

American Society of Clinical Oncology Meeting Review

June 3, 2019

Forward-looking statements

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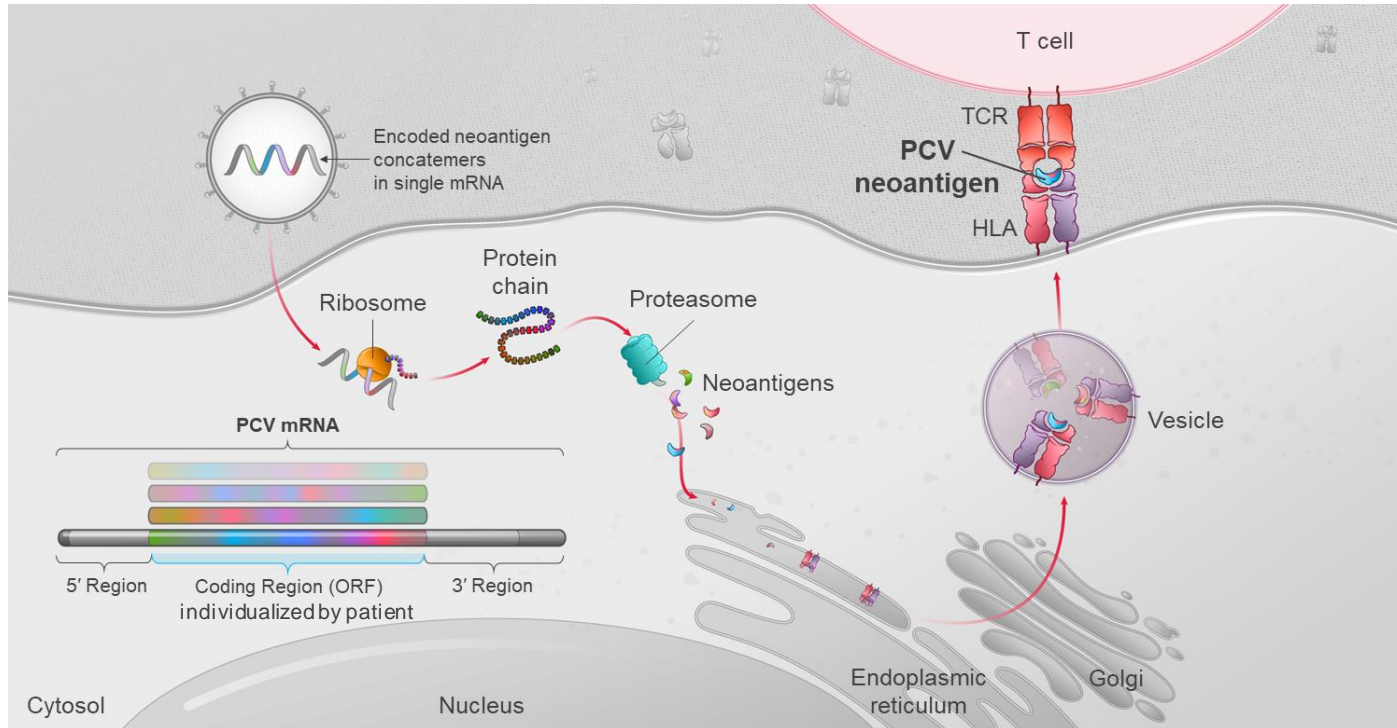
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ASCO 2019

An Interim Analysis of a Phase 1, Open-Label, Multicenter Study to Assess the Safety, Tolerability, and Immunogenicity of mRNA-4157 Alone in Subjects With Resected Solid Tumors and in Combination With Pembrolizumab in Subjects With Unresectable Solid Tumors (Keynote-603)

Cut off date for data presented: May 10, 2019

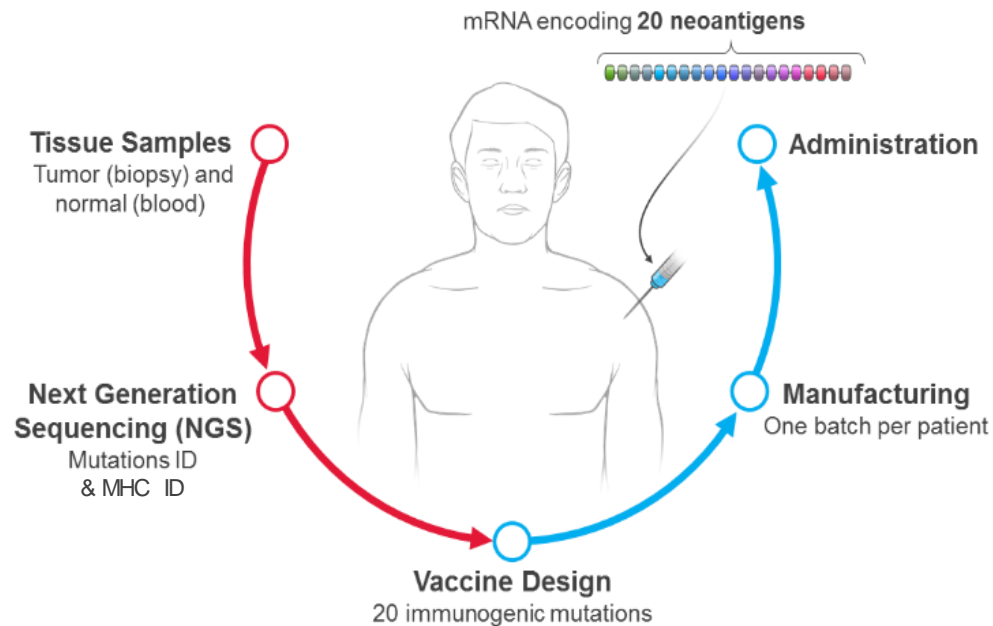
Background : The Personalized Neoantigen Approach



