UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

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

January 13, 2020
Date of report (Date of earliest event reported)

Aprea Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-39069**	**84-2246769**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

535 Boylston Street **Boston, Massachusetts** (Address of principal executive offices)	**02116** (Zip Code)

Registrant's telephone number, including area code: **(617) 463-9385**

(Former name or former address, if changed since last report): Not applicable

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

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425).

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12).

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b)).

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of each class	Trading Symbol(s)	Name of exchange on which registered:
Common stock, par value $0.001 per share	APRE	NASDAQ Global Select Market

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

Emerging growth company ☒

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

Item 2.02 Results of Operations and Financial Condition

As discussed below, in connection with its participation in the 38th Annual J.P. Morgan Healthcare Conference in San Francisco, California, Aprea Therapeutics, Inc. (the "Company") updated its corporate presentation to include disclosure that the Company had $130.1 million of cash and cash equivalents (unaudited) as of December 31, 2019.

Because the Company's consolidated financial statements for the year ended December 31, 2019 have not yet been finalized or audited, the preliminary statement of the Company's cash and cash equivalents as of December 31, 2019 in this Item 2.02 is subject to change, and the Company's actual cash and cash equivalents as of December 31, 2019 may differ materially from this preliminary estimate. Accordingly, you should not place undue reliance on this preliminary estimate.

Item 7.01 Regulation FD Disclosure

Beginning on January 13, 2020, the Company will participate in the 38th Annual J.P. Morgan Healthcare Conference in San Francisco, California. The Company has updated its corporate presentation that it intends to use in connection with its presentation on Tuesday January 14, 2020 at 3:30 p.m. Pacific Time and in meetings with investors. The updates primarily include updates on the Company's ongoing and planned clinical trials and disclosure regarding the Company's cash and cash equivalents as of December 31, 2019.

A copy of the Company's corporate presentation is attached hereto as Exhibit 99.1 and is hereby incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Aprea Therapeutics, Inc. Presentation

SIGNATURES

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

Aprea Therapeutics, Inc.

