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Clovis Oncology Inc.

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Clovis Oncology Inc.

Why Own It? Market Reaction Was Overly Punitive

- The shares of biopharma company, Clovis Oncology Inc. ("Clovis" or the "Company"), fell following disappointing news related to its experimental cancer drug, Rociletinib ("Roci")
- Investor sentiment has turned sharply negative:
  - Allegations surfaced that company officers made false and misleading statements regarding their Roci clinical studies
  - CFO recently resigned prior to the issue above (a truly personal issue: wife passed away)
  - Company botched the "optics" of their Roci drug study by using a patient population that is known to respond less favorably than the patient population used by competitor, AstraZeneca
- Market reaction was overly punitive and caused the stock to fall 70% in one day
  - Presents excellent buying opportunity

Company Fundamentals Support 2016E Price Target of $45

- Base Case: $45 Price Target
  - FDA approval expected in 2016 for Rucaparib ("Ruca") and potentially Roci
- Bull Case: $90 Price Target
  - Depends on ability to extend developmental drugs (Roci and Ruca) into additional indications (prostate, etc.)
  - Two oncology drugs in final developmental stages (Roci and Ruca) and one high-value drug in phase 2 development stage (Lucitanib)

Price Targets

2016E Price Target Build-Up (price per share)

	CLOVIS ONCOLOGY
Net Cash	**$320M** (or $8 net cash per share)
Add: Roci 1st indication (EGFR+T790M+lung cancer)	$10 - 15
Add: Ruca 1st indication (3L+BRCA+ ovarian cancer)	$25 - 30
	Base Case: $45
Add: Roci Other indications (EGFR+T790M-lung cancer, 1st line EGFR+ lung cancer)	$30
Add: Ruca Other indications (prostate, breast and gastroesophageal cancers)	$40
Add: Luci Clinical data will be available in 2016	$20
	Bull Case: $90

Source: Hayman estimates.

Crisis Creates Opportunity

Situation Overview

- **On November 16, 2015, Clovis disclosed that the FDA requested more data prior to approving Roci**
  - The Street was surprised that prior data submissions to the FDA included both "unconfirmed" and "confirmed" clinical data
  - Importantly, the "confirmed" data showed a significant decline in response rates as compared to prior data submissions

- **Differentiated Point of View on Roci**
  - Roci is still approvable in its initial indication, but with a delay
  - Roci usage in its initial indication may be higher than the market anticipates because doctors recognize the difference in study populations used in Roci's (Clovis) clinical trials vs. Tagrisso's (AstraZeneca) clinical trials
  - Roci approval could add another ~$15 to the stock on conservative assumptions of market share and peak sales

- **Most importantly, while investors have focused on Roci, they have neglected to recognize the significant value potential in Ruca**

Clovis Drug Development Pipeline

Clovis Oncology, Inc. (NASDAQ: CLVS)

- **Initial Public Offering: November 2011**
- **Market Capitalization: $1B**
- **Headquarters: Boulder, CO**
- **Net Cash: $320M**

Rociletinib (Roci)

LUNG CANCER DRUG

- **Expected FDA Approval**
  - 2016
- **Upcoming Clinical Data:**
  - June 2016: Phase 2/3
- **Current Standard of Care[1]:**
  - Drug: Tagrisso®
  - Company: AstraZeneca

Rucaparib (Ruca)

OVARIAN CANCER DRUG

- **Expected FDA Approval**
  - YE 2016
- **Upcoming Clinical Data:**
  - June 2016: Phase 2/3
- **Current Standard of Care[2]:**
  - Drug: Lynparza®
  - Company: AstraZeneca

Lucitanib (Luci)

BREAST CANCER DRUG

- **Expected FDA Approval**
  - TBD
- **Upcoming Clinical Data:**
  - June 2016: Phase 2
- **Current Standard of Care[3]:**
  - Drug: Physician's Choice
  - Company: n/a

Source: Bloomberg market capitalization data as of 11/24/2015 and expected FDA approval data provided by Company presentations.
(1) For EGFR+ T790M+ lung cancer mutations.
(2) For 3L+BRCA+ ovarian cancer mutations.
(3) Can include chemotherapy, radiation, hormone therapy, biologic targeted therapy and/or clinical trials.

