

The Global Vaccine and Immunization Research Forum (GVIRF)

Grand Hayatt Incheon Korea 28-30 March 2023

Lemonex Inc.

Innovative DDS 'DegradaBALL' for mRNA vaccine against next pandemics: '100 days mission'

Lemonex Inc.

Value Creation by NanoBiotechnology

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CTO Lemonex

Lemonex develops safe and effective RNA medicine and cancer immunotherapy based on innovative non-viral drug delivery platform technology, 'DegradaBALL'.

NIH National Institute of Allergy and Infectious Diseases

World Health Organization

BILL & MELINDA GATES foundation

Lemonex Inc.

Value Creation by NanoBiotechnology

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Chapter 1.

**Company
Competitiveness**

Chapter 2.

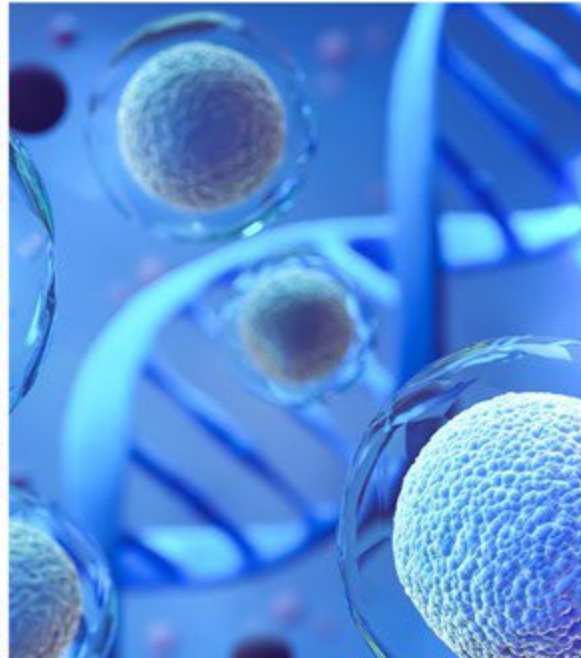
**Next DDS platform
: DegradaBALL®**

Chapter 3.

**LEM-mR203
"mRNA-DegradaBALL" vaccine**

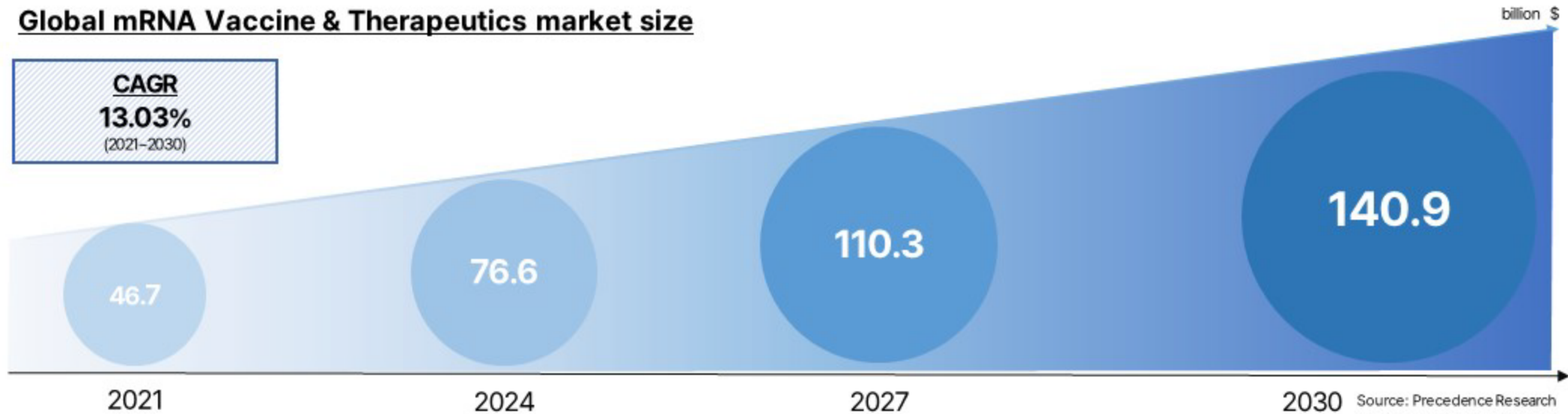
Chapter 4.