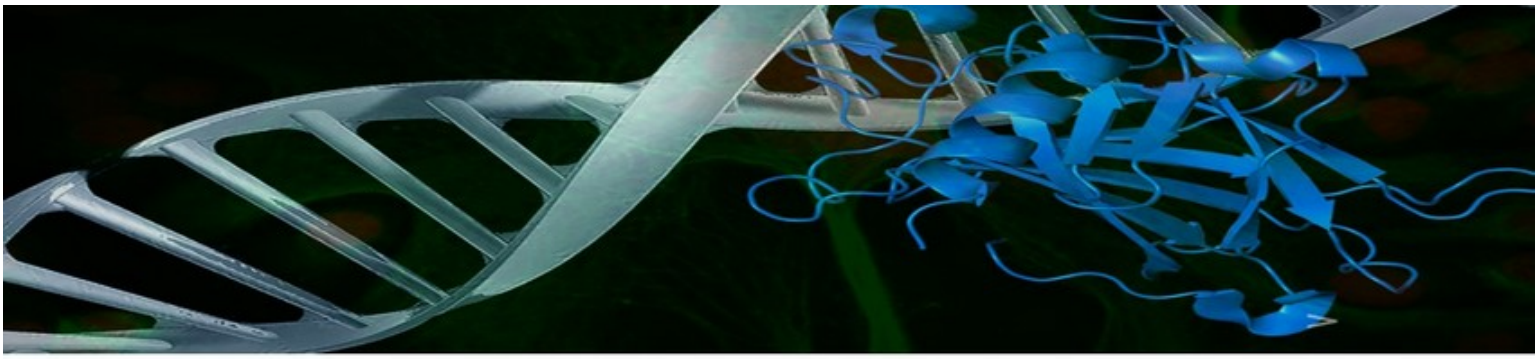
Dated: January 13, 2020

By: /s/ Christian S. Schade

Name: Christian S. Schade

Title: President and Chief Executive Officer

Exhibit 99.1



J.P. Morgan 38th Annual Healthcare Conference

January 2020

Forward-Looking Statements

Certain information contained in this press release includes "forward-looking statements", within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, related to our clinical trials and regulatory submissions. We may, in some cases use terms such as "predicts," "believes," "potential," "continue," "anticipates," "estimates," "expects," "plans," "intends," "may," "could," "might," "likely," "will," "should" or other words that convey uncertainty of the future events or outcomes to identify these forward-looking statements. Our forward-looking statements are based on current beliefs and expectations of our management team that involve risks, potential changes in circumstances, assumptions, and uncertainties. Any or all of the forward-looking statements may turn out to be wrong or be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties. These forward-looking statements are subject to risks and uncertainties including risks related to the success and timing of our clinical trials or other studies and the other risks set forth in our filings with the U.S. Securities and Exchange Commission, including our Quarterly Report on Form 10-Q. For all these reasons, actual results and developments could be materially different from those expressed in or implied by our forward-looking statements. You are cautioned not to place undue reliance on these forward-looking statements, which are made only as of the date of this press release. We undertake no obligation to publicly update such forward-looking statements to reflect subsequent events or circumstances.

Aprea Therapeutics (NASDAQ: APRE)

The p53 Reactivator Company

- **Focused on p53-targeted anticancer therapy**
  - Headquarters in Boston, MA with research facilities in Stockholm, Sweden
  - Gross proceeds of ~$98mm in October 2019 IPO
    - Use of proceeds to expand and accelerate clinical development
    - 5th best performing Biotech IPO in 2019[1]

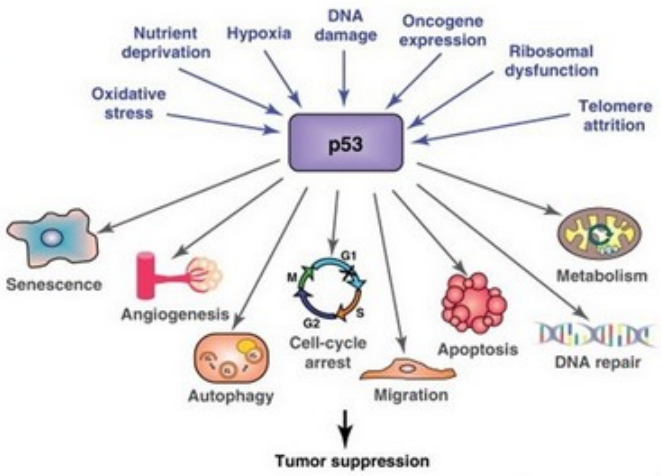
- **Significant unmet medical need: Patients with p53 mutant malignancies**
  - p53 mutation associated with poor prognosis and aggressive clinical treatment
  - Limited therapeutic options to specifically treat p53 mutant malignancies
  - APR-246: First-in-class small molecule to restore normal form and function of mutated p53
    - Broad opportunity to enhance potency of anti-cancer therapies; impact patient lives and treatment strategies

- **Aggressive Clinical Development Program**
  - APR-246:
    - Proof-of-principle Phase 2 clinical studies in p53 mutant MDS
    - Randomized Phase 3 clinical study underway in p53 mutant MDS
    - Additional Phase 2 studies underway and planned in hematological and solid tumor malignancies
  - APR-548: Next-generation p53 reactivator
    - Best-in-class small molecule with opportunity for oral administration

[1]Jefferies equity research report, "Final IPO Scorecard, Metrics, and Trends – Who are the Top Performers of 2019?", January 2, 2020

