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OX40L (mRNA-2416)

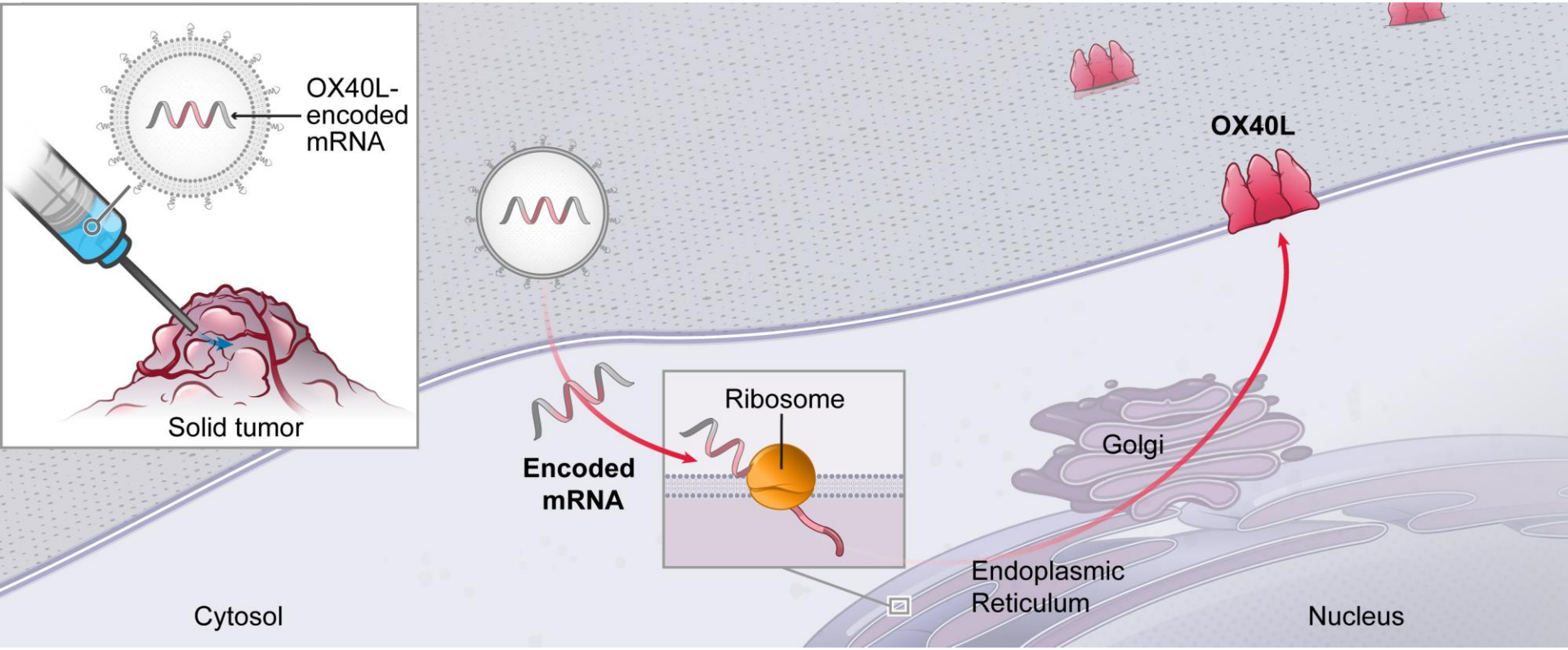
Last updated: January 8, 2019

Modality	Program #	Program *Indication*	Preclinical development	Phase 1	Phase 2	Phase 3 and commercial	Moderna rights
Intratumoral immuno-oncology	**mRNA-2416**	OX40L *Solid tumors/lymphoma* *Ovarian carcinoma*					Worldwide
	mRNA-2752	OX40L+IL23+IL36γ *Solid tumors/lymphoma*					Worldwide
	MEDI1191	IL12 *Solid tumors*					50-50 U.S. profit sharing; AZ to pay royalties on ex-U.S. sales

Protocol amendment filed with the FDA to initiate Phase 2 cohort of mRNA-2416 as monotherapy in advanced ovarian carcinoma as part of current trial

OX40L – first program in the intratumoral immuno-oncology modality

- mRNA-2416 encodes for wild-type OX40L, which is a membrane protein that cannot be manufactured by recombinant technologies
- OX40L is a potent T cell co-stimulator, which promotes T cell proliferation and enhanced survival in the presence of a recognized antigen