- T-cell targeting of mutation-derived epitopes (neoantigens) has been demonstrated to drive anti-tumor responses
- Immunizing patients against such neoantigens in combination with a checkpoint inhibitor (CPI) may elicit greater anti-tumor responses than CPI alone
- Mutations are rarely shared between patients, thus requiring a personalized approach to vaccine design

Personalized Cancer Vaccine: mRNA-4157

Process Background



- mRNA-4157 is a personalized neoantigen cancer vaccine encoding up to 20 neoantigens: (from April 2019 forward patients started to receive a vaccine encoding up to 34 neoantigens)
- Individually designed and manufactured for each patient at our Norwood facility
- Selected using a proprietary algorithm based upon each patient's HLA type and tumor mutanome from whole exome DNA and RNA sequencing from tumor and blood samples
- Delivered intramuscularly in a proprietary lipid nanoparticle (LNP) formulation
- Typical turnaround time of ~50-60 days from biopsy to injection

Study Design*

Part A (Adjuvant patients): Monotherapy mRNA4157	0.04 mg n=3	0.13 mg n=6	0.39 mg n=3	1.0 mg n=3
Part B (Metastatic patients): mRNA4157 + pembrolizumab	0.04 mg n=3	0.13 mg n=4	0.39 mg n=7	1.0 mg n=5

Histologies in part A and B:

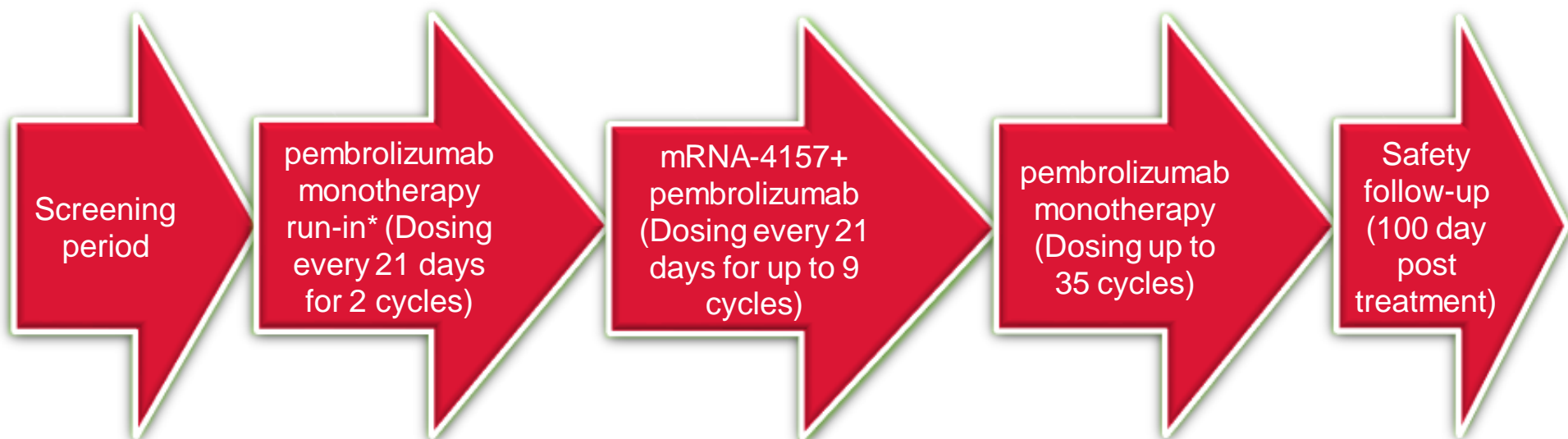
- NSCLC
- SCLC
- Cutaneous melanoma
- HPV negative HNSCC
- Bladder urothelial carcinoma
- MSI high malignancies
- TMB high malignancies

Objectives:

- Safety and tolerability of mRNA-4157 monotherapy and in combination with pembrolizumab
- Immunogenicity: Neoantigen specific T-cell responses
- Clinical activity

* Study design consists of Part A, B, C, and D. Part C, D of trial enrolling

Study Design



*Part A patients are adjuvant patients receiving mRNA-4157 monotherapy. Pembrolizumab run-in and pembrolizumab monotherapy period does not apply

Patient Demographics

	Part A: 13	Part B: 23
Age(y)		
Range:	52-85	45-88
Median:	67	64
Sex		
Male:	6	13
Female:	7	10
Race:		
Caucasian	13	19
Black	-	1
Asian	-	1

Part B Prior Therapies	N=23 (%)
Number of patients received at least 1 prior therapy	22 (95.6)
Number of patients received prior checkpoint inhibitors	15 (65.2)
Number of Prior Therapies	
0	1 (4.3)
1	3 (13.0)
2	6 (26.1)
3	2 (8.7)
3+	11 (47.8)

Histologies	N =36
Part A	13
Melanoma	3
MSI HIGH/MMR Deficient	
• Colorectal Carcinoma	2
Non-small Cell Lung Cancer	8
Part B	23
TMB High	
• Metastatic squamous cell cancer of the skin	1
Bladder Urothelial Carcinoma	5
HNSCC	2
Melanoma	1
MSI HIGH/MMR Deficient	
• Colorectal Carcinoma	2
• Metastatic Castrate Resistant Prostate Carcinoma	1
• Endometrial Carcinoma	1
Non-small Cell Lung Cancer	8
Small Cell Lung Cancer	2