Roci: Clovis Fails to "Play the Game"

Lung Cancer Study Comparison: Roci vs. Tagrisso®

	CLOVIS ONCOLOGY		AstraZeneca	
Drug:	**Roci**		**Tagrisso®**	
Study:	Tiger-X	Tiger-X	Study 1	Study 2
Dose:	500mg BID	625mg BID	80mg daily	80mg daily
Lung cancer mutations:	EGFR+ T790M+	EGFR+ T790M+	EGFR+ T790M+	EGFR+ T790M+
Median age:	63	64	62	64
Female:	75%	64%	66%	70%
Asians:	**16%**	**20%**	**58%**	**63%**
Prior lines of treatment:	Median: 3L	Median: 2L	70% >=2L	68% >=2L
Brain metastases:	40%	42%	37%	43%
Confirmed Objective Response (ORR):	**28%**	**34%**	**57%**	**61%**

- **Asians are known to respond better to certain drug classes**
- **More specifically, Asian lung cancer patients typically respond better to lung cancer treatments**

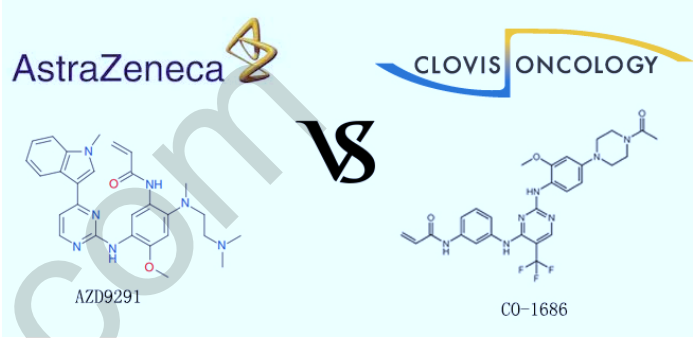
Takeaways

- AstraZeneca "stacked the deck" in their favor with a study that enrolled significantly more Asians
- Asians are known to respond better to lung cancer treatments
- Clovis' study is much more representative of the US population
- Thus, it is hard to compare AstraZeneca's ~60% ORR (i.e. % of patients with tumor shrinkage) directly with Clovis' ORR ~30% given the different types of patients enrolled in the studies
- Most doctors recognize that the studies are not directly comparable

Source: Company presentations and drug labels.

Roci: Competitive Landscape

- Tagrisso® (AstraZeneca) was recently approved (Nov 2015)
  - Doctors typically see both drugs as more similar than different
  - Differences include:
    - **<u>Side effect profile</u>:**
      - Doctors are split
      - Tagrisso® has reported interstitial lung disease, skin rash, paronychia vs. Roci has reported hyperglycemia and QTc prolongation
    - **<u>Efficacy in T790M+</u>:**
      - Tagrisso's® objective response rate (ORR) (~60%) is optically better vs. Roci (~30%)
      - While hard to compare drugs across trials, doctors largely recognize that Tagrisso® enrolled more Asian patients in their studies and to that end, "stacked the cards" in their favor with respect to having a higher ORR vs. Roci
    - **<u>Efficacy in T790M-</u>:**
      - EGFR+ lung cancer patients that relapse have either a T790M- mutation or T790M+ mutation
      - Roci beats Tagrisso® in T790M- patients
      - Roci's ORR in this subset of patients is 37%, which makes doctors optimistic that Roci may be used in all EGFR+ lung cancer patients that relapse (i.e. T790M+ and T790M-)
    - **<u>Efficacy in 1L EGFR+ patients*</u>: TBD**
      - Progression-free survival (PFS) is the most important metric. Doctors indicated they want to see ≥ ~18-20 months for it to be clinically meaningful



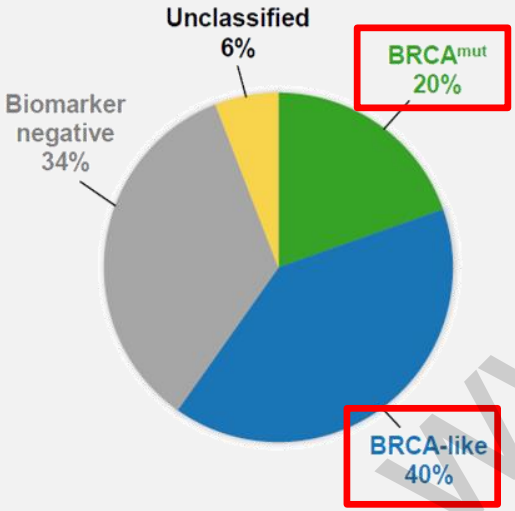
*Note: 1L indicates the first line of a treatment regimen. It is also referred to as primary treatment or therapy.