p53: Guardian of the Genome

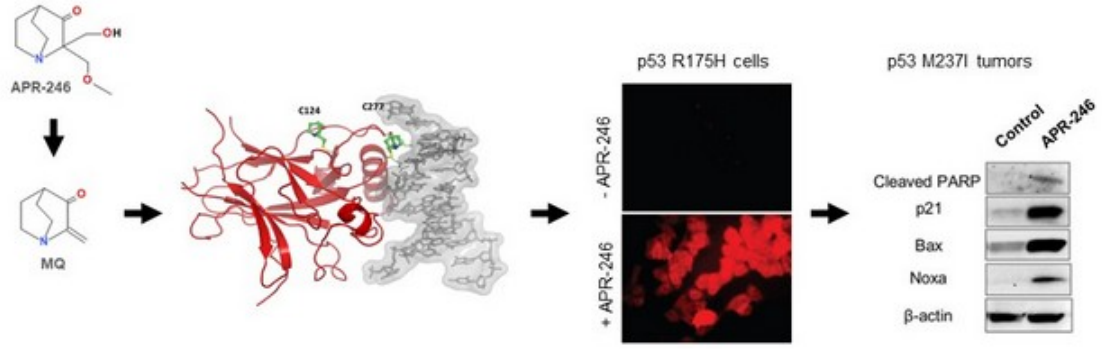
- **p53 is a critical tumor suppressor protein**
  - Normal function senses DNA damage and induces
    - Apoptosis, cell-cycle arrest, senescence
- **The gene encoding p53 is the most commonly mutated gene in cancer**
  - Mutated in over half of all liquid and solid tumors
  - Disrupts tumor suppressive function
  - Leads to acquisition of pro-tumor functions
- **Patients with p53 mutation have inferior prognosis**
  - Ineffective treatment options with non-functional pathway
  - Decreased sensitivity/resistance to approved anti-cancer agents
  - Aggressive clinical course with high rates of relapse
- **Our approach**
  - Direct conformational reactivation of mutant p53
  - Restoration of wild-type p53 structure and functional activity
  - Combination therapy with multi-agent additive/synergistic activity



Graphic: Bieging and Attardi, Trends Cell Biol, 2012, 97.

Our Approach to Reactivating p53

- **APR-246 is converted to MQ, which covalently binds mutant p53 to restore wild-type conformation, resulting in cell cycle arrest and apoptosis**



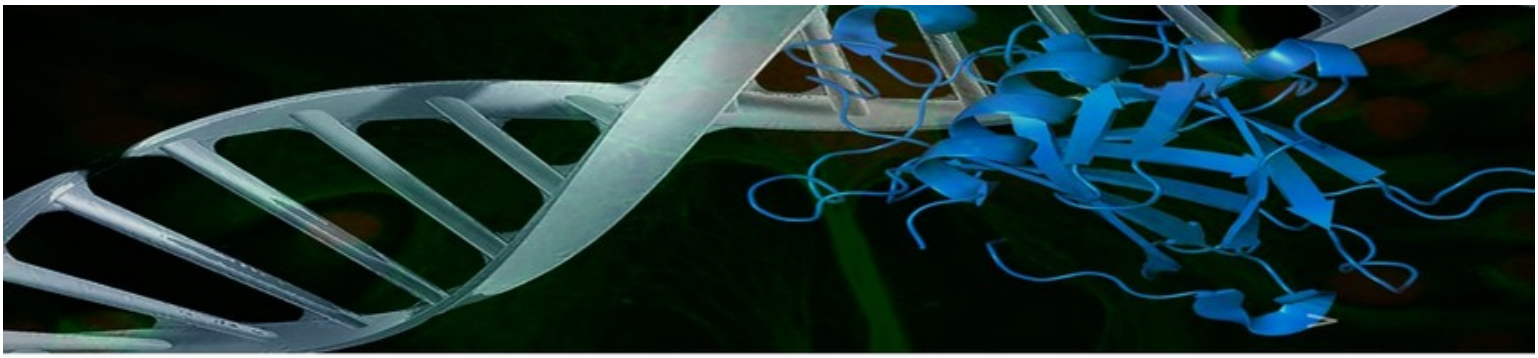
Spontaneous conversion to MQ

Green: MQ covalently bound to p53

Red: Antibody detection of restored wild-type conformation in mutant p53 with APR-246 treatment

