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

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULE 13a-16 OR 15d-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934

For the Month of February 2024

Commission File Number: 001-39997

Adagene Inc.
(Exact Name of Registrant as Specified in Its Charter)

4F, Building C14, No. 218
Xinghu Street, Suzhou Industrial Park
Suzhou, Jiangsu Province, 215123
People's Republic of China
+86-512-8777-3632
(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F ☒ Form 40-F ☐

EXPLANTATORY NOTE

On February 9, 2024, Adagene Inc. (the "Company") updated information reflected in a press release and an investor presentation, which is attached as Exhibit 99.1 and Exhibit 99.2 to this Current Report on Form 6-K, respectively. Representatives of the Company intend to use the updated presentation and information contained in the press release in meetings with investors from time to time.

SIGNATURES

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

Adagene Inc.

By: /s/ Peter Luo
Name: Peter Luo
Title: Chief Executive Officer

Date: February 9, 2024

EXHIBIT INDEX

Exhibit	Description
99.1	Press Release
99.2	Investor Presentation

ADAGENE

Adagene Announces Progress and Expansion of Clinical Collaboration Program for Masked, Anti-CTLA-4 SAFEbody® ADG126 (muzastotug) in Combination with KEYTRUDA® (pembrolizumab) to Demonstrate Further Efficacy in Patients with Metastatic Microsatellite-stable (MSS) Colorectal Cancer (CRC)

- Interim data from additional MSS CRC patients dosed at 10 mg/kg every three weeks (Q3W) in combination with pembrolizumab anticipated in 2024 at a medical conference –

- Initiated evaluation of 20 mg/kg loading doses of ADG126 in combination with pembrolizumab to explore enhanced efficacy given superior therapeutic index of ADG126 –

- Received clearance from China's Center for Drug Evaluation (CDE) to evaluate ADG126 in combination with pembrolizumab –

SAN DIEGO and SUZHOU, China, February 9, 2024 – Adagene Inc. ("Adagene") (Nasdaq: ADAG), a company transforming the discovery and development of novel antibody-based therapies, today announced progress and expansion of the clinical collaboration development program for its masked, anti-CTLA-4 SAFEbody, ADG126 in combination with Merck & Co., Inc., Rahway, NJ, USA's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab), in patients with metastatic microsatellite-stable (MSS) colorectal cancer (CRC).

"Following completion of enrollment of 12 additional patients at the end of last year, together with our ongoing expansion plans, we are on track to deliver data in 2024 that support the findings released at the recent ASCO-GI Symposium demonstrating the safety and efficacy profile of ADG126 in combination with pembrolizumab in MSS CRC," said Peter Luo, Ph.D., Chairman, CEO and President of R&D at Adagene.

He continued, "To address the requirements for Project Optimus by FDA, we have initiated evaluation of ADG126 20 mg/kg loading doses in combination with pembrolizumab, which we believe can unlock even greater efficacy for MSS CRC in planned cohort expansion, while still maintaining a robust safety profile. Additionally, we are now cleared to evaluate ADG126 in combination with pembrolizumab in China, strengthening our efficacy evaluation with additional patients enrolled at unprecedented dosing regimens for anti-CTLA-4 therapy."

The updates, which increase the ongoing phase 2 dose expansion in MSS CRC to over 50 patients, include the following:

- The company announced it completed enrollment of 12 additional patients in the fourth quarter of 2023 in the ongoing phase 2 dose expansion cohort evaluating ADG126 10 mg/kg Q3W in combination with pembrolizumab in MSS CRC. These Part 2 results are expected to support data from Part 1 of the dose expansion in MSS CRC that was recently presented at the 2024 ASCO-GI Symposium.

- Given the safety profile of ADG126, Adagene has also initiated evaluation of 20 mg/kg loading doses in combination with pembrolizumab in patients with advanced/metastatic cancer. Following the ongoing safety evaluation, the company plans to study efficacy of the loading doses followed by a maintenance regimen of ADG126 10 mg/kg Q3W in combination with pembrolizumab. The company plans dose expansion with this regimen in patients with MSS CRC in the US and Asia Pacific.

- Adagene has also received clearance from the CDE in China to initiate clinical evaluation of ADG126 in combination with pembrolizumab. This enables the company to broaden its dose expansion cohorts for MSS CRC at selected dosing regimens, and potentially in other tumor types.

2024 Milestones

Data from the ongoing phase 1b/2 clinical trial of ADG126 in combination with pembrolizumab, including dose expansion cohorts, are anticipated throughout 2024:

- Follow up of Part 1 evaluable patients at 10 mg/kg Q3W (n=12) and 10 mg/kg Q6W (n=10)
- Data from Part 2 patients at 10 mg/kg Q3W (n=12)
- Evaluation of 20 mg/kg loading doses for Project Optimus requirements:
  - Safety data with repeat doses
  - Dose expansion in MSS CRC (n~10)
- Additional patients in China (n≥10)

About Adagene

Adagene Inc. (Nasdaq: ADAG) is a platform-driven, clinical-stage biotechnology company committed to transforming the discovery and development of novel antibody-based cancer immunotherapies. Adagene combines computational biology and artificial intelligence to design novel antibodies that address unmet patient needs. Powered by its proprietary Dynamic Precision Library (DPL) platform, composed of NEObody™, SAFEbody®, and POWERbody™ technologies, Adagene's highly differentiated pipeline features novel immunotherapy programs. Adagene has forged strategic collaborations with reputable global partners that leverage its technology in multiple approaches at the vanguard of science.

For more information, please visit: https://investor.adagene.com. Follow Adagene on WeChat, LinkedIn and Twitter.

SAFEbody® is a registered trademark in the United States, China, Australia, Japan, Singapore, and the European Union.

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

Safe Harbor Statement

This press release contains forward-looking statements, including statements regarding certain clinical results of ADG126, the potential implications of clinical data for patients, and Adagene's advancement of, and anticipated preclinical activities, clinical development, regulatory milestones, and commercialization of its product candidates. Actual results may differ materially from those indicated in the forward-looking statements as a result of various important factors, including but not limited to Adagene's ability to demonstrate the safety and efficacy of its drug candidates; the clinical results for its drug candidates, which may not support further development or regulatory approval; the content and timing of decisions made by the relevant regulatory authorities regarding regulatory approval of Adagene's drug candidates; Adagene's ability to achieve commercial success for its drug candidates, if approved; Adagene's ability to obtain and maintain protection of intellectual property for its technology and drugs; Adagene's reliance on third parties to conduct drug development, manufacturing and other services; Adagene's limited operating history and Adagene's ability to obtain additional funding for operations and to complete the development and commercialization of its drug candidates; Adagene's ability to enter into additional collaboration agreements beyond its existing strategic partnerships or collaborations, and the impact of the COVID-19 pandemic on Adagene's clinical development, commercial and other operations, as well as those risks more fully discussed in the "Risk Factors" section in Adagene's filings with the U.S. Securities and Exchange Commission. All forward-looking statements are based on information currently available to Adagene, and Adagene undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required by law.