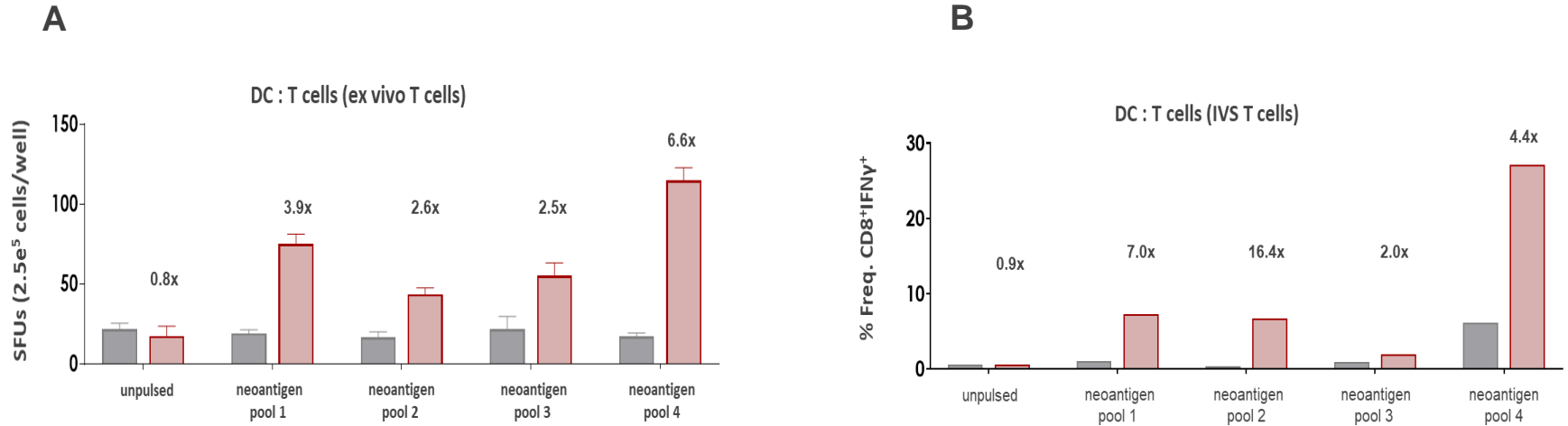
Safety Data

Related Adverse Event*	Grade 2	Grade 3
Part A: mRNA-4157 monotherapy	4	0
LEFT ARM PAIN	1	-
COLITIS	1	-
FATIGUE	1	-
MYALGIAS	1	-
Part B: pembrolizumab monotherapy	3	4
DIARRHEA	-	1
AMYLASE INCREASE	-	1
LIPASE INCREASE	-	1
ELEVATED AST	1	-
ANEMIA	1	-
WORSENERD DYS/PNEA	1	-
ELEVATED GGT	-	1
Part B: mRNA-4157 & pembrolizumab	0	0
No mRNA-4157 related grade 3/4 AEs were reported		

* Related AEs of at least grade 2 (highest grade reported with mRNA-4157)

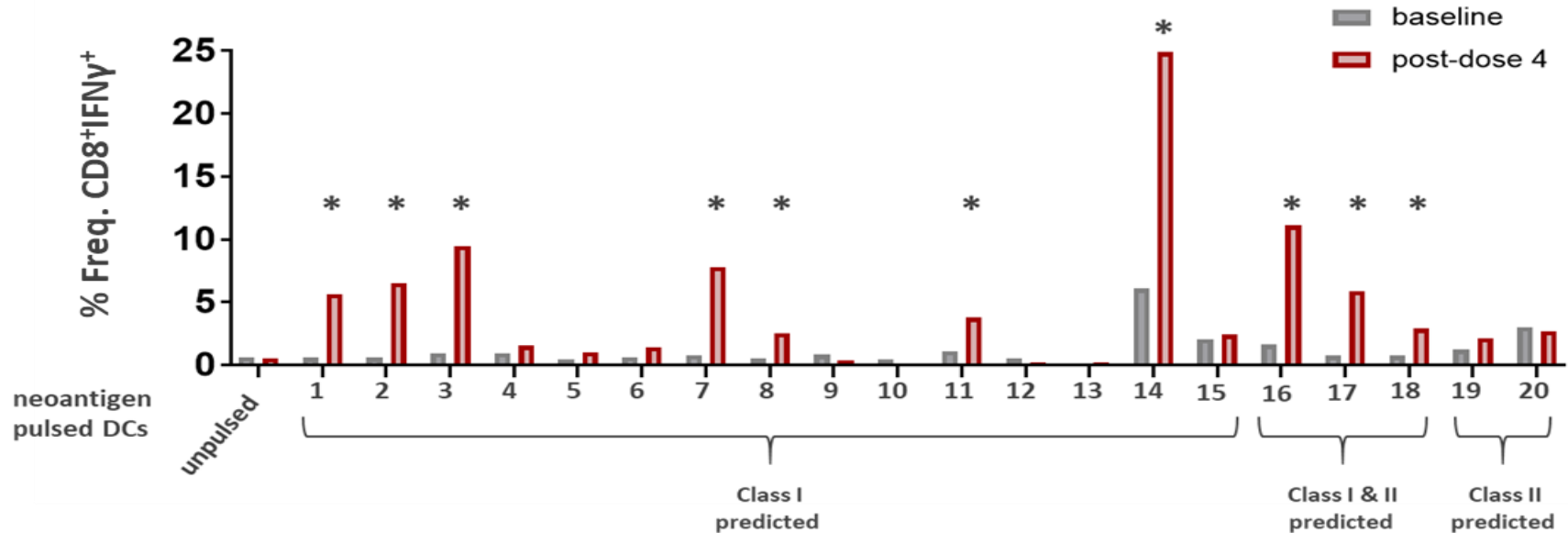
Patient 40033 (NSCLC) Neoantigen T-Cell Response Data