Conclusion



Rapid growth of the mRNA market

Global mRNA Vaccine & Therapeutics market size



Covid-19
(mRNA-LNP vaccine)



Trend changes

Vaccine
"Emerging as a next-generation vaccine platform"

- Moderna, BioNTech: Initiate development of additional infectious disease mRNA vaccines
- Development of universal vaccines

Therapeutics
"Vaccine success expedites development of mRNA therapeutics"

- Current mRNA therapies in clinical trials: 5 pipelines
- Estimated Sales Over: \$2 Billion
- Development of mRNA therapeutics platform to replace an existing protein drug



Vaccine + Therapeutics
: Expansion of mRNA coverage

Delivering Pandemic Vaccine in 100 Days



Incidence of Pandemic Viruses


	2002	2008	2012	2014	2015	2020
Virus	SARS (corona)	H5N1	EVOLA	MERS (corona)	Zika	COVID-19 (corona)
Cases	8,000	1,630,000	8,400	1,200	100 million	760 million
Deaths	770	19,600	4,033	450	N/A	6.8 million



100 Days to Outrace the Next Pandemic

 23.01.19, World Economic Forum

Vaccinate the world in six month

 GatesNotes 'No more pandemics'

Delivering Pandemic Vaccine in 100 Days

 22.07.14, N Engl J Med / CEPI

Discovery to delivery in 100 days : RNA therapeutic & their role in future pandemic

 2022; 1(4); 267-277 Vaccine Insights

The role and mission of international organizations in responding to the pandemic

What is COVAX?

COVAX

Coalition for equal supply of COVID-19 vaccines around the world



COVAX has delivered **1 billion** doses to **144** countries and territories



85% of these doses have been delivered to **86** low-and middle-income countries



Dose donations to COVAX have accounted for **38%** of all doses delivered



100 DAYS MISSION

Develop a **safe and effective vaccine** within 100 days to respond to the next pandemic "Disease X"



Accurate & Rapid Diagnosis



Prevention and Treatment



Mass Production



CEPI

BILL & MELINDA GATES foundation

- Established in 2017
- International organization that supports vaccine development for infectious diseases
- \$3.5 billion fundraising with full support from the Bill & Melinda Gates Foundation