Investor & Media Contact:

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February 2024

ADAGENE

Disclaimer and Cautionary Note on Forward-Looking Statements

The following presentation has been prepared by Adagene Inc. ("Adagene" or the "Company") solely for informational purposes and should not be construed to be, directly or indirectly, in whole or in part an offer to buy or sell and/or an invitation and/or a recommendation and/or a solicitation of an offer to buy or sell any security or instrument or to participate in any investment or trading strategy, nor sha any part of it form the basis of, or be relied on in connection with, any contract or investment decision in relation to any securities or otherwise. This presentation does not contain all relevant informatio relating to the Company or its securities, particularly with respect to the risks and special considerations involved with an investment in the securities of the Company. Nothing contained in this documen shall be relied upon as a promise or representation as to the past or future performance of the Company. Past performance does not guarantee or predict future performance. You acknowledge that an assessment of the Company that may be made by you will be independent of this document and that you will be solely responsible for your own assessment of the market and the market position of th Company and that you will conduct your own analysis and be solely responsible for forming your own view of the potential future performance of the business of the Company.

This document contains certain statements that constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1953, as amended, and Section 21E of the Securitie Exchange Act of 1934, as amended, with respect to the Company's future financial or business performance, anticipated clinical activities and development, strategies or expectations. These statement typically contain words such as "believe," "may," "will," "could," "expects" and "anticipates" and words of similar import. Any statement in this document that is not a statement of historical fact is forward-looking statement and involves known and unknown risks, uncertainties and other factors which may cause the Company's actual results, performance or achievements to be materially differen from any future results, performances or achievements expressed or implied by such forward-looking statements. Such forward-looking statements including statements regarding the potential implication of clinical data for patients, and Adagene's advancement of, and anticipated clinical activities, clinical development, regulatory milestones, and commercialization of its product candidates. Actual result may differ materially from those indicated in the forward-looking statements as a result of various important factors, including but not limited to Adagene's ability to demonstrate the safety and efficacy o its drug candidates; the clinical results for its drug candidates, which may not support further development or regulatory approval; the content and timing of decisions made by the relevant regulator authorities regarding regulatory approval of Adagene's drug candidates; Adagene's ability to achieve commercial success for its drug candidates, if approved; Adagene's ability to obtain and maintai protection of intellectual property for its technology and drugs; Adagene's reliance on third parties to conduct drug development, manufacturing and other services; Adagene's limited operating history an Adagene's ability to obtain additional funding for operations and to complete the development and commercialization of its drug candidates; Adagene's ability to enter into additional collaboratio agreements beyond its existing strategic partnerships or collaborations, and the impact of health epidemic, other outbreaks or natural disasters on Adagene's clinical development, commercial and othe operations, as well as those risks more fully discussed in the "Risk Factors" section in Adagene's filings with the U.S. Securities and Exchange Commission. There can be no assurance that the results an events contemplated by the forward-looking statements contained herein will in fact occur. None of the future projections, expectations, estimates or prospects in this document should be taken a forecasts or promises nor should they be taken as implying any indication, assurance or guarantee that the assumptions on which such future projections, expectations, estimates or prospects have bee prepared are correct or exhaustive or, in the case of assumptions, fully stated in the document. The Company also cautions that forward-looking statements are subject to numerous assumptions, risks an uncertainties, which change over time and which may be beyond the Company's control.

This presentation concerns product candidates that are or have been under clinical investigation and which have not yet been approved for marketing by the U.S. Food and Drug Administration, Europea Medicines Agency, The China National Medical Products Administration, or other foreign regulatory authorities. These product candidates are currently limited by U.S. Federal law to investigational use, an no representations are made as to their safety or effectiveness for the purposes for which they are being investigated.

This presentation contains certain comparison based on publicly available information and represents certain non-head-to-head summary comparison. The Company cautions that results of a head-to head comparison may different significantly.

The information that can be accessed through the hyperlinks included in this presentation is not incorporated by reference into this presentation or any Adagene's filings with the U.S. Securities an Exchange Commission, and you should not consider such information to be part of this presentation.

This document speaks as of **February 9, 2024**. Neither the delivery of this document nor any further discussions of the Company with any of the recipients shall, under any circumstances, create an implication that there has been no change in the affairs of the Company since that date. Adagene undertakes no obligation to publicly update or revise any forward-looking statements, whether as a resul of new information, future events or otherwise, except as may be required by law.

Company Highlights

Focus on masked, anti-CTLA-4 lead candidate	• SAFEbody® ADG126 (muzastotug) results from Ph2 dose expansion cohorts with pembrolizumab in MSS CRC show **best-in-class profile with higher, more frequent and repeat doses**
Validation of SAFEbody® technology by partners	• Sanofi and Exelixis technology licensing agreements for SAFEbody • Eligible to receive ≥$2.5B in potential milestones from existing partners
Strong cash balance with runway into 2026	• Unaudited consolidated cash balance: **~US$110M as of Dec. 31, 2023** • Potential to receive additional non-dilutive funding from collaborations • Cash runway with streamlined operations into 2026

Why Focus on Next Generation Anti-CTLA-4 Therapies?

