Personalized cancer vaccine (PCV) (mRNA-4157)

Last program update: October 29, 2020

Modality	ID #	Program *Indication*	Preclinical development	Phase 1	Phase 2	Phase 3 and commercial	Moderna rights
Cancer vaccines	**mRNA-4157**	Personalized cancer Vaccine (PCV)					50-50 global profit sharing with Merck
	mRNA-5671/ Merck V941	KRAS vaccine, CRC, NSCLC, pancreatic cancer					50-50 global profit sharing with Merck

PCV (mRNA-4157) Phase 1 and Phase 2 studies ongoing

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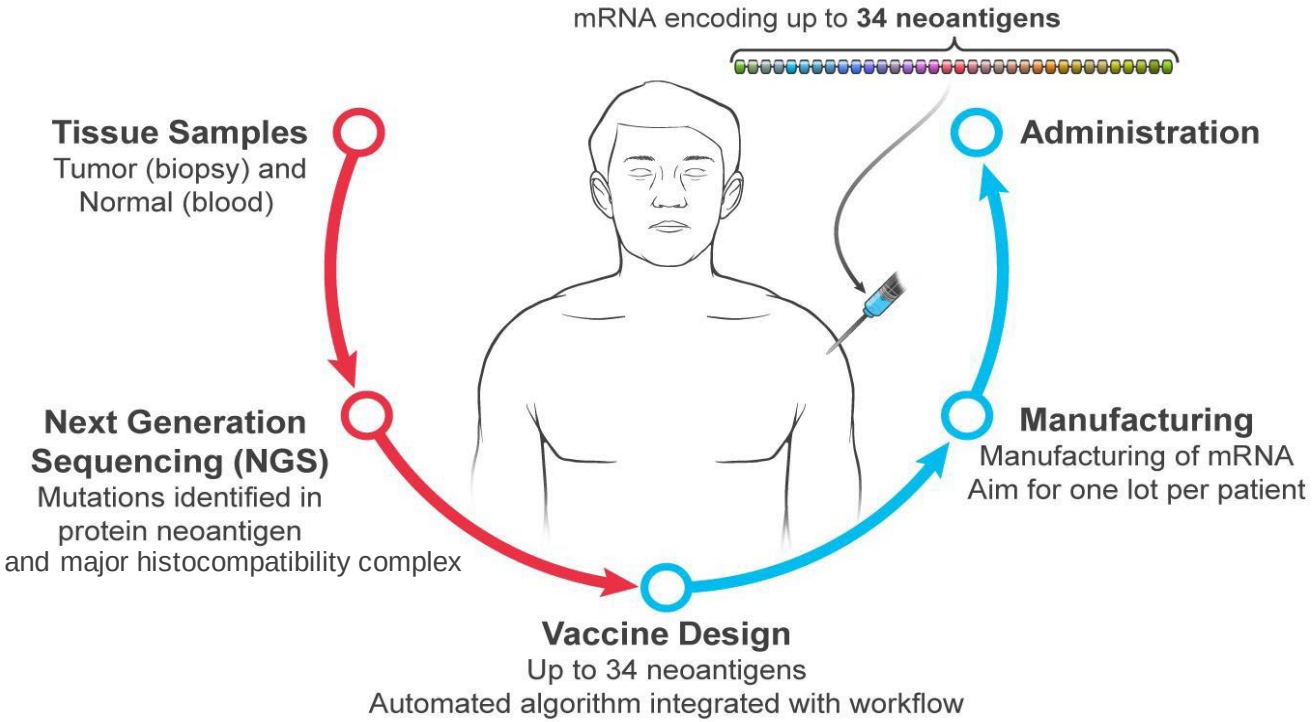
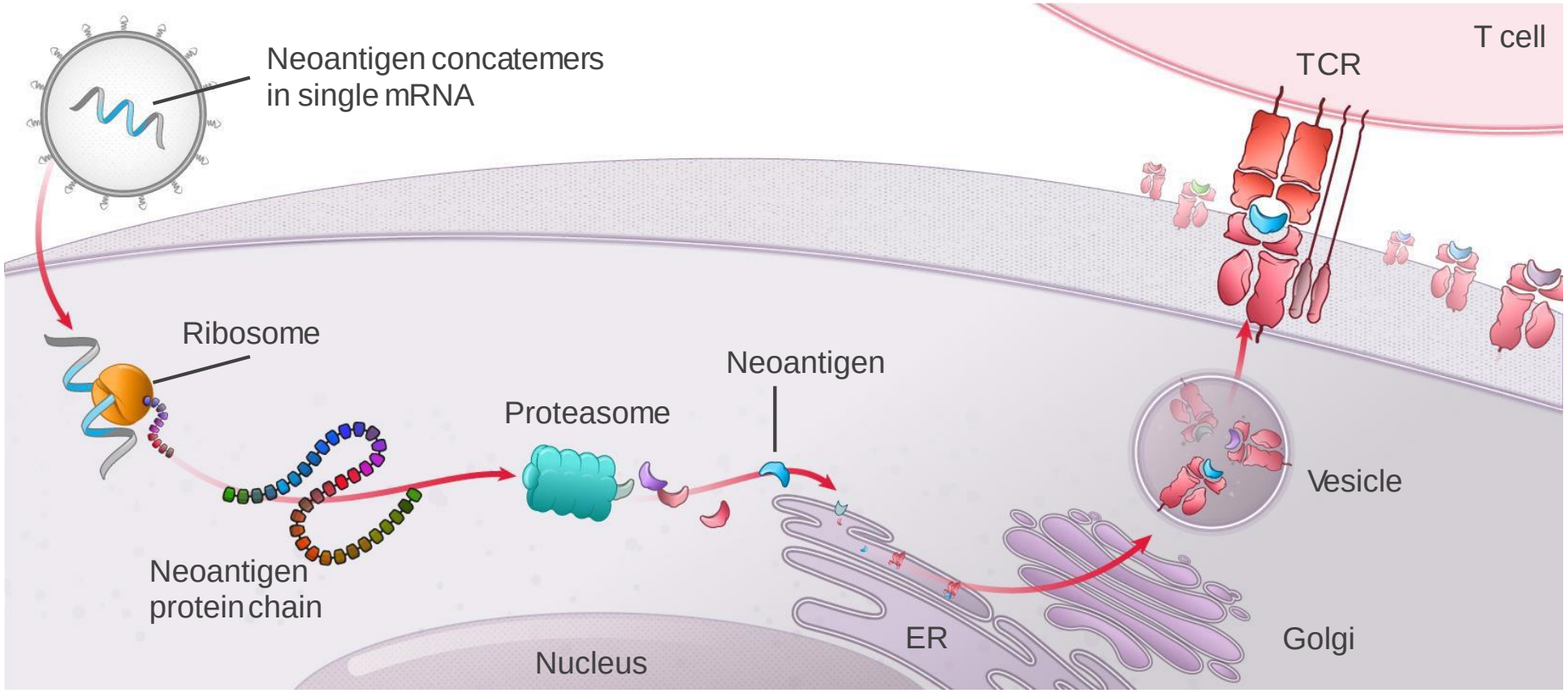
Personalized cancer vaccine (mRNA-4157)