Ruca: Clovis' Most Promising Opportunity

- Ruca is focused on the subset of patients with the BRCA (BRCA+) and the BRCA-like gene mutation
  - The BRCA mutation was popularized by Angelina Jolie
  - As a preventative measure, after testing positive for the BRCA mutation, Angelina Jolie first underwent a double mastectomy
  - She then removed her ovaries

Ovarian Cancer: At A Glance

Ovarian Cancer Patient Characteristics by Gene Mutation



Ovarian Cancer Cases in the US

Estimated New Cases in 2015	21,290
% of All New Cancer Cases	1.3%
Estimated Deaths in 2015	14,180
% of All Cancer Deaths	2.4%

"This surgery decision is more straightforward than the decision to have the breasts removed."

In an op-ed in the *New York Times*, Angelina Jolie Pitt announced that she recently had surgery to remove her ovaries and fallopian tubes. The procedure put her into menopause at age 39, and she will take replacement hormones for another decade or so.

Source: National Cancer Institute and Company presentation.

Ruca: Competitive Landscape

- **Efficacy:** Ruca appears to be superior to the current standard of care ("SOC"), Lynparza®
- **Safety:** Ruca appears to be in line with Lynparza® and adverse events appear manageable
- **Commercial:** Ruca appears to have the most robust dataset and is the closest to being commercialized

- **Other ovarian cancer drugs in development:**
  - **Niraparib (produced by Tesaro, Inc)**
    Potentially viable, but with limited number of patients and behind Ruca in time-to-market
  - **MDVN 673 (produced by BioMarin/Medivation):**
    Potentially viable, but with limited number of patients thus far and behind Niraparib in time-to-market
  - **Veliparib (produced by AbbVie):**
    Does not appear to be pursuing monotherapy in BRCA+ ovarian cancer at this time (pursuing combination studies with chemotherapy)

APPENDIX

Investment Recap

Summary

- The market is not giving full value to Ruca's initial ovarian cancer indication and optionality for future indications
  - Ruca's initial indication will be in ovarian cancer patients with a specific genetic mutation called "BRCA+" after these patients have failed three or more treatment options (i.e. a 3L+ drug)
  - Ruca has a superior clinical profile as compared to Lynparza®, the current SOC in 3L+ BRCA+ ovarian cancer
  - Ruca is expected to file for FDA approval of its ovarian cancer indication in 2Q16 with potential for FDA approval by YE16
  - Estimated peak sales of $300M for the ovarian cancer indication

- Clovis, at current price levels, provides multiple option-like opportunities:
  - **Near Term: June 2016**
    - Luci: Will have clinical data at the American Society of Clinical Oncology Meeting (ASCO 2016) (Street gives zero value for this asset)
    - Roci: 1L EGFR+ lung cancer, a substantially larger market than EGFR+ T790M+ market, which is the initial indication, will have clinical data at ASCO 2016 (Street gives zero value for this indication)
  - **Medium Term: 2H16+**
    - Ruca: "BRCA-like" ovarian cancer, a substantially larger market than 3L+ BRCA+ ovarian cancer, which is the initial indication (Street gives minimal value)
    - Roci: Potentially still approvable in its 1st indication (EGFR+ T790M+) with a delay (Street has taken almost all of the value out for this indication)
  - **Long Term: Data from Clinical Studies 2H17+**
    - Ruca: Prostate, breast and gastroesophageal cancers (Street gives zero value for these indications)
    - Roci: EGFR+ T790M- lung cancer (Street gives zero value for this indication)