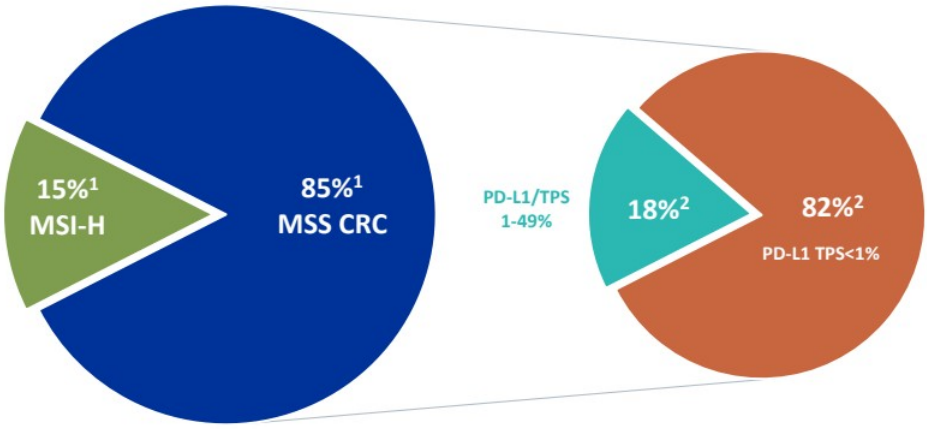
- CTLA-4 is a proven target where safety is limiting its therapeutic potential

- T regulatory cell depletion is crucial for overcoming immune suppression in the tumor microenvironment (TME) where CTLA-4 is overexpressed on Tregs

We are taking anti-CTLA-4 therapy to a new level by targeting a unique epitope combined with SAFEbody precision masking technology to reach tumor tissues with the best therapeutic index and unleash anti-CTLA-4 therapy

Reimagining the Anti-CTLA-4 Opportunity: MSS CRC is a High Unmet Medical Need Where CTLA-4 Mediated Treg Depletion Matters

MSS CRC	
W.W. Annual Incidence[1]	***~1.6 million (all stages)***



- **No PD-1 approved in MSS CRC; only approved in MSI-H CRC tumors**
- **PD-L1 expression is low in this cold tumor**

[1] Learn.colontown.org (MSS CRC accounts for ~85% of colorectal cancer cases across all stages and ~96% of stage 4 cases), Cancer.net
[2] Shun Xu et al. Distribution of PD-L1 expression level across major tumor types

3L+ MSS CRC: A Promising Opportunity with High Unmet Need

	Standard of Care (FDA)				
Company	**Bayer**	**TAIHO**		**HutchMed/Takeda**	
Compounds	**Rego[1,2]**	**TAS-102[3,4]**	**Sunlight[5,6]** TAS102 plus Avastin	**Fruquintinib[7,8]** w/o Liver mets	**Fruquintinib[7,8]** with Liver mets
ORR (%)	**1**	**2**	**6.3**	**4.3**	**4.9**
mPFS (month)	**1.9**	**2.0**	**5.6**	**3.9**	**3.7**
mOS (month)	6.4	7.1	10.8	10.8	8.6
≥G3 TRAEs	**54%**	**69%**	**72.4%**	**61.2%**	

[1]Grothey et al. Lancet. 2013;381: 303-312.; [2]FDA label, 12/10/2020; [3]Mayer et al. N Eng J Med. 2015;372:1909-1919; [4] Marcus et al. Clin Cancer Res; 23(12) June 15, 2017;2924-2927
[5]Josep Tabernero et al. 2023 ASCO Gastrointestinal; [6] Gerald W. Prager et al. N Engl J Med 2023 May 04;388(18); [7]Shukui Qin et al. 2019 CSCO; [8]Jin Li et al. JAMA. 2018;319(24):2486-2496;
[9]Andrea J. Bullock et al. 2023 ESMO-GI; [10]Anthony B et al. 2023 ASCO-GI; [11]Elena et al. 2021 ASCO; [12]E. Garralda et al. 2022 ESMO OPEN
*overall PFS ** N=87 + N=101

Failures of Immunotherapy and Their Combinations in MSS CRC

Regorafenib/Pembrolizumab Misses PFS End Point in MSS CRC, But Biomarker Analyses Are Ongoing

March 21, 2022
Ryan Scott

In Partnership With: City of Hope.

Article

ESMO > Oncology News > Archive

ESMO World GI Congress 2018: IMblaze370 study Did Not Meet Its Primary Endpoint

Studying combination of atezolizumab with cobimetinib in patients with MSS/MSI-L metastatic CRC

MEDPAGETODAY

Meeting Coverage > GICS

Immunotherapy Not Additive to Standard of Care for Untreated Metastatic CRC

— No difference in survival outcomes with add-on nivolumab to chemo, bevacizumab

by Charles Bankhead, Senior Editor, MedPage Today January 23, 2022

This article is a collaboration between MedPage Today and: aga

SAN FRANCISCO -- Immunotherapy's limited activity against microsatellite stable (MSS) colorectal cancer (CRC) failed to improve when added to standard-of-care (SOC) therapy, a phase II randomized trial showed.

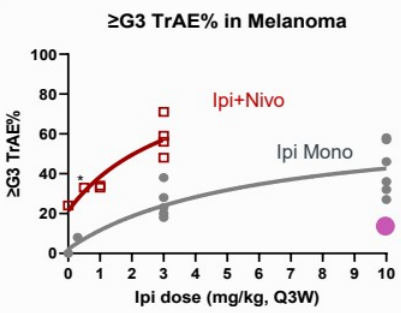
NEWS

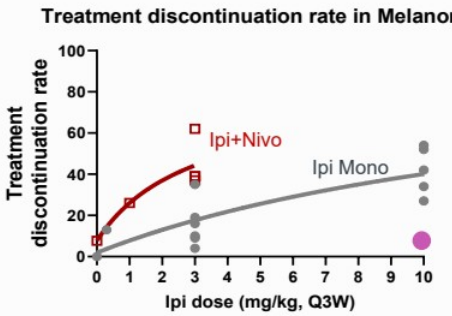
BMS's RELATIVITY-123 Trial Fail: A Devastating End

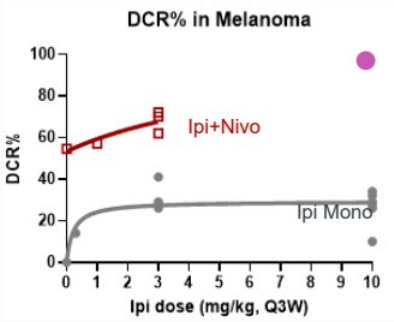
By Ferry Darma - December 18, 2023

Bristol Myers Squibb announced the discontinuation of the Phase 3 RELATIVITY-123 trial, which was evaluating the fixed-dose combination of nivolumab and relatlimab as a treatment for microsatellite stable (MSS) metastatic colorectal cancer (mCRC) patients. This decision comes afte an independent data monitoring committee determined that the trial was unlikely to meet its primary endpoints of overall survival.