Expression of cell cycle arrest and pro-apoptotic genes with APR-246 treatment

Sources: Aprea unpublished data; Furukawa et al, Cancer Sci, 2018



Clinical Development

Current Pipeline

Molecule	Indication	Treatment Line	Preclinical	Phase 1	Phase 2	Phase 3
APR-246	*TP53* Mutant MDS	Frontline	Combination with azacitidine			
	TP53 Mutant MDS / AML	Frontline (U.S. study)[1]	Combination with azacitidine			
		Frontline (French study)[1]	Combination with azacitidine			
		Post-Transplant Maintenance	Combination with azacitidine			
	TP53 Mutant AML	Frontline and Relapsed / Refractory	Combination with venetoclax[2]			
APR-548	*TP53* Mutant MDS / AML					

[1]Investigator-initiated trial; [2]With or without azacitidine

TP53 Mutant MDS and AML are Diseases of Older Adults and Have Limited Treatment Options and Poor Outcomes

- **MDS and AML are bone marrow disorders in which malignant blood cells impair normal blood production and lead to death due to infection and bleeding**

	Estimated Global Prevalence[1]	Annual Growth Rate[1]
MDS	~ 200,000	Mature markets: 2-3% Emerging markets: 3-4%
AML	~ 213,000	Mature markets: 1-2% Emerging markets: 2-3%

- ***TP53* mutations (~20% of MDS/AML[2,3]) are associated with significantly poorer survival**
- **No established curative pharmacologic therapies**
- **Most patients receive azacitidine for frontline therapy**

	Response Rate[3]	Median OS[3]
MDS	ORR: 40-45% CR: 15-20%	~ 7-8 months
AML	ORR: 40-50% CR: 10-20%	~ 7-8 months

Sources: [1]Decision Resources Group, 2019; [2]Lindsley et al, New England J Med, 2017, 536; [3]Dohner et al, Leukemia, 2018, 2546; Sallman et al, ASH poster #1817, 2018; Bories et al, ASH poster 2745, 2018; Takahashi et al, Oncotarget, 2016.

Phase 1b/2 Trials in *TP53* Mutant MDS/AML: Overview

ASH 2019 Update[1]

Two parallel investigator-initiated trials evaluating frontline APR-246 + azacitidine (AZA)

- All patients confirmed as *TP53* mutant by next-generation sequencing
- Patients receive 4 days APR-246 followed by 7 days AZA in 28-day cycles
- Endpoints include complete remission (CR) rate (primary), overall response rate (ORR), duration of response (DoR) and overall survival (OS)

Patient Demographics

	U.S. Trial[1]		French Trial[2]	
	All (N=55)	MDS (N=40)	All (N=53)	MDS (N=34)
Age in years, median (range)	66 (34 – 85)	66 (34 – 80)	73 (44 – 87)	74 (46 – 87)
Disease type, n (%)				
MDS	40 (73)		34 (64)	
IPSS-R: Intermediate	4 (7)	4 (10)	3 (6)	3 (9)
IPSS-R: High	**8 (15)**	**8 (20)**	**3 (6)**	**3 (9)**
IPSS-R: Very high	**28 (51)**	**28 (70)**	**28 (53)**	**28 (82)**
AML	11 (20)		19 (36)	
MDS-MPN / CMML	4 (7)		0 (0)	
Complex karyotype, n (%)	**47 (85)**	**36 (90)**	**46 (87)**	**28 (83)**

[1]Updates as of data cutoffs presented at ASH 2019; [2]Sallman et al, ASH 2019, data cutoff November 15, 2019; [3]Cluzeau et al, ASH 2019, data cutoff November 29, 2019