CEPI supported Covid-19 vaccine

moderna



AstraZeneca



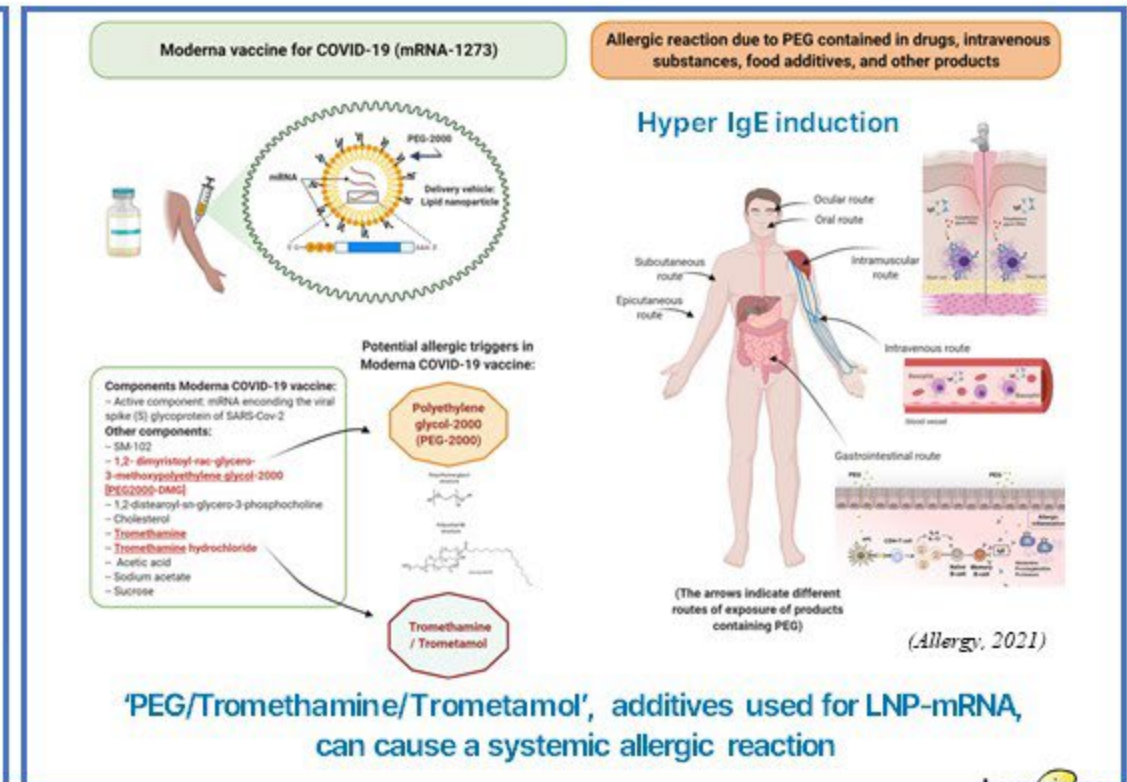
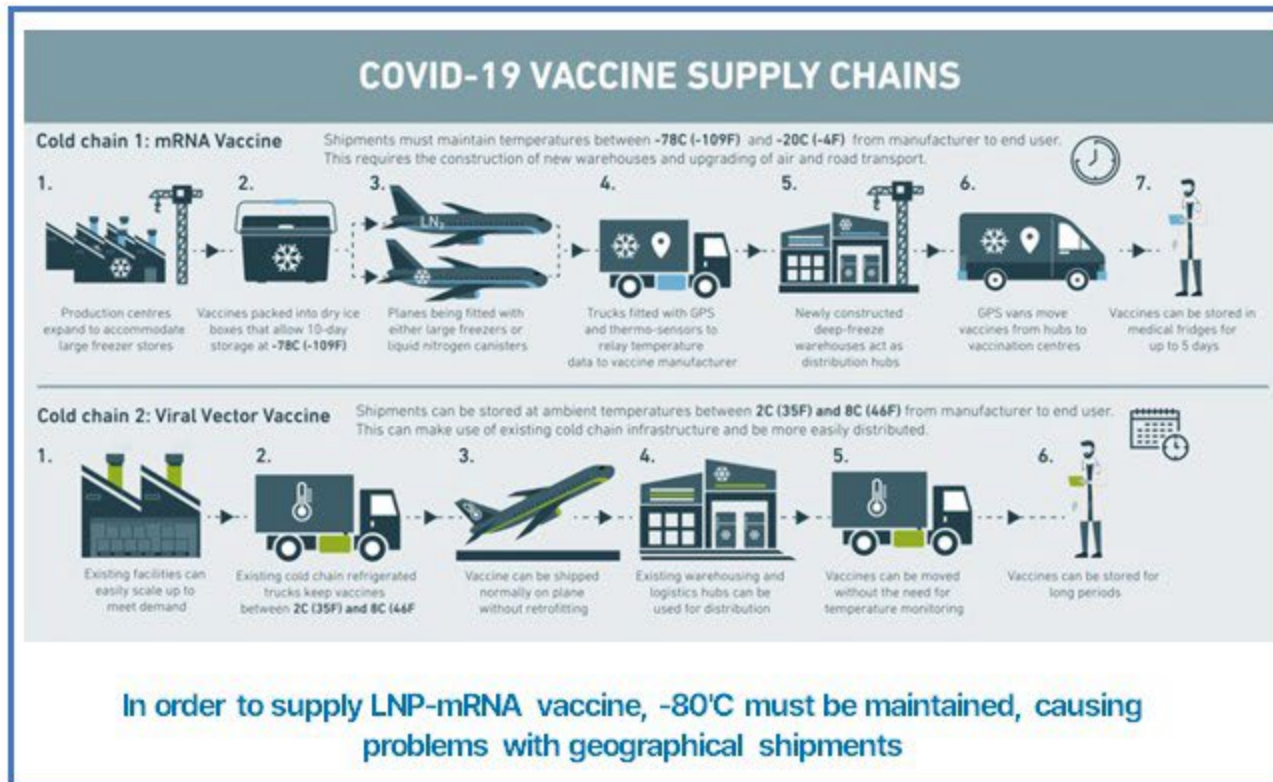
SK bioscience