Published Ipilimumab (Ipi) Data Show High Dose-dependent Toxicity and Efficacy, Exaggerated in Combination with Nivo, but ADG126 Is Exceptional







* Ipi at 1mpk Q6W was graphed as 0.5mpk Q3W

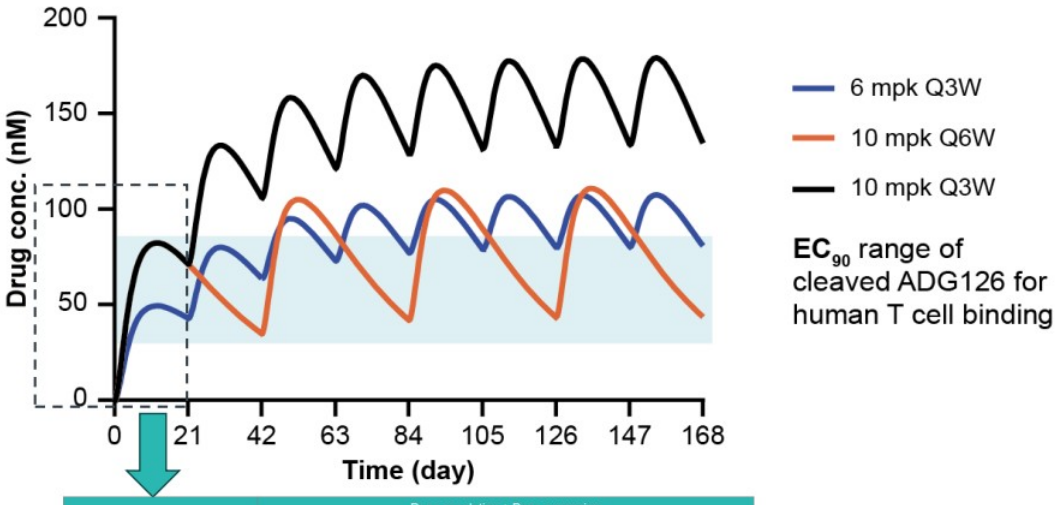
Dose escalation and expansion data from 10 mg/kg ADG126 Q3W in combo with anti-PD-1 for patient w/o liver and peritoneal Mets

- Stronger dose-dependent increase in ≥G3 TRAEs relative to efficacy for Ipi monotherapy
- The dose-dependent efficacy and toxicity are much stronger in combo therapy, despite a 3-fold reduction in Ipi dose
- ADG126 successfully decouples safety from efficacy despite a 10-fold increase in dose of 126 vs Ipi, showing 100% DCR and <15% G3 TRAEs and <10% discontinuation rate in MSS CRC* at 10 mpk q3w (shown with purple dots)

Publications on file.

Analysis of Cleaved ADG126 Supports Increased Clinical Efficacy at 10 mg/kg Q3W vs 10 mg/kg Q6W in a Combination Setting with anti-PD1

Model-predicted mean tumor ISF cleaved ADG126

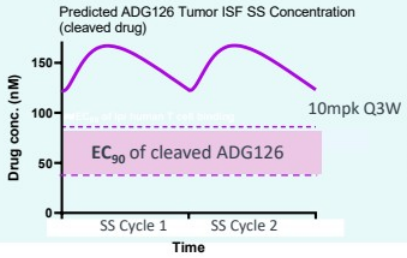


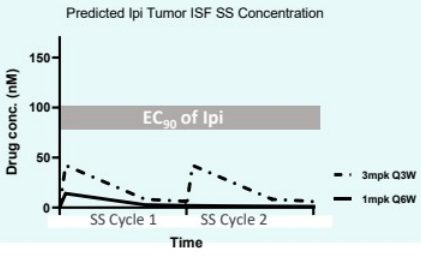
ADG126 + Pembrolizumab (NCT05405595)	Dose escalation + Dose expansion				
	Safety (TRAEs)			Efficacy	
ADG126 Dosing Regimen	Patients Dosed[1] (N=46)	≥ G3 TRAEs*	Discontinuation Rate due to TRAEs	Patients Evaluable[2] (N=37)	DCR
6 mg/kg Q3W	5	20%	0%	5	20%
10 mg/kg Q6W	17	6%	0%	16	56%
10 mg/kg Q3W	24	13%	0%	16	75%

PK Modeling Quantifies the Enhanced Therapeutic Index (TI) of SAFEbody ADG126 Over Ipilimumab

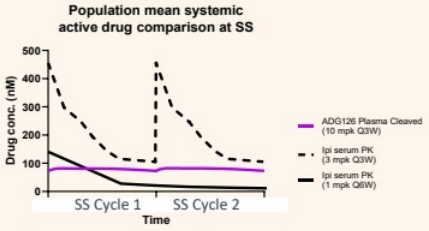
Dosage	Predicted $AUC_{ss,\ tumor\ ISF}$ fold difference	Predicted $C_{max,ss,tumor\ ISF}$ fold difference
ADG126 (10 mg/kg Q3W) vs. Ipilimumab (1 mg/kg Q6W) in combination with anti-PD-1	**~30X**	**~10X**

>90% RO (Receptor Occupancy) of activated ADG12610 mg/kg Q3W in tumor



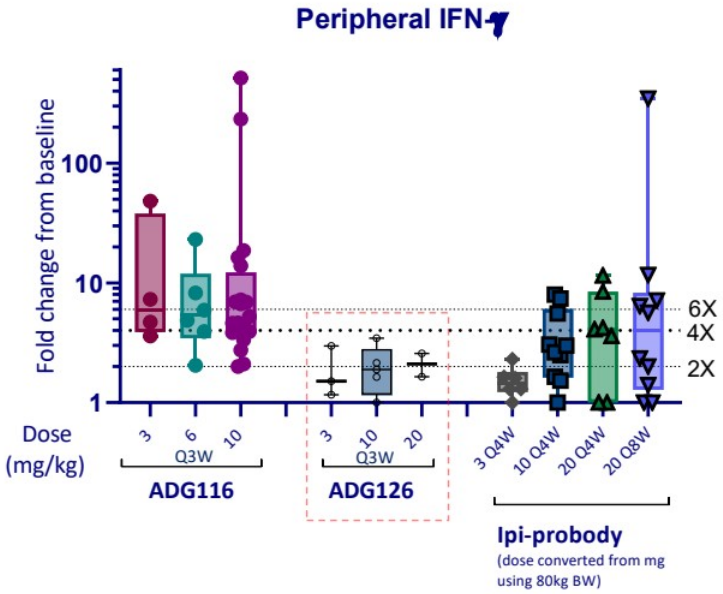


Reduced exposures of activated ADG126 in plasn



This slide contains information from various studies which are not head-to-head comparisons. Data on file. Ipi PK digitized from Sanghavi, K., et al. CPT Pharmacometrics Syst. Pharmacol. 2020;9:29-39.
Assuming ipi concentration ~10% tumor drug partition based on Ipi serum PK.