Designed to target an individual patient's unique tumor mutations



- First patient dosed in November 2017
- Partnered with Merck (Keytruda combo)
- Vaccine process change implemented to increase number of neoantigens included in each vaccine to a maximum of 34

Moderna's mRNA vaccines elicit Tcells required for curative cancer therapy



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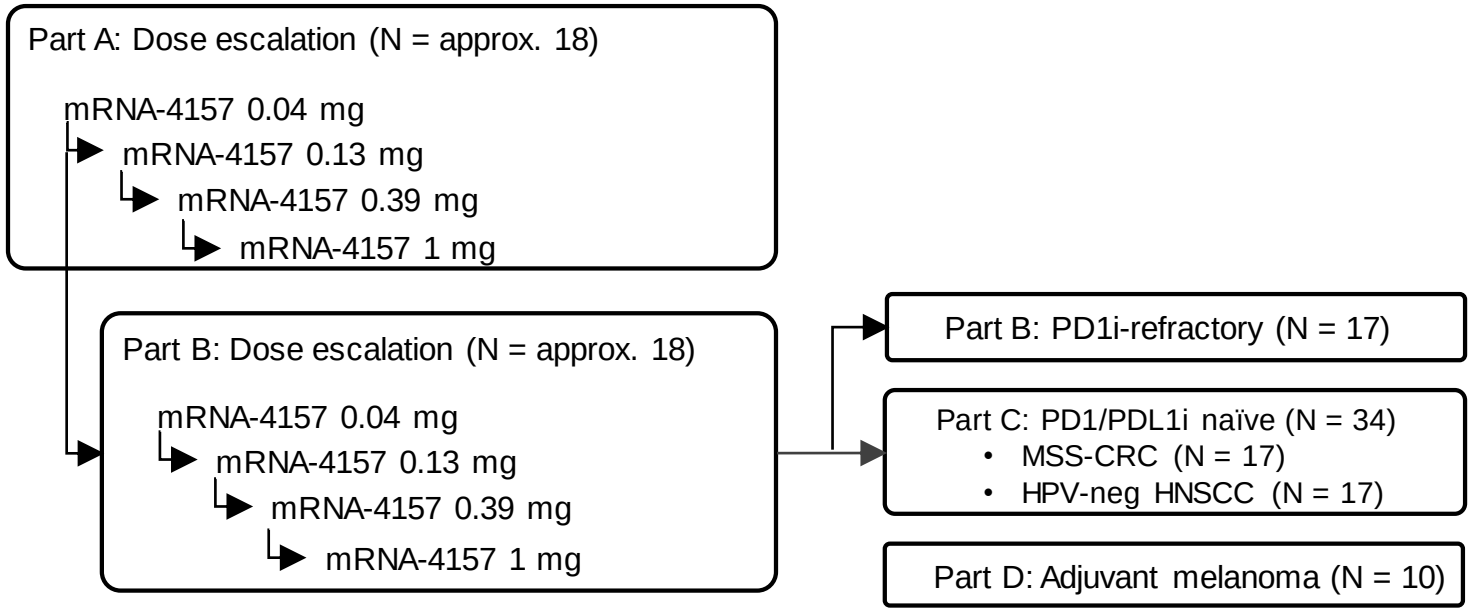
Personalized cancer vaccine (mRNA-4157)

Phase 1 study ongoing

Key Objectives

- Part A — To assess the safety and tolerability of mRNA-4157 monotherapy in subjects with resected solid tumors, including an apheresis cohort
- Parts B, C and D — To assess the safety, tolerability, and recommended Phase 2 dose of mRNA-4157 administered in combination with pembrolizumab
- Part D — To assess the immunogenicity of mRNA-4157 with pembrolizumab from apheresis samples in certain subjects