1-4. Medical Unmet Needs of mRNA vaccine & therapeutics?

1. **Stability** issue (cold chain)

2. **Safety**: Systemic side effects

3. **Speed**: How to prepare '100 days mission' for next pandemic?



1-5. Lemonex's DDS platform DegradaBALL can address the unmet needs

1. Stability issue (cold chain)

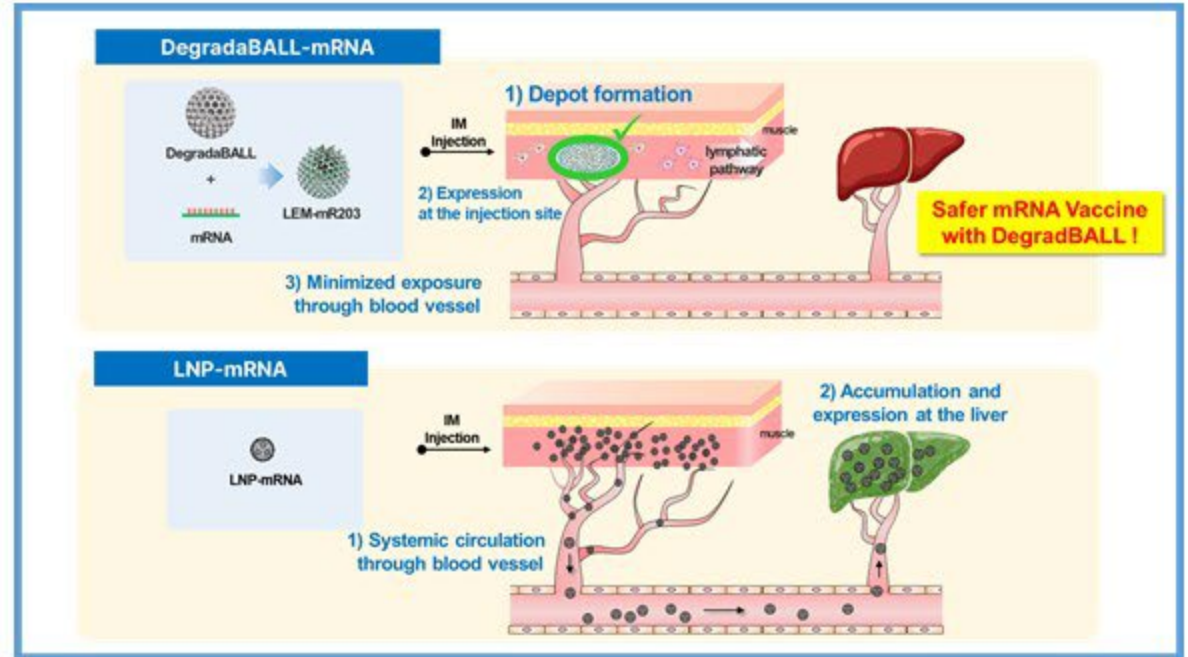
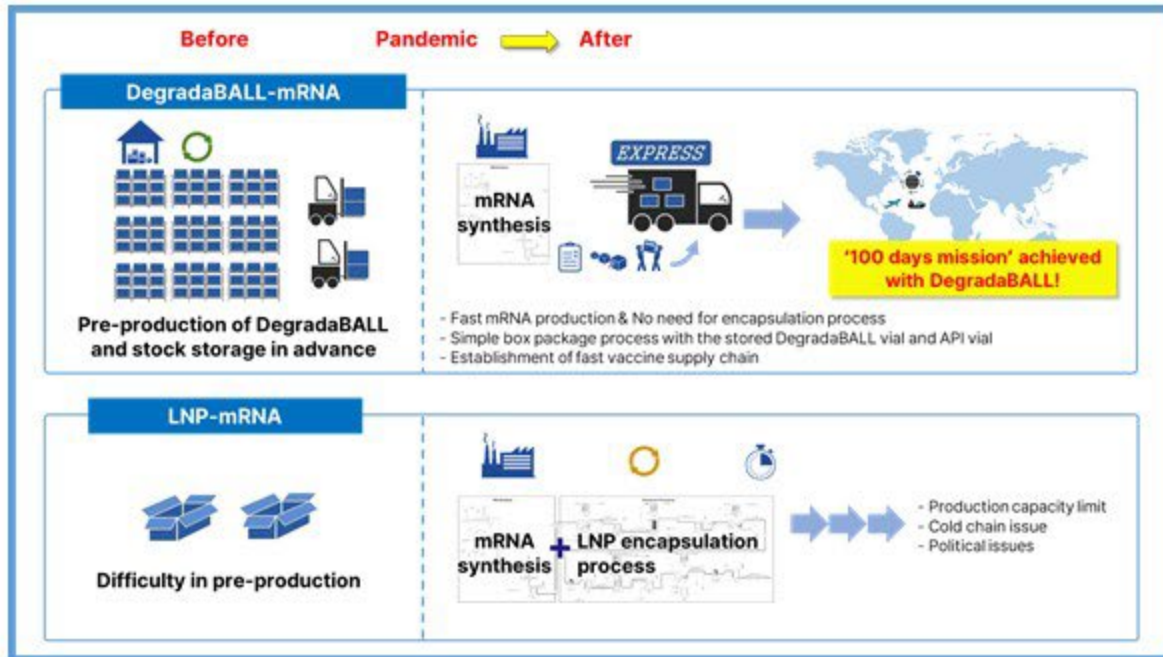
: DegradaBALL improves the thermo-stability of mRNA → Supply vaccine without freezing!

2. Safety: Systemic side effects

: Avoids systemic circulation of vaccine through blood vessels and minimizes side effects by forming a DegradaBALL depot at the injection site

3. Speed: How to prepare '100 days mission' for next pandemic?

: Highly stable for more than 2 years at room temperature and enables to stock up on inventory through pre-production and to provide the mRNA-DegradBALL vaccine quickly to the next pandemic and new variants