First adjuvant patient dosed with monotherapy mRNA-4157 at 1mg dose



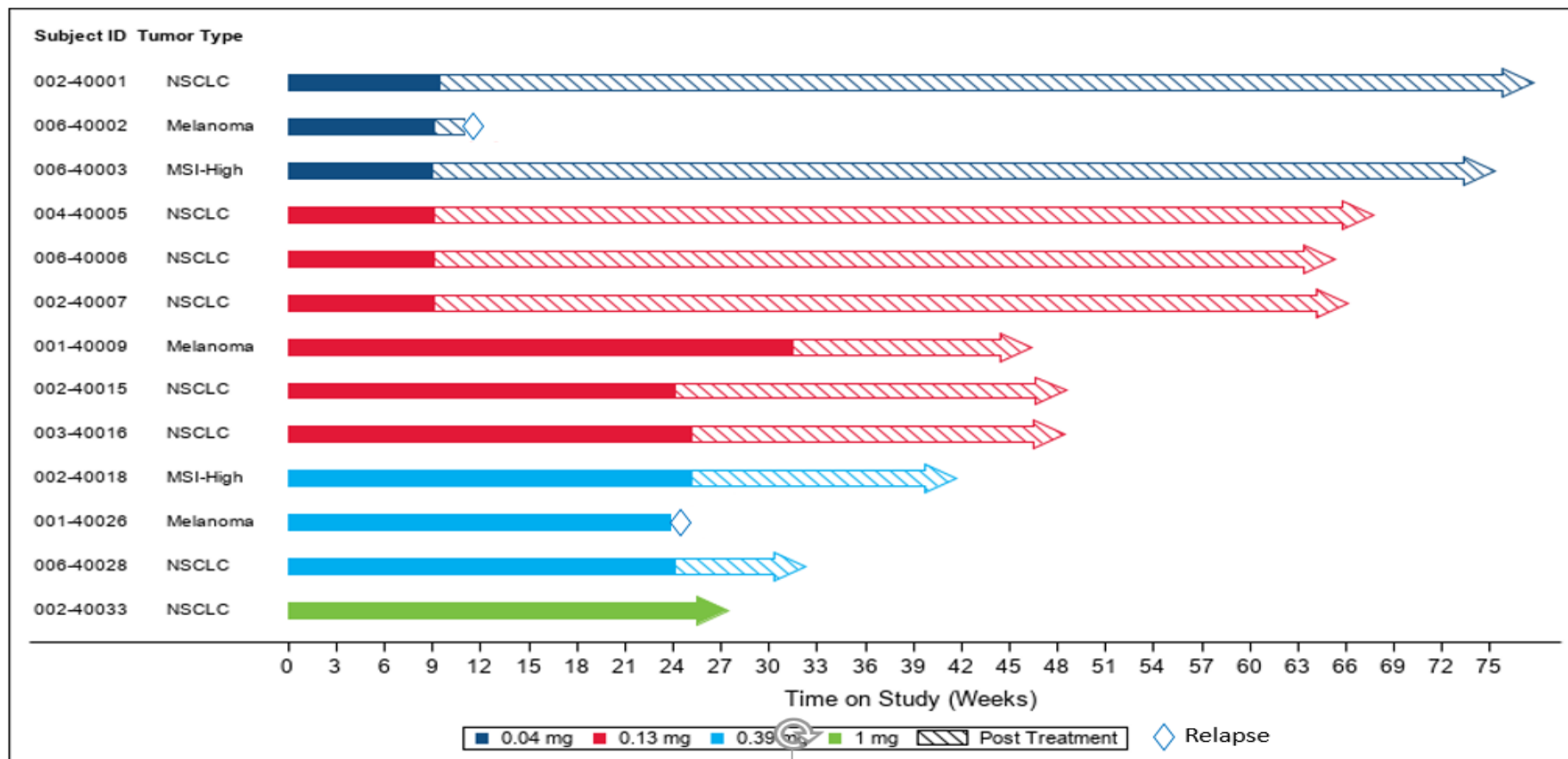
- Patient was dosed with 1mg of vaccine monotherapy and underwent apheresis at baseline and 7d post 4th dose.
- Increases in *ex-vivo* (unexpanded) T-cell responses were detected against all neoantigen pulsed DC pools post vaccination (A).
- Increases in *in-vitro* stimulated (IVS, expanded) T-cell responses were detected against all neoantigen pulsed DCs pools post vaccination (B).

Greater than 3x CD8 T-Cell Responses Detected Post-Vaccine Dose 4 to 55% of Predicted Class I Neoantigens



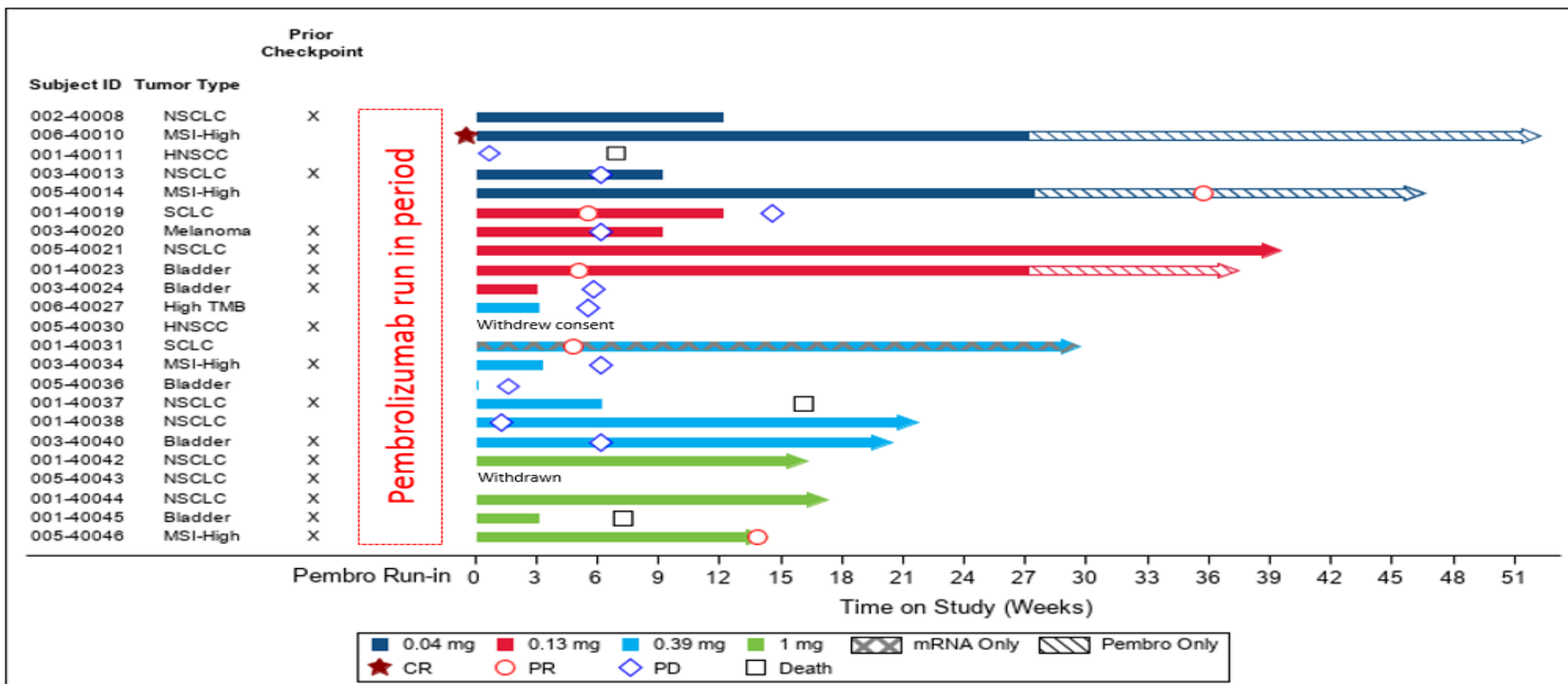
- CD8 T cell responses to individual neoantigens were measured in in vitro stimulated (IVS, expanded) T cells
- Flow cytometry plots show increases in % freq. of CD8 cells producing IFN γ 7d post 4th vaccine dose to multiple neoantigens
- Greater than 3x (*in summary graph) increases in neoantigen specific CD8 T-cells were detected post vaccination against 10 out of 18 class I targeted neoantigens included in patient 40033 vaccine
- All positive CD8 T-cell responses post vaccination were to neoantigens with high predicted binding affinity of < 500 nm.