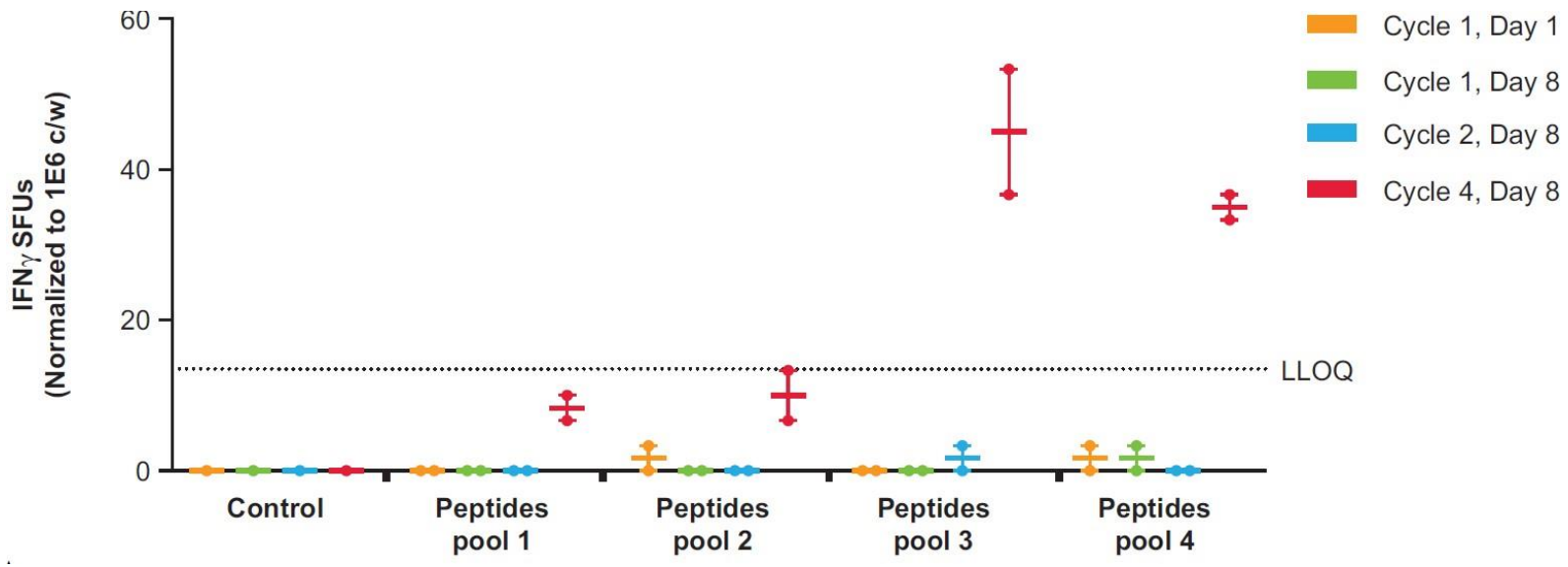


Personalized cancer vaccine (mRNA-4157)

Early Phase 1 data shows antigen-specific Tcell response

Melanoma
Part A (mRNA-4157 monotherapy)
0.13 mg dose

First patient with melanoma treated at the 0.13 mg dose level has shown an induction of mutation-specific T cells after the 4th cycle (week 12), as measured by ELISPOT assay



Data as of November 9, 2018

Personalized cancer vaccine (mRNA-4157)

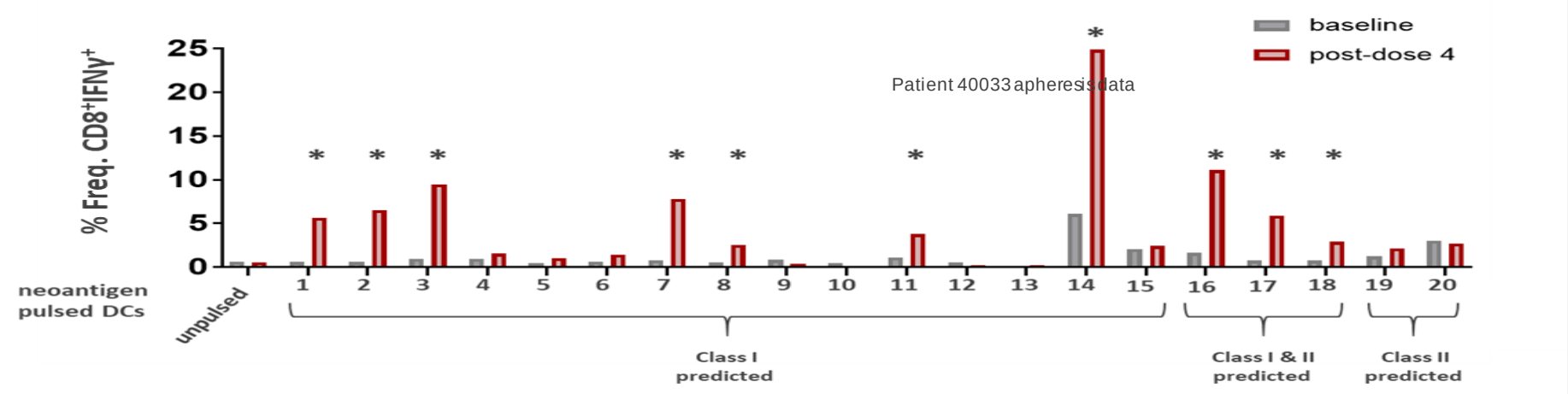
Phase 1 human data for PCV

Clinical & regulatory update

- **Enrolling patients in Phase 1 safety, tolerability and immunogenicity trial monotherapy and in combination with pembrolizumab**
- **Interim safety, tolerability immunogenicity data presented at ASCO 2019[1]**