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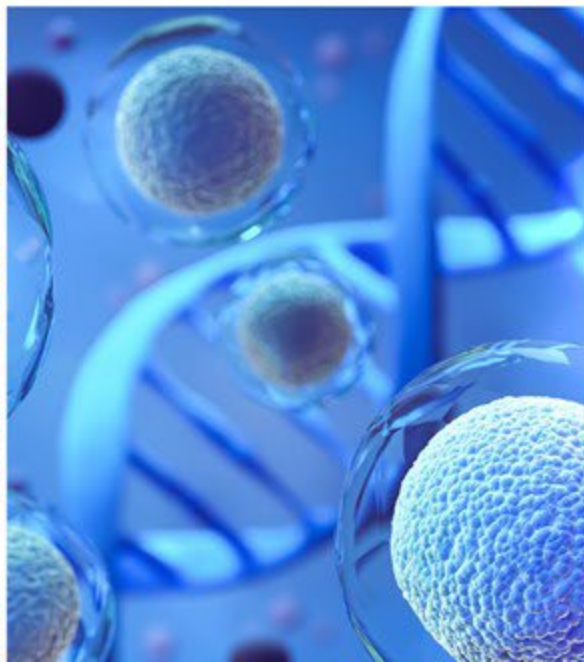
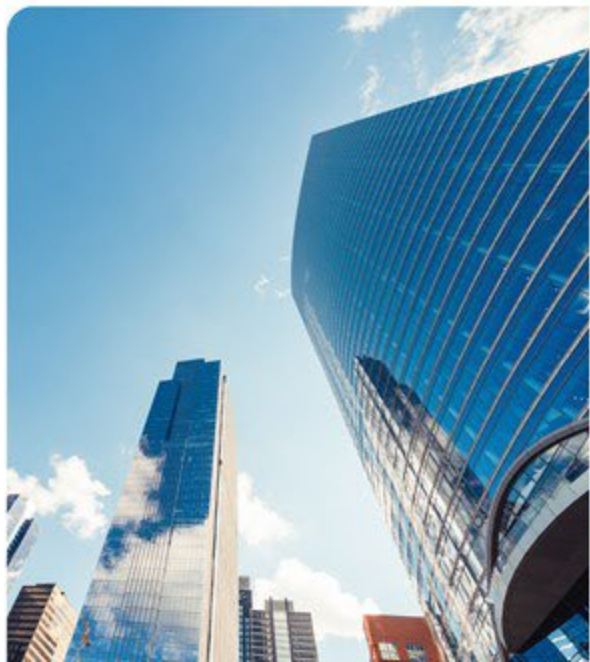
Next DDS platform
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Nature Biopharma Dealmakers, 2021

Small but mighty: transforming immunoncology and RNA medicine with the power of nanobiotechnology

Lemonex is opening a new era of safe and highly effective immunotherapy and RNA therapy with a pipeline of candidates based on DegradaBALL, its proprietary porous nanoparticle drug-delivery platform

The creative spark to invent new technologies can come from many sources. For Lemonex, Inc., based in Seoul, South Korea, the inspiration came from a natural phenomenon: the porous lava rock found on the volcanic island of Jeju, 130km off the coast of the Korean Peninsula.

Lemonex is dedicated to developing innovative technology from the laboratory bench to the patient's bedside, and creating highly effective therapies that allow for the highest quality of life. Taking a lead from nature, Lemonex has created a next-generation and potentially best-in-class porous nanoparticle (NP) drug-delivery platform called DegradaBALL that increases the efficacy and safety of a wide range of therapeutic modalities, from small interfering RNAs (siRNAs) and mRNAs to cytokines and antibodies. Building on this platform, Lemonex has established a pipeline of candidates that combine DegradaBALL technology with these modalities and which have demonstrated great promise in preclinical studies (Fig. 1).