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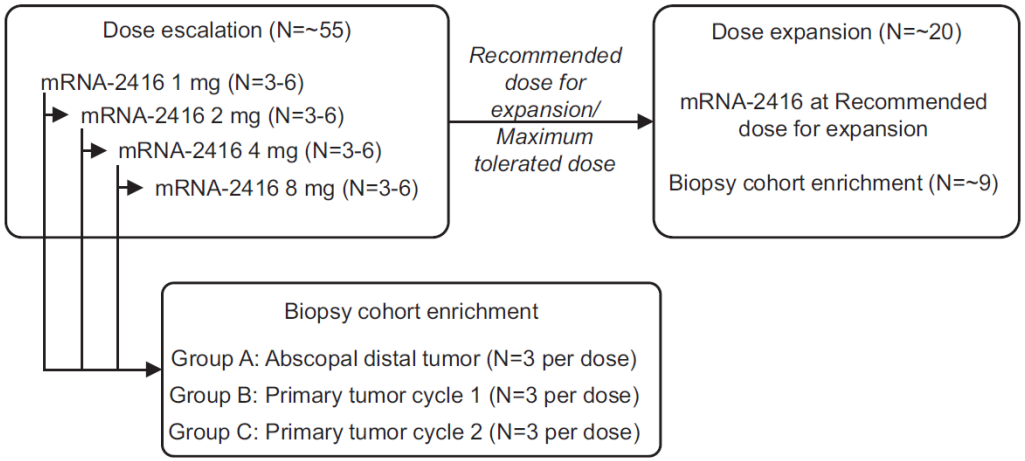
Phase 1 design

Key Objectives

- Evaluate safety and tolerability of mRNA-2416 administered intratumorally
- Define the maximum tolerated dose and recommended dose for expansion
- Other endpoints include PK analyses as well as assessment of biomarkers of immunological response in tumor



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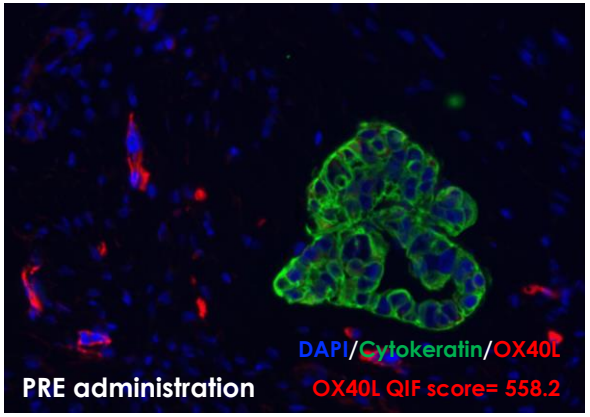
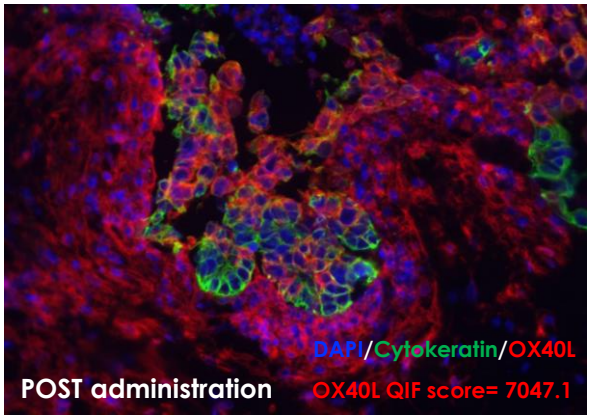
Early Phase 1 data – clinical observations of regression in certain ovarian cancer lesions

OX40L protein production in tumor cells of an injected lesion of a patient with ovarian cancer

Ovarian carcinoma 1 mg dose





Reduction in lesions observed in 2 ovarian cancer patients after intratumoral administration of mRNA-2416

- As of November 15, 2018, 28 patients dosed with mRNA-2416; 2 with ovarian cancer
- Highest dose level planned is 8 mg, no dose limiting toxicities to date
  - In 18% of patients, we have observed acute onset of multiple grade 2 and a single grade 3 transient reversible injection related reactions, all of which were resolved with antihistamines, corticosteroids, or supplemental oxygen
- Both ovarian cancer patients have clinical observations of regression of injected lesions
  - One patient at 1 mg dose level
  - One patient at 2 mg dose level, where regression of an adjacent, uninjected lesion was also observed
- In remaining patients, no evidence of clinical response
- *No regressions to date meet partial response criteria as per RECIST guidelines version 1.1*

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