Part A: Adjuvant Patients Receiving mRNA-4157 Monotherapy



- 13 adjuvant patients have been treated with mRNA-4157
- 13 patients have completed full course of vaccination per protocol
- 11 patients remain disease free up to 72 weeks on study

Part B: Metastatic Patients Receiving mRNA-4157/Pembrolizumab Combination

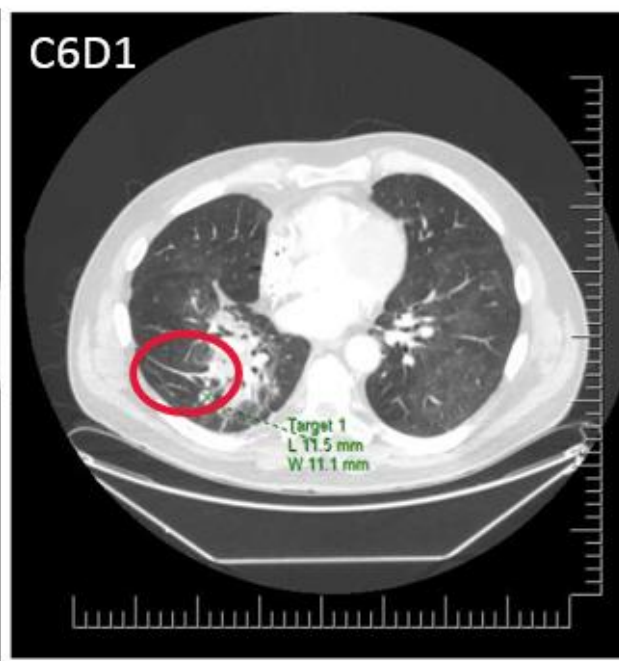
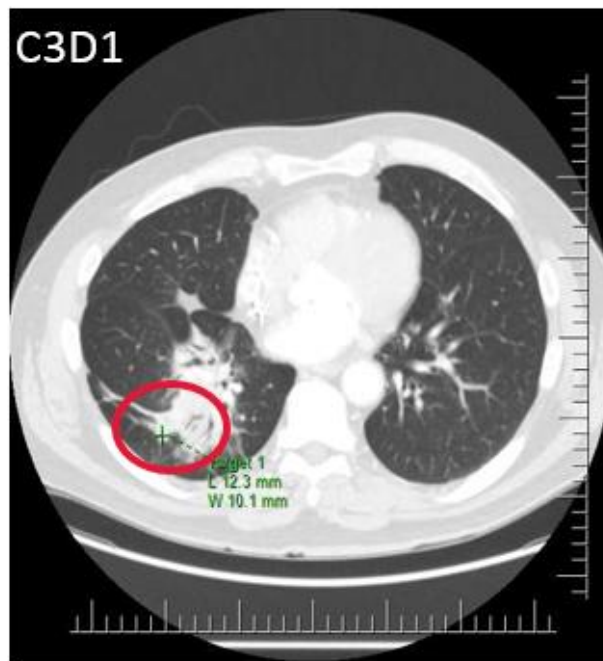
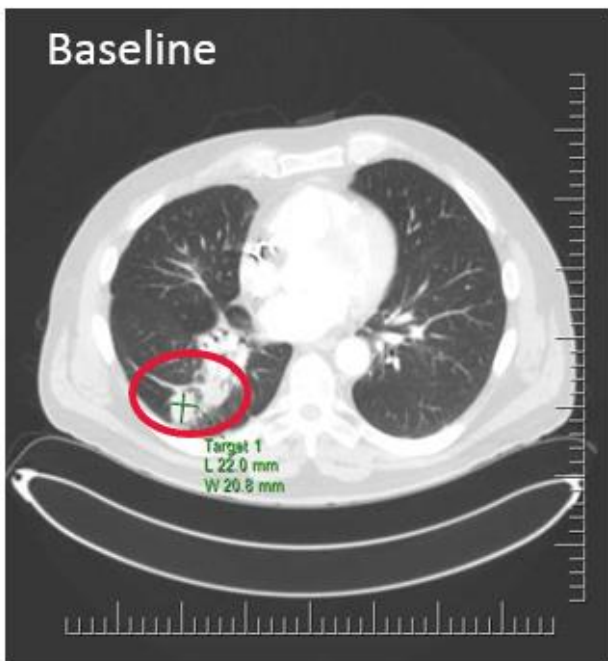