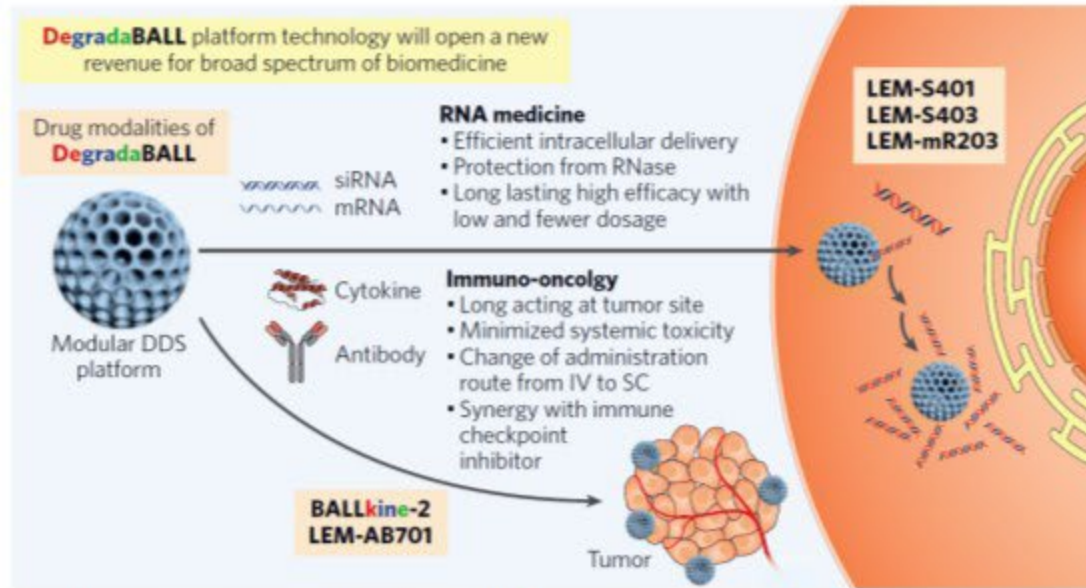


Fig. 1 | Drug modalities delivered by DegradaBALL. DegradaBALLs are able to carry these four different drug modalities: siRNA, mRNA, cytokines and antibodies. IV, intravenous; SC, subcutaneous.

www.nature.com/articles/d43747-021-00037-7



<https://youtu.be/m6V3GM9PFIU>

No.1

Global Best-in-Class DDS platform: DegradaBALL

Lemonex Inc.

- Completed **efficacy study with DegradaBALL-various API** formulations
- **Confirmed safety in human** through Phase I clinical trial
- Operating **clinical GMP** with capacity of >400,000 vials / year

Global Partner

Major global pharmaceutical companies and international vaccine development network

Pipeline

based on Modular DDS platform DegradaBALL®

<p>siRNA</p> <p>LEM-S401 (Hypertrophic scar)</p>	<p>mRNA</p> <p>LEM-mR203 (Covid-19)</p>	<p>Dual acting-RNA</p> <p>LEM-S403 (Solid tumor)</p>	<p>IL-2</p> <p>BALLkine-2 (Solid tumor)</p>
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R&D

Management and research personnel composed of experts in the fields

10,168회
Citation : 10,168

Patent

DegradabALL platform patents secured

Year	Patents total	Patents granted
2012	0	0
2013	0	0
2014	0	0
2015	0	0
2016	0	0
2017	0	0
2018	~10	~5
2019	~30	~10
2020	~60	~20
2021	~100	~30
2022	136	49

Unmet medical needs exist due to various side effects and instability problems of COVID-19 mRNA-LNP vaccine

Limitations of current vaccines

	Company A	Company B	Company C
Approval	USA, UK	USA	UK
clinical trial participants	>16 yrs old (43,448 people)	>18 yrs old (30,351)	>18 yrs old (23,745)
Side effects	Anaphylaxis, myocarditis/pericarditis, thrombosis, etc.		
Cause	PEG/Tromethamine/Trometamol in LNP formulation induce allergic reactions and systemic side effects		

Unmet medical needs

- **Safer vaccine** that can be administered periodically
- Vaccine platform that can respond **quickly to mutations or the next pandemic**

Strategy of Lemonex

① Phase I clinical trial of LEM-mR203 (to evaluate safety of mRNA-DegradaBALL platform)



② Establishment of DegradaBALL-mRNA vaccine platform



Universally applicable modular vaccine development with a well-defined mechanism of action

LEM-mR203 Project

- Stable at room temp for > 2 yr
→ Pre-mass production and storage possible
- Minimized systemic side effect improves patient compliance
- Two vial system: 1) DegradaBALL vial, 2) API vial (separate 'fill & finish') → Efficient global sales and supply
- Patents owned by Lemonex