Data Summary of APR-246 + AZA in *TP53* Mutant MDS Patients

ASH 2019 Update

- **Highly concordant responses observed across U.S. and French Trials**

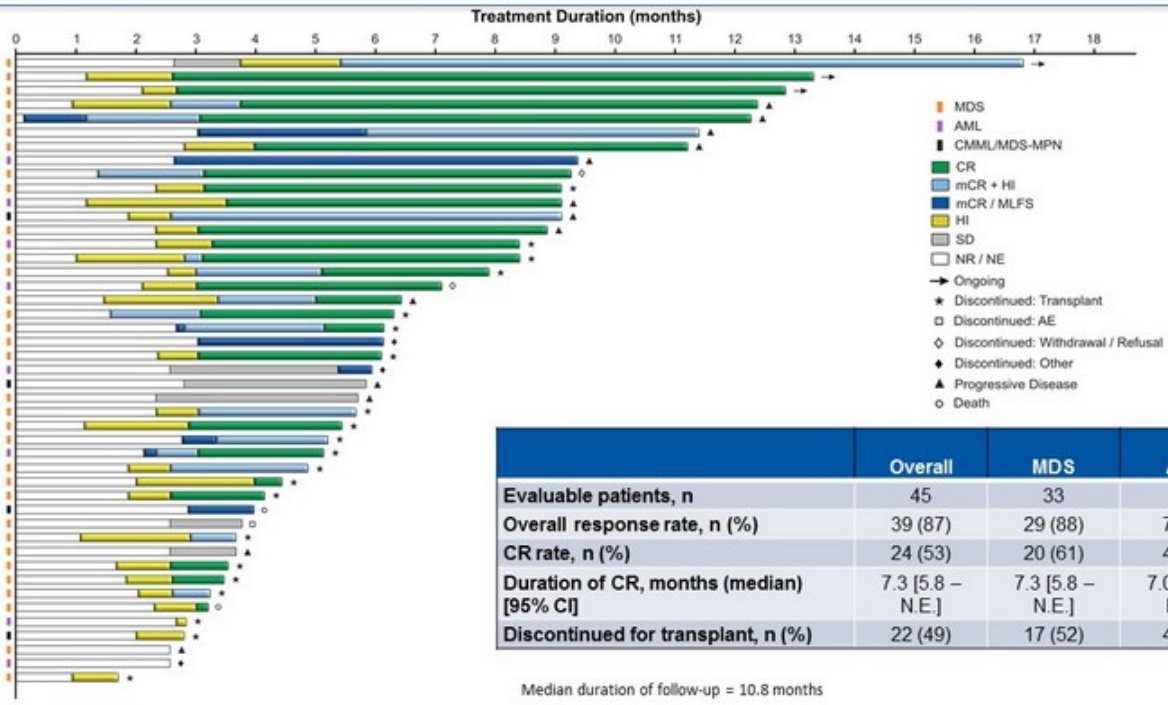
	U.S. Trial[2]	French Trial[3]	AZA Historical[4]
Evaluable[1] MDS patients, n	33	27	
Response rates			
ORR	88%	74%	40-45%
CR	**61%**	**59%**	**15-20%**
Median duration of follow-up, months	10.8	6.4	
Median DoR, months			
Overall	8.4	not reached	4-5
CR	7.3	not reached	
Median OS, months	10.4	not reached	7-8

- **52% of evaluable MDS patients in U.S. trial discontinued study treatment for transplant**
- **APR-246 + AZA combination regimen is well-tolerated**
  - Majority of adverse events were low grade (< 3) and associated with the underlying disease

[1]Evaluable patients: patients who have undergone repeat bone marrow biopsy; [2]Sallman et al, ASH 2019; [3]Cluzeau et al, ASH 2019; [4]Sallman et al, ASH poster #1817, 2018; Bally et al. Leuk Res. 2014; Takahashi et al. Oncotarget. 2016; Kulasekararaj et al, Br J Haematol, 2013; Bejar et al, Blood, 2014 Falconi et al, Leukemia, 2018

Response and Duration in Evaluable Patients - U.S. Trial[1] (N=45)

ASH 2019 Update



	Overall	MDS	AML	MDS-MPN + CMML
Evaluable patients, n	45	33	8	4
Overall response rate, n (%)	39 (87)	29 (88)	7 (88)	3 (75)
CR rate, n (%)	24 (53)	20 (61)	4 (50)	0 (0)
Duration of CR, months (median) [95% CI]	7.3 [5.8 – N.E.]	7.3 [5.8 – N.E.]	7.0 [3.3 – N.E.]	N.E.
Discontinued for transplant, n (%)	22 (49)	17 (52)	4 (50)	1 (25)