- 20 out of 23 advanced/metastatic patients have been treated with mRNA-4157/pembrolizumab combination.
- 1 patient with MSI-High CRC had a CR on pembrolizumab monotherapy prior to vaccination
- 5 patients had a PR including 2 patients who have progressed with prior checkpoint inhibitor therapy, patient 40031 received 1 dose of pembrolizumab and continued with monotherapy mRNA-4157
- 7 patients had stable disease
- 10 patients remain on study treatment as of 10-May-2019, includes patient 40038 deemed a pseudoprogressor and patient 40040 who had a new lesion which improved at subsequent follow-up. Both patients remain on study
- Clinical responses seen across all doses

Best Overall Response

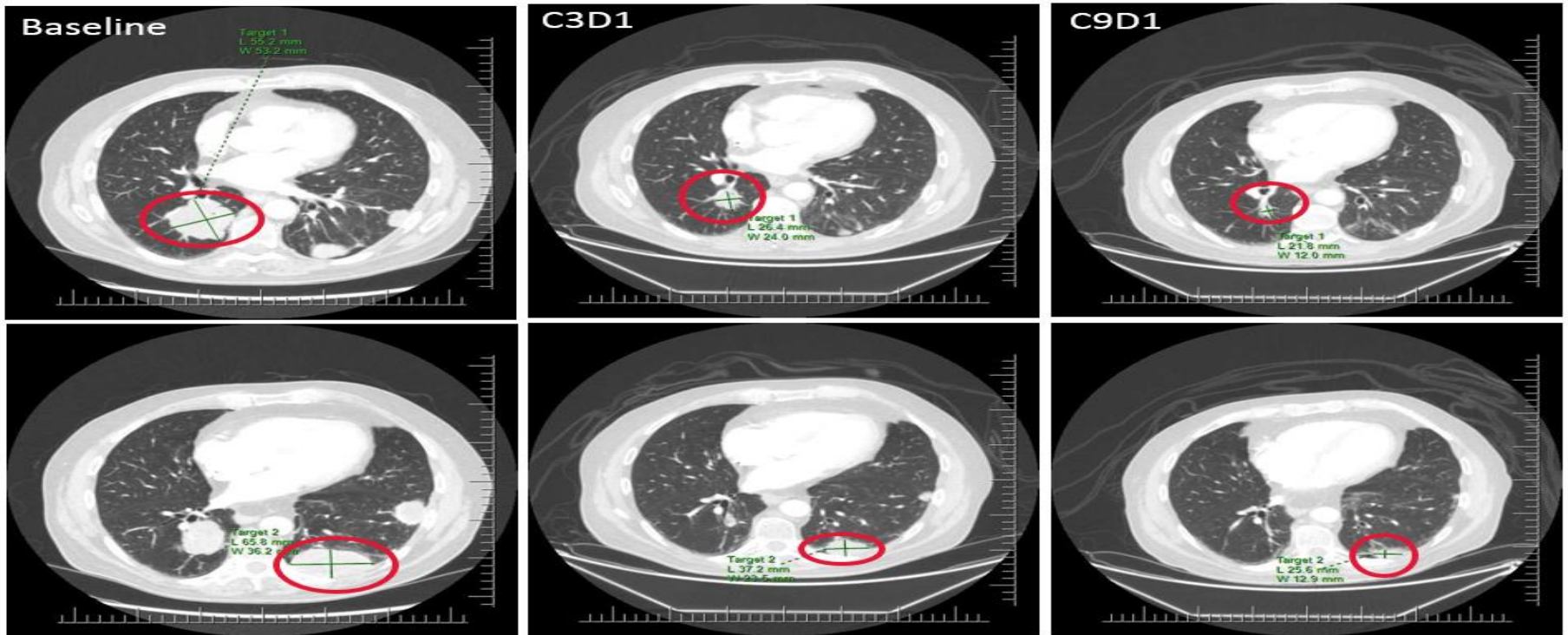
Responses in patients receiving combination	Total (N=20)
Best Overall Response	
Complete Response (CR)	1
Partial Response (PR)	5
Stable Disease (SD)	6
Progressive Disease (PD)	8

Patient 40019 - Small Cell Lung Carcinoma



- Small cell lung cancer patient
- Previously treated with chemoradiation and prophylactic cranial irradiation
- After 2 cycles of monotherapy pembrolizumab and 2 cycles of mRNA-4157 (0.13mg)/pembrolizumab combination, patient had a partial response (PR)
- The patient had progressive disease (PD) at subsequent evaluation due to enlargement of a non-biopsied lesion

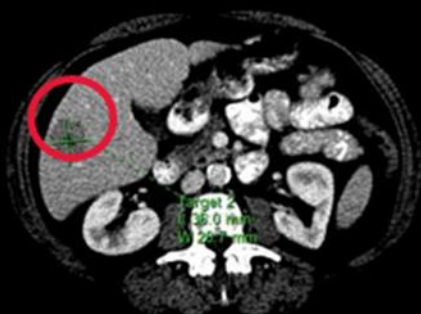
Patient 40023 – Bladder Carcinoma



- Bladder urothelial carcinoma patient
- Previously treated with radical cystoprostatectomy, cisplatin/gemcitabine, HRS7-SN38, four cycles of atezolizumab, and vinorelbine along with frontal lobe resection with radical for brain metastasis
- After 2 cycles of monotherapy pembrolizumab and 2 cycles of mRN-4157 (0.13mg)/pembrolizumab combination patient had a partial response (PR) and has continued to improve on study

Patient 40031 - Small Cell Lung Carcinoma

Baseline



C3D1



C9D1



- Small cell lung cancer patient
- Previously treated with cisplatin/etoposide and doxorubicin/lurbinectedin
- After 1 cycle of pembrolizumab run-in, patient experienced an irAE which led to treatment with monotherapy mRNA-4157 (0.39mg)
- Patient had a partial response (PR) at first post-baseline scan and remains on the study with a partial response.