Representative clinical data

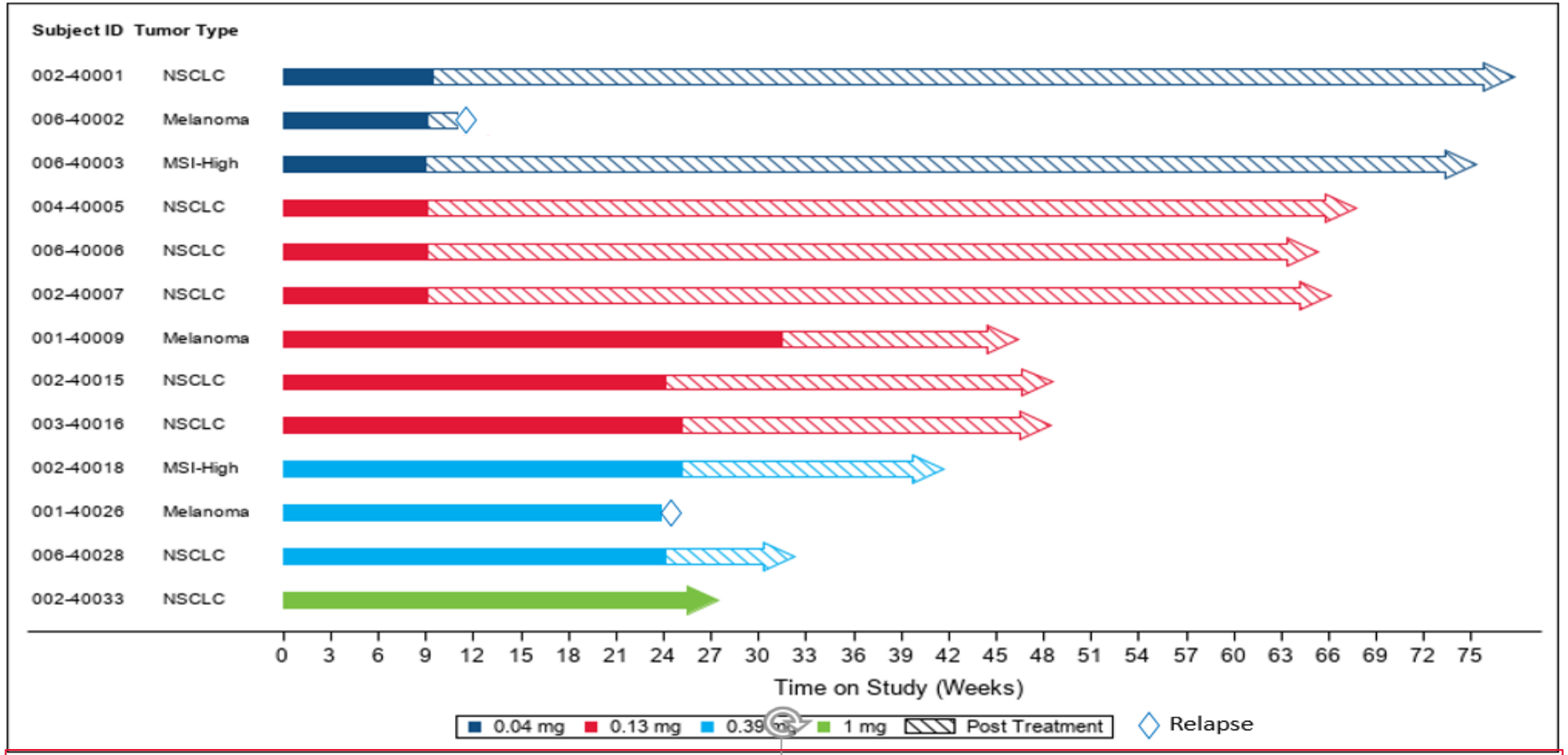
- **Safety:** mRNA-4157 is well tolerated at all dose levels studied with no DLTs reported. No mRNA-4157 related grade 3/4 AE or SAE was reported. The most common grade 2 adverse events were fatigue, soreness at the injection site, colitis and myalgias.
- **Activity:** Neoantigen specific CD8 T-cell 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



- **Early clinical:** 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.