Peripheral IFN-γ Data of ADG126 Reinforce Superior Safety Profile



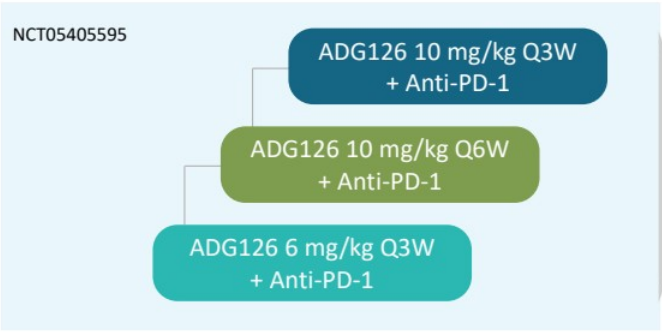
ADG126 is safe and well masked in circulation with reduced systemic cleavage compared to its parental ADG116 and masked 'Ipi-probody':

- ADG126 showed ~3X lower median peripheral IFN-γ levels relative to ADG116
- ADG126 showed ~2X lower median peripheral IFN-γ at 10 mpk for ADG126 @ Q3W vs. BMS-986249 (Ipi-probody) @Q4W

This slide contains information from various studies which are not head-to-head comparisons. Data on file.
BMS-986249 (Ipi-probody) data were digitized from poster 740P presented at European Society for Medical Oncology (ESMO) Congress 2022.
Ipi-Probody PK data were digitized from poster 3058 presented at 2020 ASCO Annual Meeting.

ADG126-P001 Study Design

Dose Escalation with Anti-PD-1



Dose Expansion

- MSS CRC free of liver metastasis
- Two different dose schedules of ADG126 are evaluated: 10 mg/kg Q6W and Q3W

Pembrolizumab is used at 200 mg Q3W

- The ADG126 starting dose was at 6 mg/kg Q3W for the combination due to the well tolerated monotherapy safety profile up to 20 mg/kg Q3W, with no DLT or Grade ≥3 TRAEs after repeat dosing in the global ADG126-1001 study

Baseline Characteristics of Patients in DE and EXP

- Results of 46 Pts who participated in study ADG126-P001
- Three dose levels were evaluated in dose escalation phase (N = 11). The cancer types consisted of ovarian (N=1), colorectal (N=6), pancreatic (N=1), endometrial (n=1), cervical (N=1) and neuroendocrine tumor (N=1)
- Two dose schedules of ADG126 10 mg/kg were evaluated in dose expansion phase (N = 35)
- Tumor types were advanced MSS CRC (free of liver metastasis; N = 24) and other cancer types (I/O naïve and experienced; N=11)
- Majority of Pts (74.5%) have what are generally considered immunologically "cold" tumors
- Baseline characteristics of reported patients are summarized in table at right
- Median follow-ups (month) for DE and EXP patients included in this report are 10.9 (8.6-NR) and 6.7 (4.6-NR), respectively

Baseline Characteristics

Characteristics	N=46
Dose Escalation (# of pts)	11
Dose Expansion (# of Pts)	35
Age (Years), Median (Range)	60 (26-75)
Female, n (%)	21 (46%)
Race, n (%)	
Caucasian, n (%)	19 (41%)
Asian, n (%)	23 (50%)
Black or African American, n (%)	1 (2%)
Other, n (%)	3 (7%)
ECOG, n (%)	
0	20 (43%)
1	26 (56%)
Prior treatment regimens ≥3	17 (37%)
Prior immunotherapy, n (%)	6 (13%)

Data cutoff: Nov 30, 2023

Clinical Safety (TRAEs, N = 46)

- Highly manageable safety and tolerability profile; no dose-limiting toxicities
- Most TRAEs are G1 and G2, with no G4/5 TRAEs. A total of 5 Pts developed Grade 3 TRAEs (10.8%).
- Three Pts with TRAEs (G2 pneumonitis, G3 pancreatitis and G2 Diarrhea) led to study discontinuation (6.5%)
- Twelve Pts developed SAEs and 5 are treatment related, which are diarrhea (G2), secondary adrenocortical insufficiency, pancreatitis, asthenia and type 1 diabetes mellitus and hyperglycemia (G3)

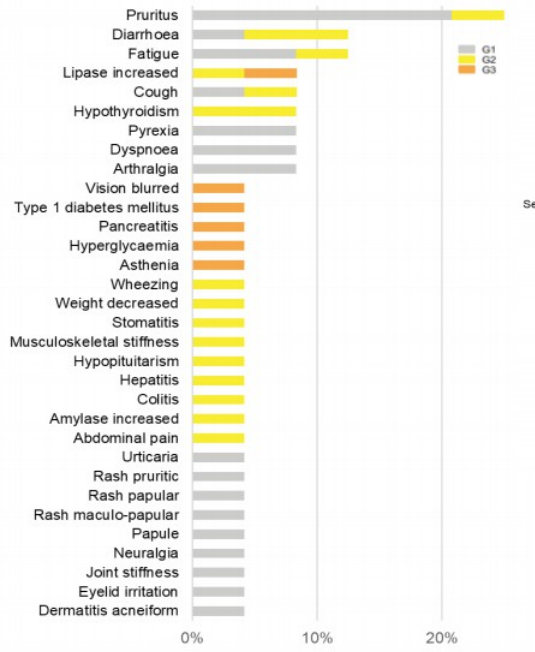
TRAEs By Grade and Dose Level

ADG126 Dose Level	N	All Grades (%)	G1 (%)	G2 (%)	G3 (%)	G4-5 (%)	Discont. Rate
6 mg/kg Q3W	5	3 (60%)	1 (20%)	1 (20%)	1 (20%)	0	20%
10 mg/kg Q6W	17	12 (71%)	3 (18%)	8 (47%)	1 (6%)	0	0
10 mg/kg Q3W	24	16 (67%)	5 (21%)	8 (33%)	3 (13%)	0	8%