Conclusions

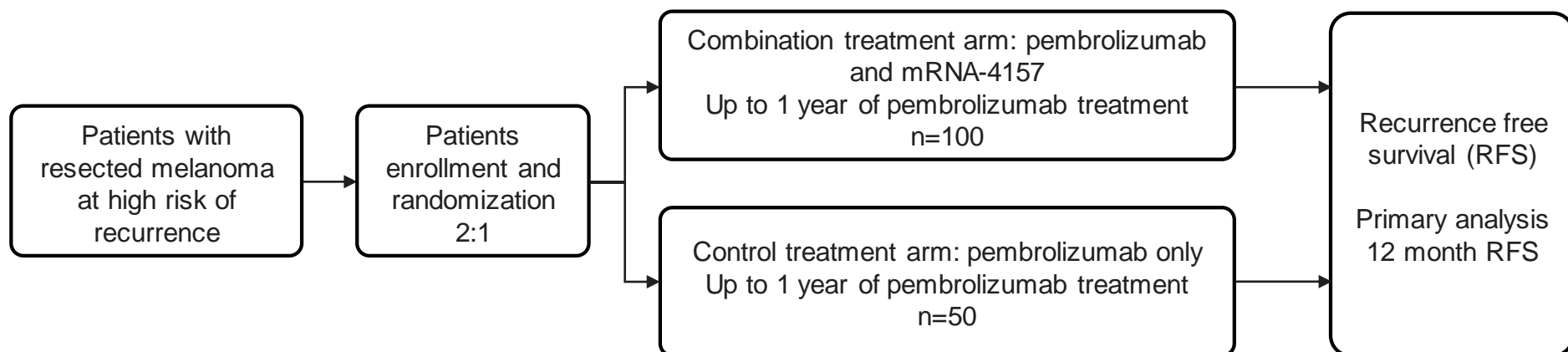
- mRNA-4157 is well tolerated at all dose levels studied with no DLTs reported
- No mRNA-4157 related grade 3/4 AE or SAE was reported
- Neoantigen specific CD8 T-cell responses were detected in 10 out of 18 class I neoantigens in patient 40033, the first patient dosed at 1 mg who underwent apheresis. 100% of positive CD8 T-cell responses post vaccination were to neoantigens with a high predicted binding affinity of <500 nm
- Safety, tolerability and immunogenicity data supports the advancement of mRNA-4157 to phase 2 at the 1 mg dose
- Clinical responses have been seen in 6 out of 20 patients treated with mRNA-4157/pembrolizumab combination. Of these 6 patients, 2 responses have been seen in patients previously treated with PD-(L)1 inhibitor.

Anticipated Clinical Next Steps

- Randomized Phase 2, PCV + pembrolizumab vs. pembrolizumab alone in resected melanoma at high risk of recurrence

Key Objectives

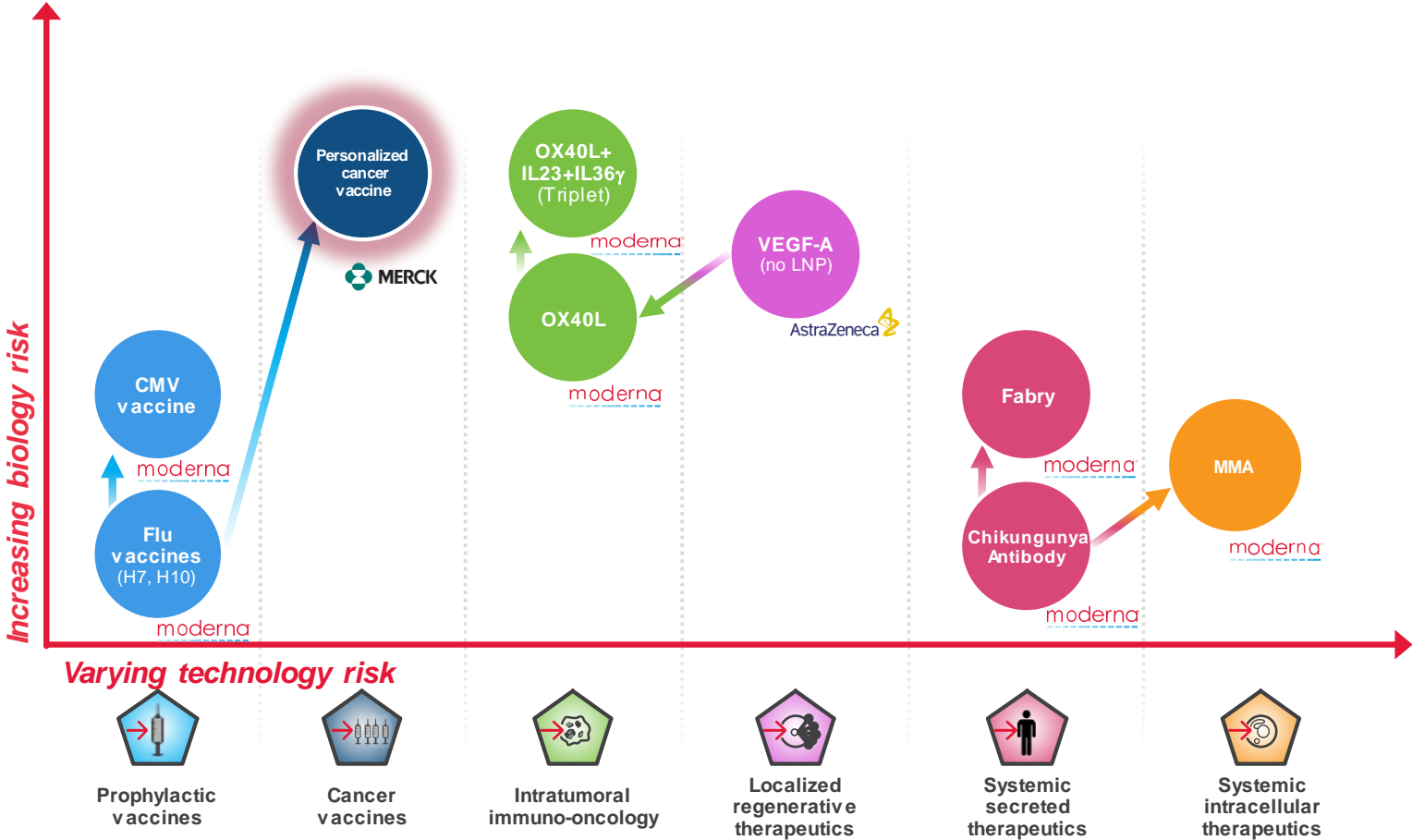
- Assess whether postoperative adjuvant therapy with mRNA-4157 and pembrolizumab improves recurrence free survival compared to pembrolizumab only in patients with complete resection of cutaneous melanoma at high risk of recurrence
- Primary endpoint: recurrence free survival at 12 months