1. Data cutoff as of May 10, 2019

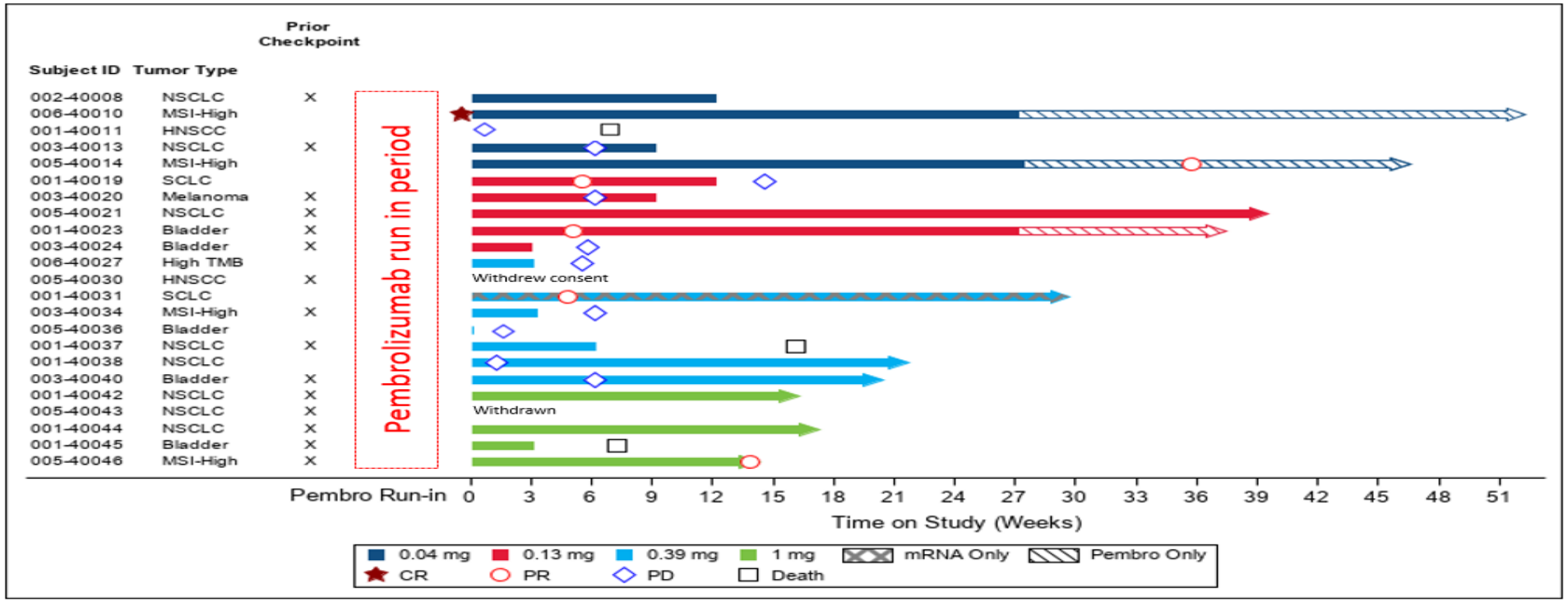
Part A: Adjuvant patients receiving mRNA-4157 monotherapy



- 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

Data cutoff as of May 10, 2019

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

Data cutoff as of May 10, 2019

Best overall responses

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

Data cutoff as of May 10, 2019

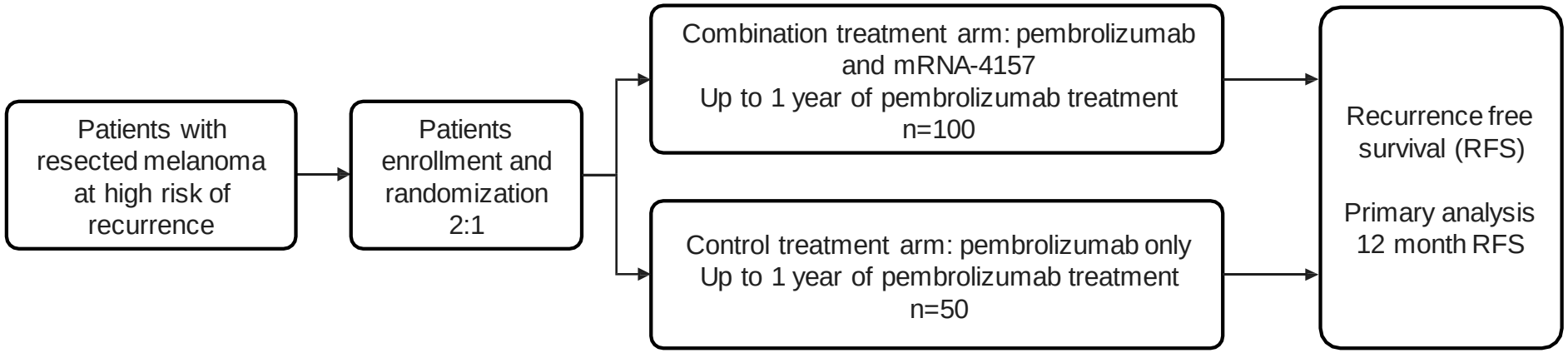
Personalized cancer vaccine (mRNA-4157)

Phase 2 study ongoing

- 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



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