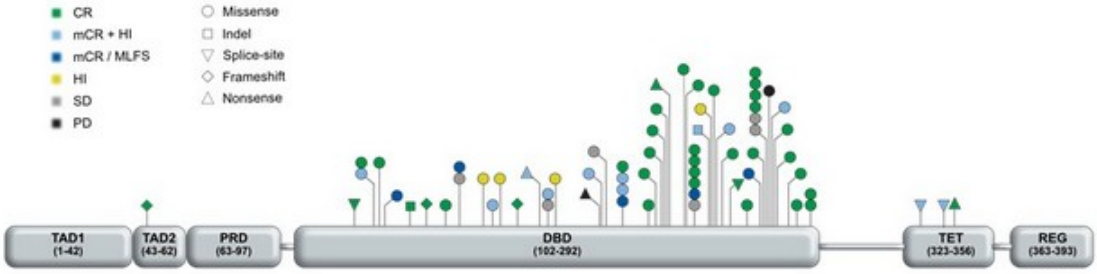
Median duration of follow-up = 10.8 months

[1]Sallman et al, ASH 2019

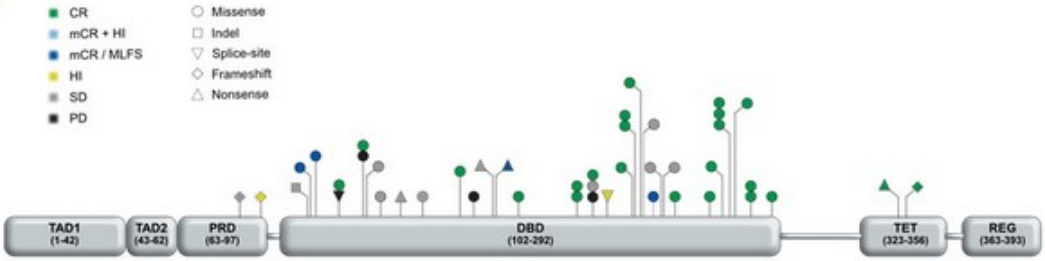
Responses Observed Across p53 Mutation Types and Locations

ASH 2019 Update

U.S. Trial[1]



French Trial[2]

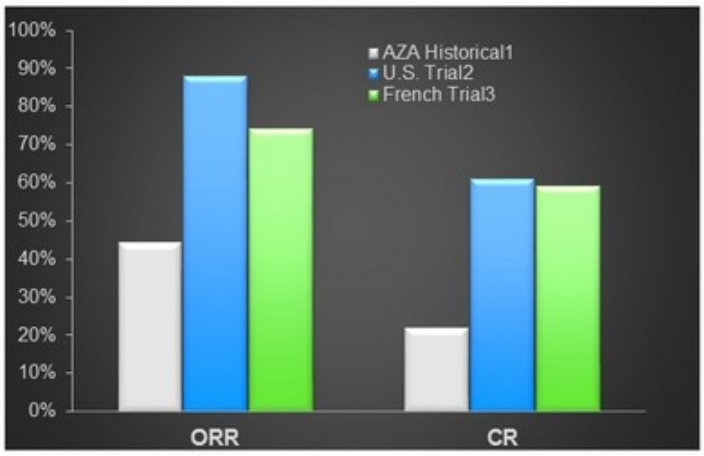


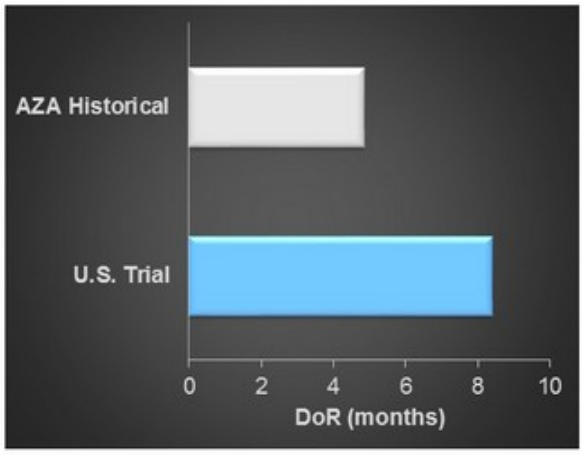
TAD: Transactivation domain PRD: Proline-rich domain DBD: DNA-binding domain TET: Tetramerization domain REG: C-terminal regulatory domain