Valuation: Methodology

Fundamental 2016E Target Price: $45

- Averaging DCF & EV/Sales Analysis (M&A Scenario): $45 2016E Price Target
  - Reflects value for only 1st indication of Ruca (in 3L+ BRCA+ ovarian cancer)
  - Reflects value for only 1st indication of Roci (in EGFR+ T790M+ lung cancer)
  - Several catalysts could drive valuation to $60+ with upside to reach $90
- DCF Analysis: $39
  - Ruca peak sales occur in 2023 (based on 7 years of Orphan Drug Exclusivity with launch in 2017)
  - Estimated peak sales ~$320M
  - Assume Roci is approved, but significantly delayed to market (2H17) with small market share (20% market share: $200M peak global sales)
  - EBIT margins: high 30% / low 40% range
  - Tax rate: 35%
  - CAPEX: mid teens % of sales
  - Discount rate: 10%
  - Terminal value growth rate: 4%
- EV/Sales Analysis (M&A Scenario): $52
  - NTM EV/Sales multiple: 6X
  - Peak sales: $530M (2023)
  - Discount rate: 10%

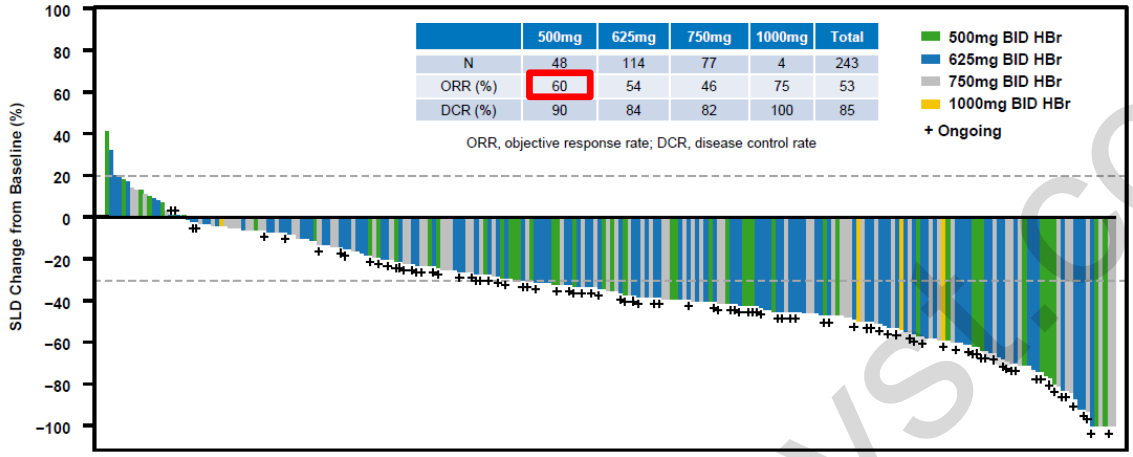
Valuation: Another Perspective

Why Clovis is Undervalued

- Liquidation value of Ruca is estimated at ~$600M
  - BioMarin Pharmaceutical Inc. ("BMRN") sold its similar drug, a PARP inhibitor, for $410M cash +$160M in milestones + mid-single digit royalties
  - Ruca is at the FDA's doorsteps for approval, implying that it should be worth more than the ~$600M paid for BMRN's drug
- ~$320M Clovis Net Cash = $605.9M (3Q15 Cash) - $287.5M (Convertible Debt)
  - Shares outstanding: 38.3 M
  - Net cash per share: $8.36 per share
- Divesting Ruca ($600M) + Net Cash ($320M) = $920M+ (vs. Clovis' current market cap of ~$1B)
- For less than $100M, investors retain three valuable near-to-medium term options and two long-term options:
  - **Near-to-medium term options:**
    1. Luci: will have clinical data in June 2016 (ASCO Meeting)
    2. Roci: for 1st line EGFR+ lung cancer will have clinical data in June 2016 (ASCO Meeting)
    3. Roci: is potentially still approvable in its 1st indication (EGFR+ T790M+) in 2016
  - **Long-term options:**
    4. Ruca: prostate, breast and gastroesophageal cancers
    5. Roci: EGFR+ T790M- lung cancer