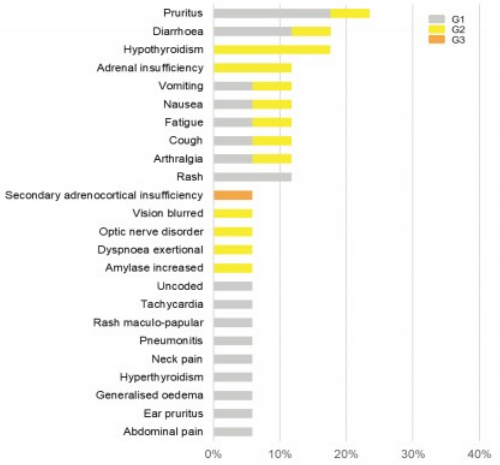
Data cutoff: Nov 30, 2023

Safety ADG126 + Pembrolizumab Combo is Comparable to Pembrolizumab Alone

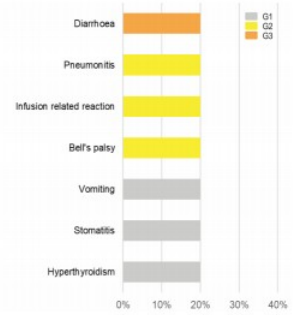
ADG126 10 mg/kg Q3W (N = 24)



ADG126 10 mg/kg Q6W (N = 17)



ADG126 6 mg/kg Q3W (N = 5)

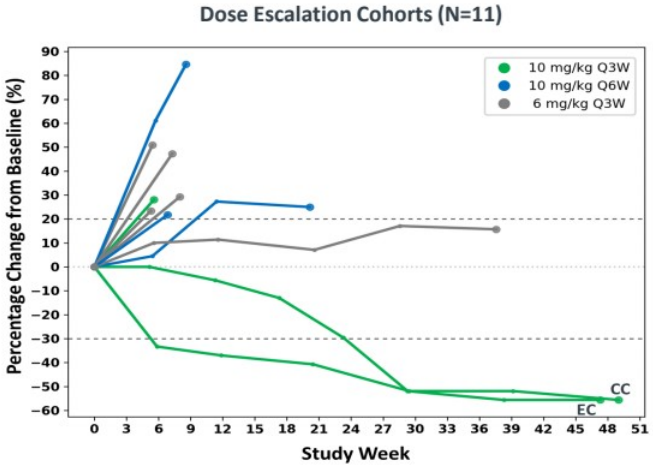


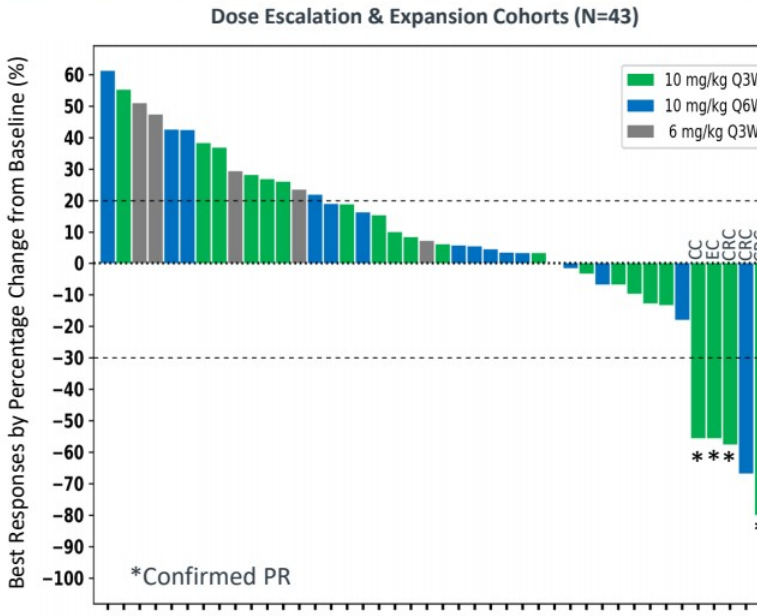
TRAEs by Grade and Dose Level

ADG126 Dose Level	N	All Grades (%)	G1 (%)	G2 (%)	G3 (%)	G4-5 (%)	Discont. Rate
6 mg/kg Q3W	5	3 (60%)	1 (20%)	1 (20%)	1 (20%)	0	20%
10 mg/kg Q6W	17	12 (71%)	3 (18%)	8 (47%)	1 (6%)	0	0
10 mg/kg Q3W	24	16 (67%)	5 (21%)	8 (33%)	3 (13%)	0	8%

Data cutoff: Nov 30, 2023

Efficacy Data of Evaluable Subjects from the Combo Dose Escalation & Expansion Cohorts





- Four of five confirmed PRs are from 10 mg/kg Q3W cohorts

Data cutoff: Nov 30, 2023

Clinical Efficacy of Patients with MSS CRC (Free of Liver Mets) in Dose Expansion

MSS CRC Patients Baseline Characteristics

CRC Patients Characteristics	N=24
Age (Years; median range)	60 (41-75)
Female, n (%)	12 (50%)
Race, n (%)	
Caucasian, n (%)	9 (38%)
Asian, n (%)	15 (62%)
Other	-
ECOG, n (%)	
0	9 (38%)
1	15 (62%)
With peritoneal metastasis, n (%)	8 (33%)
Prior Treatment ≥3	10 (42%)
Prior immunotherapy, n (%)	0

Summary of Response Rate in Evaluable MSS CRC Patients

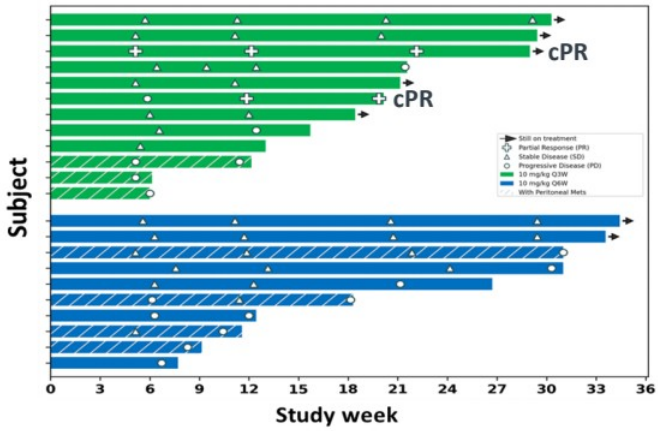
Response Rate of MSS CRC		
ADG126 Dose and subset (N)	**10mpk Q3W** (12)	**10mpk Q3W w/o peritoneal metastasis** (9)
Confirmed ORR, % (95% CI)	**17** (2-48)	**22** (3-60)
BoR, N (%)		
PR	**2** (17)	**2** (22)
SD	**7** (58)	**7** (78)
DCR (CR+PR+SD), % (95% CI)	**75** (43-95)	**100** (66-100)

cPR: confirmed partial response. PFS: Progression-free survival. BoR: Best of Response. DCR: Disease control rate. NR: Not reached