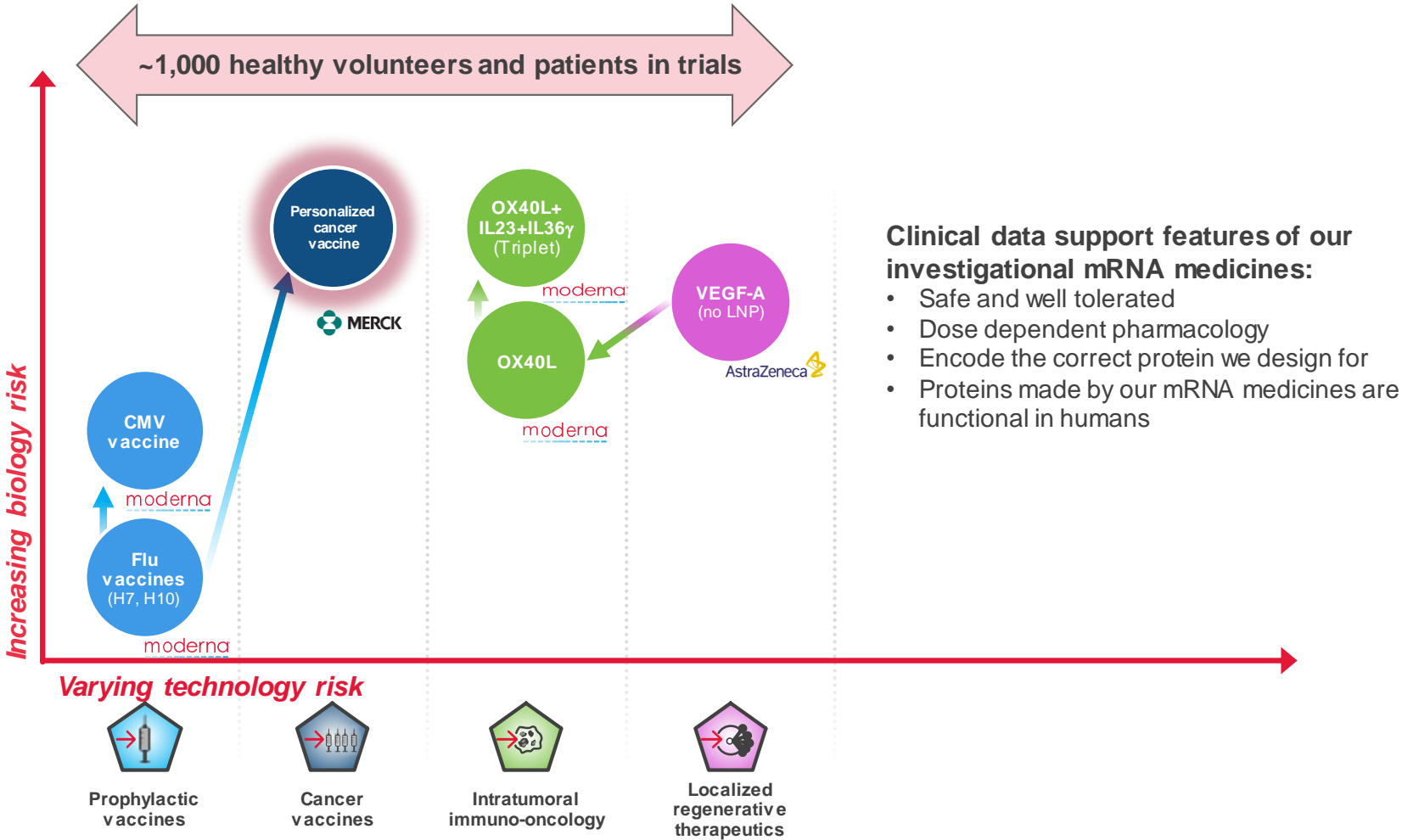
Closing Remarks

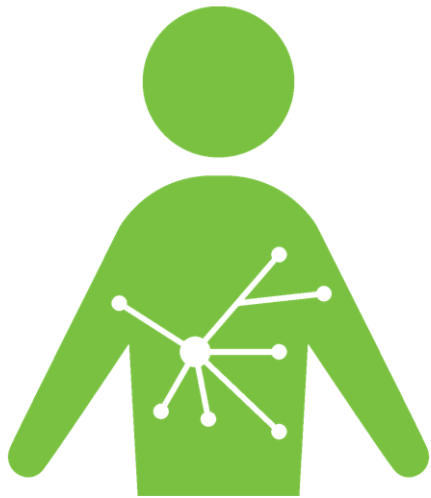
Stephane Bancel, CEO

Interim Analysis of Personalized Cancer Vaccine Phase 1 Presented Saturday June 1, 2019 at ASCO



Personalized Cancer Vaccine Interim Phase 1 Data Strengthens Our Mosaic of Human Data in the First 4 Modalities





Our Mission

To deliver on the promise of mRNA science to create a new generation of transformative medicines for patients.