[1]Sallman et al, ASH 2019; [2]Cluzeau et al, ASH 2019

Response and Duration of APR-246/AZA Compared to Published Data for AZA Alone

TP53 Mutant MDS





[1]Sallman et al, ASH poster #1817, 2018; Bally et al. Leuk Res. 2014; Takahashi et al. Oncotarget. 2016; Kulasekararaj et al, Br J Haematol, 2013; Bejar et al, Blood, 2014 Falconi et al, Leukemia, 2018; [2]Sallman et al, ASH 2019; [3]Cluzeau et al, ASH 2019

Randomized Phase 3 MDS Trial[1]

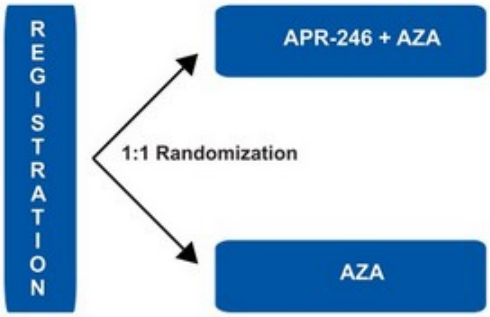
Topline Data Expected Q3 2020

Randomized study of frontline AZA ± APR-246 in *TP53* mutant MDS

Phase 3

Target Enrollment, n=154

Enrollment ongoing: 4500 mg/d fixed dose



- Intermediate/High/Very High Risk *TP53* mutant MDS
- Primary endpoint: CR rate
- Secondary endpoints: ORR, DoR, PFS, LFS, OS, transplant rate
- Highly powered at 90% to detect 2-sided alpha of 0.05 provided by overestimating CR of 25% in control AZA arm and underestimating CR of 50% in APR-246 + AZA arm

❑ **Status**

- 102/154 patients currently enrolled with 9 in screening[2]
- Full enrollment anticipated 1Q 2020 with CR primary endpoint readout expected 3Q 2020
- Fast Track Designation for MDS granted by FDA in April 2019
- Orphan Drug Designations for MDS granted by FDA in April 2019 and EMA in July 2019

[1]ClinicalTrials.gov NCT03745716; [2]As of January 10, 2020

Current Pipeline Update and Overview

Phase 2 Post-Transplant Trial

- Only a minority of patients proceed to stem cell transplant (SCT) due to lack of sufficient response to initial therapies, advanced age, comorbidities and lack of a suitable donor
- APR-246 + AZA maintenance for post-transplant *TP53* mutant MDS/AML
- 6/31 patients currently enrolled, 17 patients in screening[1]
- Full enrollment anticipated 1H 2020 with 1-year RFS primary endpoint readout 1H 2021
- Benchmark: ~30% 1-year relapse-free survival in transplanted *TP53* mutant MDS/AML patients

Phase 1/2 AML Ven-Combo Trial

- Preclinical data demonstrate strong synergistic activity of APR-246 + Bcl-2 inhibitor (venetoclax)
- APR-246 + venetoclax ± AZA in 1L and R/R *TP53* mutant AML
- Study evaluating safety and preliminary efficacy
- 2 patients enrolled[1]
- Expansion into 1L and R/R AML cohorts with doublet and triplet therapies following safety lead-in phase

[1]As of January 10, 2020

Future Pipeline Plans

Hematological Malignancies

- Phase 1 in relapsed/refractory *TP53* mutant non-Hodgkins lymphomas (CLL, MCL)
  - APR-246 + venetoclax and APR-246 + ibrutinib
  - Study evaluating safety and preliminary efficacy
  - Anticipate first patient enrolled 2H 2020