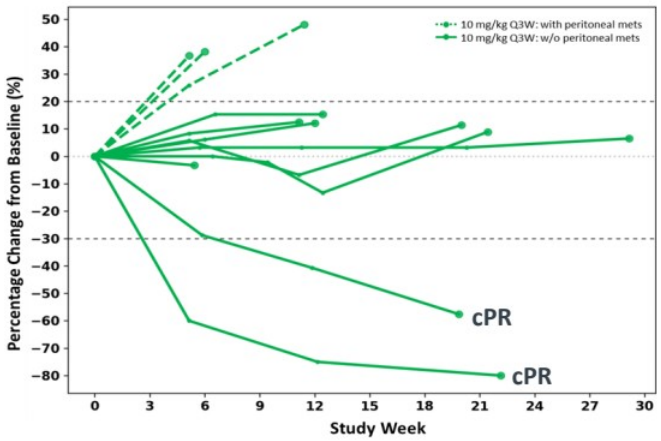
Data cutoff: Nov 30, 2023

Clinical Efficacy of Patients with MSS CRC (Free of Liver Mets) in Dose Expansion

Duration of Treatment of MSS CRC Pts by 10mg/kg Q3W and Q6W of ADG126/pembrolizumab
(N=22 efficacy evaluable pts with at least one CT scan)

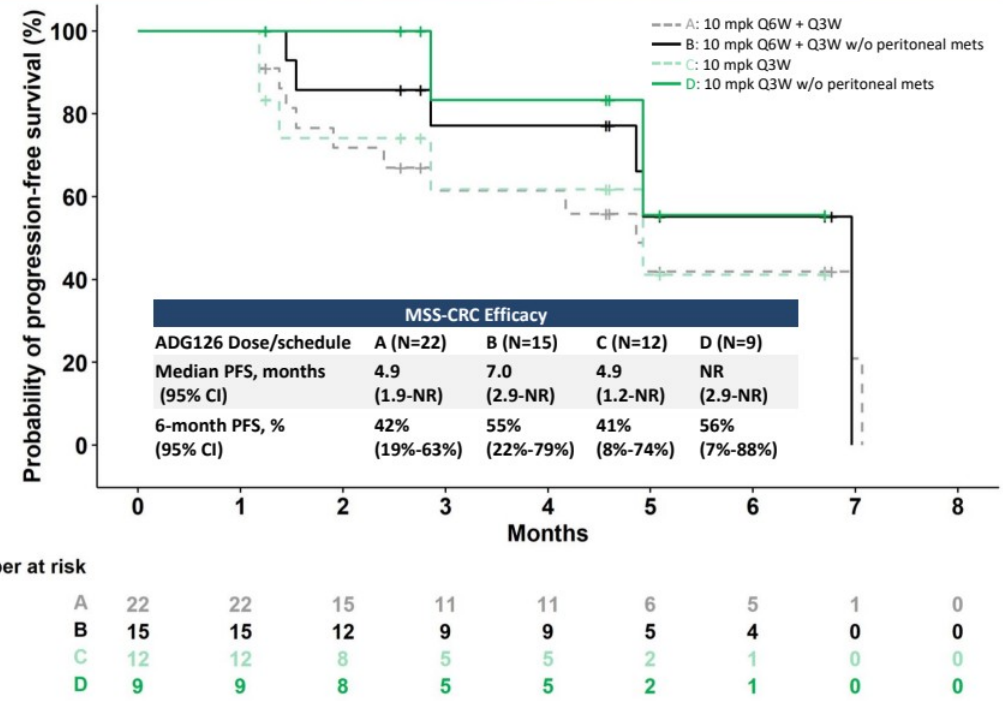


Spider plot of evaluable MSS CRC Pts treated by 10 mg/kg Q3W ADG126/Pembrolizumab (N = 12)



Data cutoff: Nov 30, 2023

PFS Summary of Efficacy in Evaluable MSS-CRC Pts (N=22)



MSS-CRC Efficacy				
ADG126 Dose/schedule	A (N=22)	B (N=15)	C (N=12)	D (N=9)
Median PFS, months (95% CI)	4.9 (1.9-NR)	7.0 (2.9-NR)	4.9 (1.2-NR)	NR (2.9-NR)
6-month PFS, % (95% CI)	42% (19%-63%)	55% (22%-79%)	41% (8%-74%)	56% (7%-88%)

Number at risk

A	22	22	15	11	11	6	5	1	0
B	15	15	12	9	9	5	4	0	0
C	12	12	8	5	5	2	1	0	0
D	9	9	8	5	5	2	1	0	0

Data cutoff: Nov 30, 2023

Case Study : ADG126 10 mpk Q3W + Pembro 3L MSS CRC Patient: Confirmed PR and Reduced Liver Lesions

Tumor Type:

Female, 66 years old

Advanced rectal adenocarcinoma stage IV with lymph and lung metastasis

- KRAS WT, BRAF normal, MSS, TMB 11.07muts/mb

Prior Therapies:

Previously received 2 lines of therapies:

- FOLFIRI + Vectibix
- Clinical trial G1290 with Rivoceranib + SOC Lonsurf

Dose Regimen:

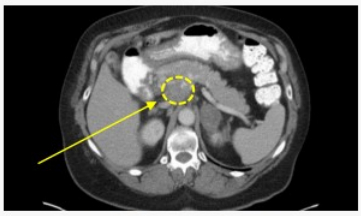
ADG126 **10 mg/kg Q3W** + Pembro 200 mg Q3W (5 cycles)

Case Study Continued: ADG126 10 mpk Q3W + Pembro 3L MSS CRC Patient: Confirmed PR and Reduced Liver Lesions

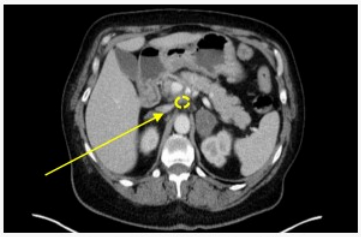
	Lesion #	Location	Baseline	Week 6	Week 12	Week 21
Target lesion (mm)	TL#1	Right lung	14 mm	10	8	8
	TL#2	Right lung	8 mm	8	6	0
	TL#3	Lymph node	22 mm	14	13	9
	TL#4	Lymph node	15 mm	10	8	8
	Total		59 mm	42 (-29%)	35 (-41%)	25 (-58%)
Non target lesions			Present	Present	Present	Present
New lesion (mm)	#1	Liver		16	8	0
	#2	Liver		12	7	6
	#3	Other		9	3	0
	Total			37	18 (-51%)	6 (-84%)
Overall response				uPD	PR	PR

