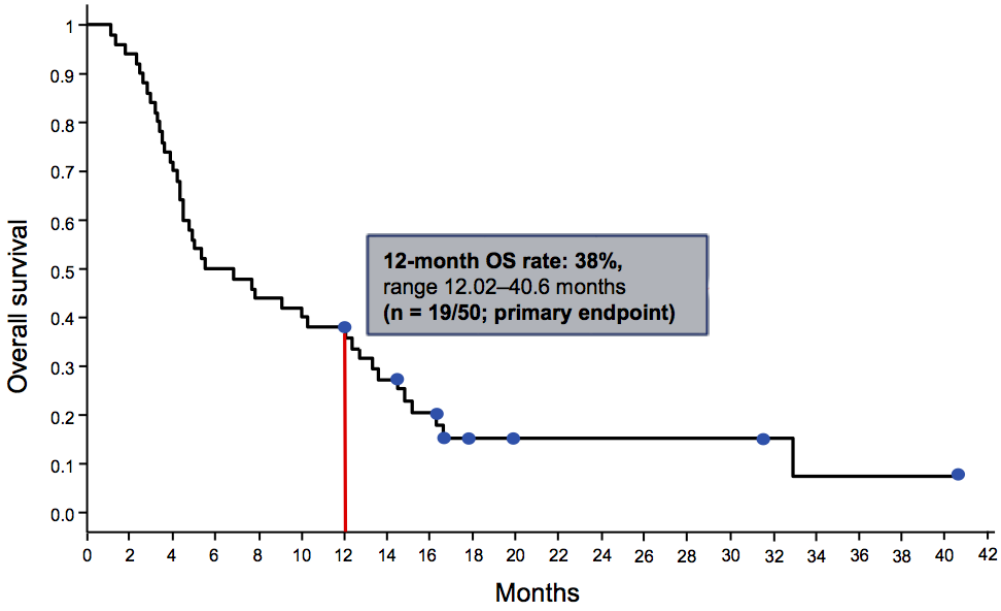
Price	$8.81
Market Cap (M)	$355
EV (M)	$218
Shares Outstanding (M)	40.3
Fully Diluted Shares (M)	48.4
Avg Daily Vol	717,594
52-week Range:	$6.47 - $16.30
Cash (M)	$136.9
Net Cash/Share	$3.40
Annualized Cash Burn (M)	$56.4
Years of Cash Left	~2.4
Short Interest (M)	8.58
Short Interest (% of Float)	24.1%

Financials

FY Oct		2015A	2016A	2017A
EPS	Q1	(0.33)A	(0.59)A	(0.43)A
	Q2	(0.52)A	(0.45)A	NA
	Q3	(0.44)A	(0.48)A	NA
	Q4	NA	NA	NA
	FY	(1.68)A	(2.08)A	NA

For analyst certification and disclosures please see page 4

Figure 1. Survival Curve from Phase II GOG-0265 Study with AXAL



Source: Company Presentation

- **Treatment with AXAL was Well Tolerated.** Treatment with AXAL was overall well tolerated by patients. This is encouraging since the enrolled population had late stage disease, and typically has trouble tolerating cancer treatments. 36% of patients experienced a Grade 3 treatment related adverse event (TRAE); 28% of the Grade 3 events were anemia. There were 2 patients who had potential Grade 4 TRAEs. One patient had a *Klebsiella*-related lung infection and sepsis that the investigator listed as possibly related to treatment. The other patient experienced Grade 4 hypotension and cytokine release syndrome that resolved over time. Other TRAEs were considered mild to moderate, and mainly consisted of fatigue (52%), chills (52%), anemia (38%), nausea (32%), and fever (30%).

- **Phase II PRmCC Study Design.** Run in collaboration with GOG, this was an open-label Phase II study with AXAL monotherapy in patients with persistent or recurrent HPV-associated cervical cancer. 50 patients were treated with AXAL across two stages of the trial. The first stage enrolled 29 patients, and 26 were treated with 1 x 10^9 colony forming units (CFU) of AXAL once every 28 days for a maximum of three infusions. Initiation of stage 2 was triggered when 20% of patients in stage 1 survived at least 12 months along with an acceptable safety profile. In Stage 2, patients who received at least 1 prior line of therapy were enrolled, and received 1 x 10^9 CFU of AXAL once every 28 days until disease progression. The primary endpoints were 12-month OS and safety. Secondary endpoints included OS, progression free survival, and overall response rate.

Expected Upcoming Milestones

- H1 2017 – Initiate pivotal Phase II/III trial with AXAL in locally advanced anal cancer in collaboration with the Radiation Therapy Oncology Group.
- H1 2017 – Expected completion of enrollment initial cohort for ADXS-PSA plus pembrolizumab trial.
- H2 2017 – Potential filing for European approval with AXAL in PRmCC.
- 2017 – Preliminary data expected from first 2 cohorts in ADXS-PSA plus pembrolizumab trial.
- 2017 – Commencement of GOG study of ADXS-HER2 in pediatric osteosarcoma.
- Mid-2017 – Multiple presentations expected at ASCO conference including enrollment update for Phase III AIM2CERV trial, update from Phase II BrUOG trial in anal cancer, and preliminary Phase I data for ADXS-HER2 in multiple tumor types.
- H2 2017 – Commencement of Phase III trial of AXAL in metastatic cervical cancer.
- H2 2017 – File IND for ADXS-HOT program.
- H2 2017 – Updated data from AXAL plus durvalumab trial in HNSCC.
- H2 2017 – Data expected from FAWCETT Stage 1 trial in anal cancer and beginning of Stage 2.
- Q4 2017 – Completion of enrollment of expansion cohort for ADXS-PSA plus pembrolizumab trial.
- H1 2018 – Preliminary data expected for ADXS-PSA plus pembrolizumab in prostate cancer.
- Mid-2020 – Data expected from Phase III AIM2CERV trial of AXAL in HRLACC.

Risk to Invesment

We consider an investment in Advaxis to be a high-risk investment. Advaxis is a development stage company with no history of taking a treatment to market and currently has no FDA-approved drugs in its portfolio. The Company's lead program has not yet completed Phase III trials. Furthermore, early indications of efficacy do not necessarily translate into positive late-stage results. Phase III clinical trials will result in significant additional expenses to the Company and may require additional rounds of dilutive financing. As with any company, Advaxis may be unable to obtain sufficient capital to fund planned development programs. There are regulatory risks associated with the development of any drug, and Advaxis may not receive FDA approval for its candidates despite significant time and financial investments. Regulatory approval to market and sell a drug does not guarantee that the drug will penetrate the market, and sales may not meet expectations.

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