Roci: Data Superior to the Current Standard of Care*

Observed Tumor Change: Sum of Longest (SLD) Change from Baseline

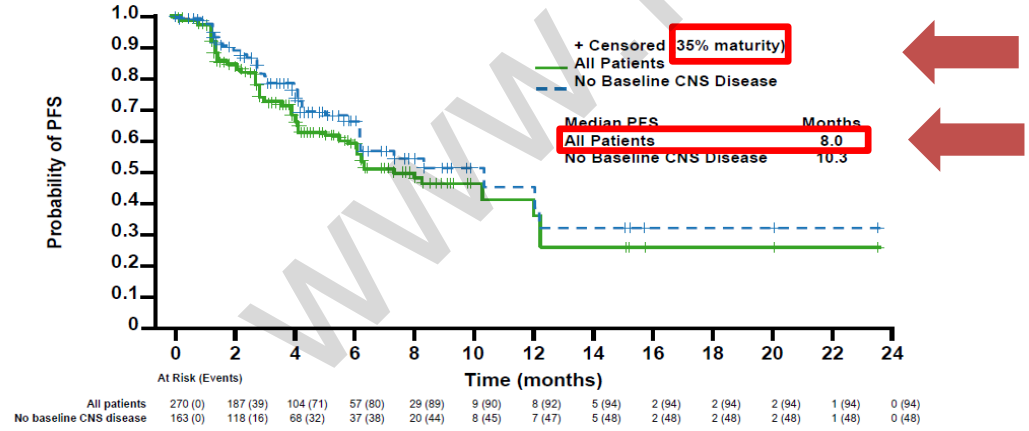


	500mg	625mg	750mg	1000mg	Total
N	48	114	77	4	243
ORR (%)	60	54	46	75	53
DCR (%)	90	84	82	100	85

ORR, objective response rate; DCR, disease control rate

- T790M+ is the 1st indication Roci is seeking FDA approval on
- 60% is the combined confirmed and unconfirmed objective response rate (ORR). Confirmed ORR of 30% in line with standard of care's (SOC) 20-35% ORR. However, Roci has better side effects ("SE") vs. chemotherapy

Probability of Progression-Free Survival (PFS) vs. Time



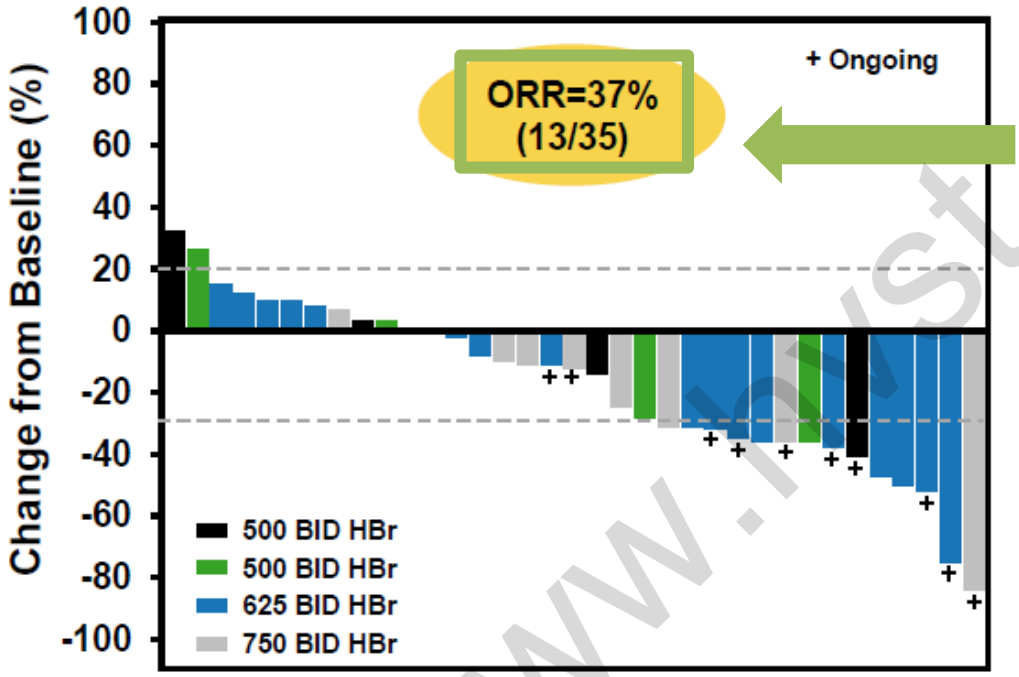
- 35% maturity is too early to make conclusions
- However, if PFS of 8 months holds in line with SOC (PFS 6-7 months), doctors still prefer Roci because:
  - Better SE than chemo
  - Oral (Roci) > IV (chemo)

*Note: For EGFR+T790M+ lung cancer mutations.
Source: Company presentation.

*Data analyzed 27 Apr 2015.
PFS=progression-free survival.