*Based on iRECIST assessment

The treatment-induced change in the perihepatic lymph node



May 15, 2023 (Baseline)



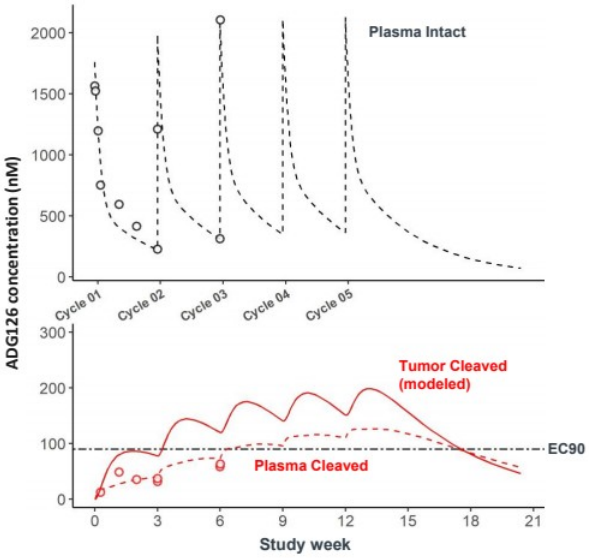
Oct 16, 2023 (week 21)

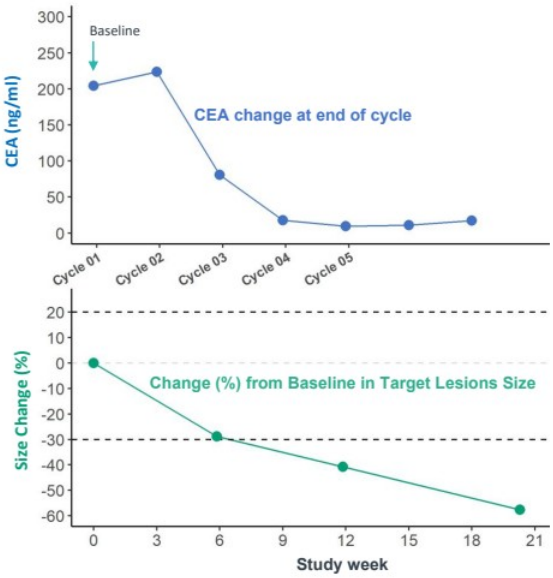
Courtesy of Dr Tammy Lamb, Florida Cancer Specialists

Data cutoff: Nov 30, 2023

Case Study Continued- CEA Decrease and Tumor Accumulation Over Time

ADG126 10 mg/kg Q3W plus Pembro





Data cutoff: Nov 30, 2023

ADG126/Pembrolizumab Demonstrates a Superior Safety Profile with Similar ORR but longe PFS to Bot/Bal in MSS CRC

	Safety (TRAEs)		
	Patients Dosed	≥ G3 TRAE	Discontinuation Rate
ADG126 10 mg/kg Q3W + Pembrolizumab 200 mg Q3W	24#	13%+	8%
Botensilimab 1 or 2 mg/kg Q6W + Balstilimab 3 mpk Q2W*	101	39%	33%

	Efficacy				
	Patient Group	Evaluable subjects	ORR	DCR	PFS m (95%
ADG126 10 mg/kg Q3W + Pembrolizumab 200 mg Q3W	MSS CRC w/o liver & peritoneal Mets	9	22%	100%	NE (2.9-
	MSS CRC w/o liver Mets	12	17%	75%	4.9 (1.2-
Botensilimab 1 or 2 mg/kg Q6W + Balstilimab 3 mpk Q2W*	MSS CRC w/o liver Mets	69	23%	80%	4.1 (2.8-

+No G4/5 TRAEs
Two patients used infliximab for the treatment-related diarrhea/colitis
Comparison based on publicly available information and represents a non-head-to-head summary comparison. Results of a -head-to-head comparison may different significantly.

#For the safety evaluation, the patients of other cancer types are included in addition to those with MSS CRC free of liver Mets
*Bullock AJ et al., Results from an expanded phase 1 trial of botensilimab, a multifunctional anti-CTLA4, plus balstilimab for metastatic heavily pretreated MSS CRC ESMO GI 2023
^Combined dataset for those with and without liver Mets, El-Khoueiry AB et al., Results from a phase 1a/ab study of botensilimab (BOT), a novel innate/adaptive immune activator, plus balstilimab (BAL; anti-PD-1 antibody) in metastatic heavily pretreated MSS CRC ASCO GI 2023

Conclusions

- The masked anti-CTLA-4 SAFEbody ADG126 (muzastotug) is designed to widen the therapeutic index by targeting a unique epitope of CTLA-4, precision masking for enhanced intra-tumoral Treg depletion.
- ADG126 administered at up to 10 mg/kg Q3W with repeat dosing in combination with pembrolizumab is well tolerated with 13% G3 TRAEs, 8% discontinuation rate and no G4/5 TRAEs or DLT.
- In dose escalation, 2 confirmed PR were observed among 3 subjects treated with 10 mg/kg Q3W ADG126/Pembro, which triggered dose expansion at this dose level.
- In dose expansion, 10 mg/kg Q3W ADG126/Pembro treatment in 12 subjects with MSS CRC (9 w/out peritoneal metastasis) resulted in 2 confirmed PRs, and reduction of new liver lesions. This triggered further expansion into Stage 2 of the Simon's 2-stage design at this dose level.
- The favorable safety profile of ADG126/Pembro allows for continued treatment with repeated dosing, resulting in a long PFS (≥ 7 mons), especially in MSS CRC patients without liver and peritoneal metastasis.
- These promising data support further evaluation of this potential best-in-class anti-CTLA-4 antibody ADG126 (muzastotug) in combination with pembrolizumab in MSS CRC.

2024 Milestones

- Data from ongoing Ph 1b/2 clinical trial of masked, anti-CTLA-4 SAFEbody ADG126 in combination dose with pembrolizumab, including dose expansion cohorts:
  - Follow up of Part 1 evaluable patients at 10 mg/kg Q3W (n= 12) and 10 mg/kg Q6W (n=10)
  - Additional patients from Part 2 at 10 mg/kg Q3W (n=12)
- Evaluation of 20 mg/kg loading doses in combination with pembrolizumab for Project Optimus requirements, including safety data with repeat doses and dose expansion in MSS CRC (n~10)
- Data from additional patients in China for ADG126 in combination with pembrolizumab in MSS CRC (n≥10)
- Additional technology licensing agreement(s) and/or milestone(s)