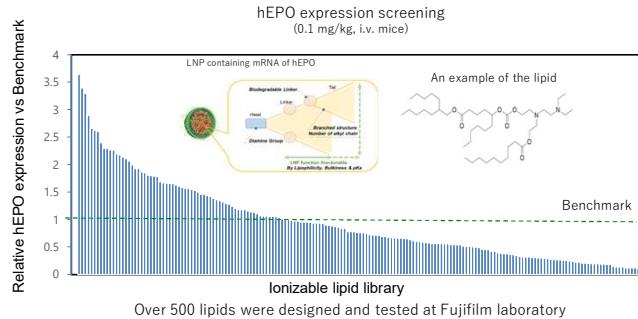




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Contact: dds-cdmo-service@fujifilm.com

Ionizable lipids library



List of the lipids

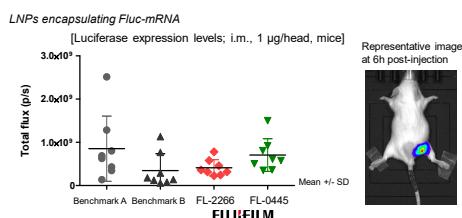
List of the ionizable lipids for external collaborations

Type	Lead Lipid	GMP Mfg.	IP	Application		
				siRNA	mRNA	pDNA
A	FL-2266	Launched	Issued	✓	✓	✓
	FL-0445	Launched	Issued			
B	FL-0207T		Pending			
	FL-0179T		Pending		✓	
C	FL-1252T		Pending			
	FL-1207T		Pending		✓	
D	FL-1923T		Pending			✓

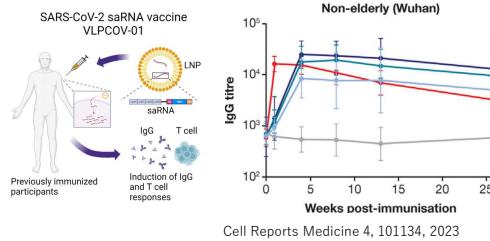
The lipids listed can be shared under MTA for evaluation use

mRNA delivery (IM)

[FL-2266-0445 LNPs] Protein expression in Mouse (i.m.)



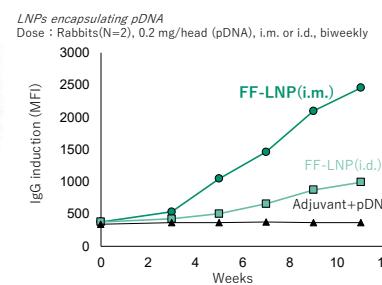
A result of Fujifilm lipid use in clinical trial



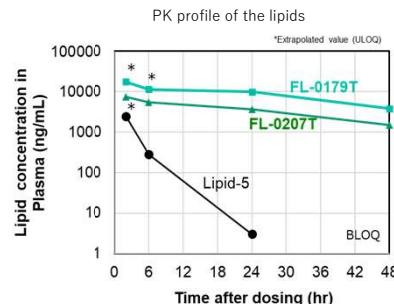
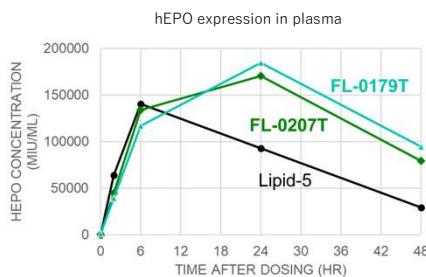
Track record of Fujifilm's ionizable lipids and LNPs for use in clinical trial

pDNA delivery (IM)

pDNA delivery and IgG induction in Rabbits (i.m. / i.d.)



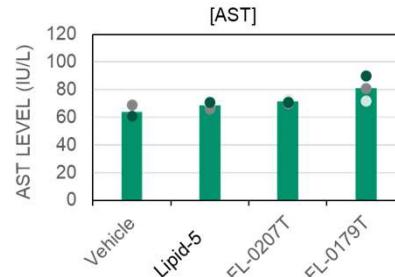
mRNA delivery in NHP (IV)



LNPs encapsulating hEPO-mRNA

Experimental animal : Cynomolgus monkey (male, 4y, N=2)
Dose : 0.2 mg/kg (mRNA), 1hr infusion, i.v.

Toxicity study in rat (IV)



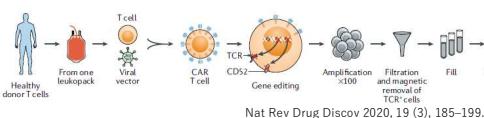
LNPs encapsulating hEPO-mRNA

Experimental animal : SD Rat (female, 6w, N=3)
Dose : 1 mg/kg (mRNA), i.v.

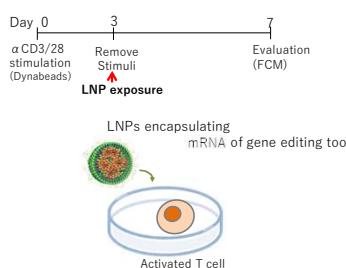
LNP ex vivo use for T cell therapies

Manufacturing process of allogenic CAR T:

TCR KO by gene editing is an essential step



Gene editing tool transfected by LNP to CAR T Cell



One stop shop CDMO services for mRNA/LNP



Seam less scales of the manufacturing



- ✓ mRNA IVT 1g to 50 g/batch
- ✓ LNP / Liposome NxGen™ Microfluidic mixer (0.2 – 100L)
- ✓ KrosFlo® TFF and Mobius Flex Ready® from mL scale to ~100 L
- ✓ Vial filling system with isolator, 3,000 vials/hour
- ✓ Full range analytical services for GMP batch release

GMP manufacturing – Facility



GMP facility (Toyama)



R&D lab (Toyama)

Headquarter (Tokyo)

R&D lab (Kanagawa)



International Marketing
(Boston, MA)

FUJIFILM Pharmaceuticals U.S.A., Inc.

Fill finish line with isolator

	701F
Filling Speed	3,000 vials/hour
Filling Amount	0.5-20ml
Vial Size	2R/4R/6R/10R/20R
Annual filling capacity	3.6million Vial/Year