## Personalized cancer vaccine (PCV) (mRNA-4157)

*Last program update: August 5, 2020*

<table>
<thead>
<tr>
<th>Modality</th>
<th>ID #</th>
<th>Program Indication</th>
<th>Preclinical development</th>
<th>Phase 1</th>
<th>Phase 2</th>
<th>Phase 3 and commercial</th>
<th>Moderna rights</th>
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</thead>
<tbody>
<tr>
<td>Cancer vaccines</td>
<td>mRNA-4157</td>
<td>Personalized cancer Vaccine (PCV)</td>
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<td>50-50 global profit sharing with Merck</td>
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<tr>
<td></td>
<td>mRNA-5671/ Merck V941</td>
<td>KRAS vaccine, CRC, NSCLC, pancreatic cancer</td>
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<td>50-50 global profit sharing with Merck</td>
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</tbody>
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PCV (mRNA-4157) Phase 1 and Phase 2 studies ongoing
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
Modernia’s mRNA vaccines elicit T cells required for curative cancer therapy
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

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![Diagram](image-url)

**Part A: Dose escalation (N = approx. 18)**

- mRNA-4157 0.04 mg
- mRNA-4157 0.13 mg
- mRNA-4157 0.39 mg
- mRNA-4157 1 mg

**Part B: Dose escalation (N = approx. 18)**

- mRNA-4157 0.04 mg
- mRNA-4157 0.13 mg
- mRNA-4157 0.39 mg
- mRNA-4157 1 mg

**Part B: PD1i-refractory (N = 17)**

**Part C: PD1/PDL1i naïve (N = 34)**
- MSS-CRC (N = 17)
- HPV-neg HNSCC (N = 17)

**Part D: Adjuvant melanoma (N = 10)**
Personalized cancer vaccine (mRNA-4157)

Early Phase 1 data shows antigen-specific T cell 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

### 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.

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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
## Best overall responses

<table>
<thead>
<tr>
<th>Responses in patients receiving combination</th>
<th>Total (N=20)</th>
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<tbody>
<tr>
<td>Best Overall Response</td>
<td></td>
</tr>
<tr>
<td>Complete Response (CR)</td>
<td>1</td>
</tr>
<tr>
<td>Partial Response (PR)</td>
<td>5</td>
</tr>
<tr>
<td>Stable Disease (SD)</td>
<td>6</td>
</tr>
<tr>
<td>Progressive Disease (PD)</td>
<td>8</td>
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</tbody>
</table>

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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