Roci: Data Superior to the Current Standard of Care*

Best Response for Target Lesions in Centrally Confirmed T790M- Patients



T790M- is the 2nd indication Roci is seeking FDA approval on

Key Considerations

1) N=35 is a small study

2) However, if ORR=37% holds in line with SOC 20-35%, doctors still prefer Roci because:
   - Better SE than chemo
   - Oral (Roci) > IV (chemo)

3) **Big deal: If data holds, Roci will be used in all 2L patients (no need to determine T790M mutation status).**
   - AstraZeneca does not appear to be pursuing T790M- population

*Note: For EGFR+T790M- lung cancer mutations.
Source: Company presentation.

Ruca: Replacing the Current Standard of Care*

The Current Standard of Care: Lynparza®

- While there are a variety of issues in comparing data points across trials (e.g. baseline patient demographics may be different between the studies), in reality, unless there is head-to-head studies, the market does not have anything else
- Lynparza® showed the following ORR (i.e. % of patients with tumor shrinkage):

Table: Overall Response Rate (ORR) & Duration of Response (DOR) in Patients With gBRCA-mutuated Advanced Ovarian Cancer (Who Received 3 or More Prior Lines of Chemotherapy in Study I)

	N=137
Objective Response Rate (95% CI)	34% (26, 42)
Complete Response	2%
Partial Response	32%
Median DOR in months (95% CI)	7.9 (5.6, 9.6)

ORR for SOC:
What new 3L+BRCA+ ovarian cancer drugs have to beat

DOR for SOC:
What new 3L+BRCA+ ovarian cancer drugs have to beat

*Note: For 3L+BRCA+ ovarian cancer mutations.
Source: Company presentation.

Ruca: Data is Superior to Standard of Care*

Ruca vs. Standard of Care (SOC)

HRD molecular subgroup	Objective RECIST response rate, % (N)	Median duration of response, mo (95% CI)
tBRCA^{mut}	75 (30/40)	9.5 (7.4, 12.9)
tBRCA-like	36 (28/77)	8.2 (5.6, 10.8)
Biomarker negative	16 (11/68)	5.5 (2.1, 7.4)

- **Ruca:** ORR of 75% and 9.5 month duration of response (BRCA+)

VS.

- **SOC:** ORR of 34% and 7.9 month duration of response (BRCA+)

- **Ruca:** ORR of 36% and 8.2 month duration of response (BRCA-like)

VS.

- **SOC:** ORR of 34% and 7.9 month duration of response (BRCA-like)

- **Suggests that there is an opportunity for Ruca to also be used in the BRCA-like mutation patients, where there are currently no approved treatments**

*Note: For 3L+BRCA+ ovarian cancer mutations.
Source: Company presentation.

Ruca: Another Study Underscoring Strong Results

Ruca vs. Standard of Care (SOC)

	Rucaparib^
Objective response rate (RECIST)	61%
Complete response	13%
Partial response	48%
Median DoR (mo)	11.3+

- **Ruca:** **ORR of 61% (BRCA+, specifically germ-like mutations)**

VS.

- **SOC:** **ORR of 34% (BRCA+, specifically germ-like mutations)**

- **Ruca:** **Complete Response of 13% (BRCA+, specifically germ-like mutations)**

VS.

- **SOC:** **Complete Response of 2% (BRCA+, specifically germ-like mutations)**

Source: Company presentation.

Ruca: Side Effects Appear Manageable

Adverse event*	Treatment-related AEs reported in ≥15% of patients 204 total patients, n (%)	
	All grade	Grade 3/4
Nausea	143 (70)	7 (3)
Asthenia/Fatigue	135 (66)	15 (7)
ALT/AST increased**	80 (39)	23 (11)
Dysgeusia	79 (39)	0
Decreased appetite	70 (34)	2 (1)
Anemia/Decreased hemoglobin	62 (30)	38 (19)
Vomiting	61 (30)	2 (1)
Constipation	60 (29)	2 (1)
Diarrhea	40 (20)	3 (2)

- **Importantly, no myelodysplastic syndromes (MDS) or acute myeloid leukemia (AML) (i.e. blood cancers)**
- **Grade 3/4 adverse events appear manageable**

*No cases of myelodysplastic syndrome or acute myeloid leukemia reported.
**ALT/AST elevations are transient, self-limiting, and not associated with other signs of liver toxicity.
AE=adverse event; ALT=alanine transaminase; AST=aspartate transaminase.

Source: Company presentation.