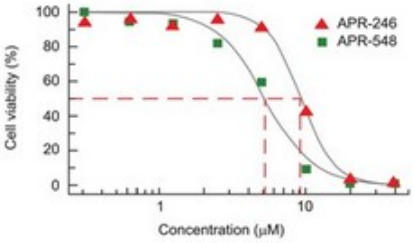
Solid Tumors

- APR-246 + anti-PD-1 therapy in solid tumors
  - Rationale: Data from MSKCC demonstrate APR-246 enhances effects of PD-1 blockade in murine melanoma and colorectal carcinoma models (AACR, 2019)[1]
  - Indications
    - Relapsed/refractory gastric cancer
    - Relapsed/refractory bladder cancer
    - Relapsed/refractory non-small cell lung cancer
  - Study evaluating safety and preliminary efficacy
  - Anticipate first patient enrolled 2H 2020

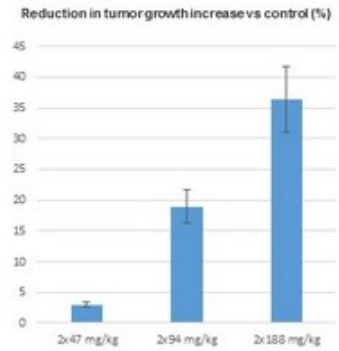
Ghosh et al. 2019 AACR Annual Meeting. Abstract 4843

APR-548: Oral Next-Generation p53 Reactivator

- **Similar mechanism of action to APR-246 (MQ)**
- **More potent than APR-246 *in vitro***
  - ≥ 40% reduction in IC_{50}



- **High oral bioavailability: 80-99%**
- **Orally active BID in xenograft model**



- **IND enabling studies in progress**
  - No inhibition/induction of key metabolic enzymes, no hERG signal
  - Pivotal repeat-dose GLP toxicology studies near completion; reports pending
- **Scalable, high-purity manufacture developed and on schedule for clinical studies**
- **IND filing anticipated 1H 2020**

Financial Overview

» ~$130.1 million of cash and cash equivalents (unaudited) at December 31, 2019
» No outstanding debt
» Anticipated cash burn for 2020: $35.0 million – $40.0 million
» Existing cash should fund operations into 2023

» ~21.0 million common shares outstanding at November 13, 2019
» ~24.5 million common shares outstanding on a fully-diluted basis

» 13 full-time employees at December 31, 2019
» Up to 7 additional full-time employees planned for 2020

2020 Anticipated Milestones

Milestones	Timeline
Phase 3 Frontline MDS	
CR primary endpoint readout	3Q 2020
NDA Submission	4Q 2020
Phase 1/2 Frontline MDS/AML (French Trial)	
CR rate, duration, survival	1H 2020
Phase 2 MDS / AML post-transplant maintenance	
Full enrollment	1H 2020
Phase 1/2 AML Ven-Combo Trial	
FPI	Jan 2020
Phase 1/2 NHL Trial	
First patient enrolled	2H 2020
Phase 1/2 Solid Tumor I-O Trials	
First patient enrolled	2H 2020
2nd Gen p53 reactivator, APR-548	
IND	1H 2020
First patient enrolled in Phase 1	1H 2020

Summary

- **Continued strong execution of current APR-246 clinical development plan**
  - Positive and concordant efficacy data in Phase 1b/2 trials for MDS/AML
  - Randomized Phase 3 trial for MDS on track for full enrollment 1Q 2020 and primary CR endpoint readout 3Q 2020
  - Excellent enrollment trajectory in Phase 2 trial for MDS/AML post-transplant maintenance
  - First patients dosed in Phase 1/2 ven-combo AML trial

- **Aggressively broadening pipeline with upcoming studies in hematologic malignancies and solid tumors**
  - Non-Hodgkins lymphomas (CLL, MCL)
  - Gastric cancer
  - Bladder cancer
  - Non-small cell lung cancer

- **Next-generation, oral p53 reactivator APR-548 poised to enter clinical trials**
  - IND timeline: 1H 2020

- **~$130.1 million cash and cash equivalents (unaudited) at December 31, 2019 to fund operations into 2023**