Development strategy

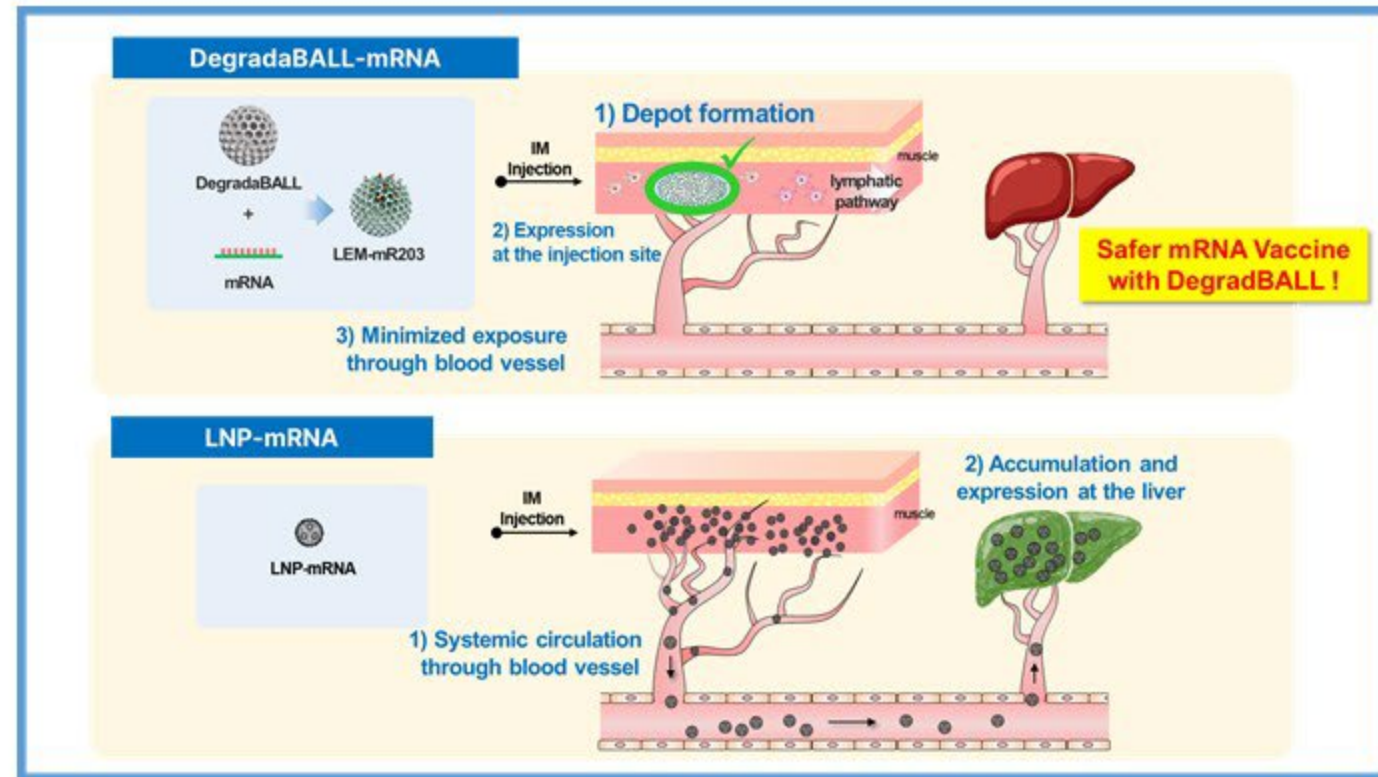
① Depot formation in injection site

- Minimize systemic diffusion through blood vessel
- Induce DC recruitment

② Ag-specific immunity

- Induce Th1/Th2/Tfh cells
- Antibody production in B cells
- Germinal center reaction
- Induce the development of memory T cells & memory B cells

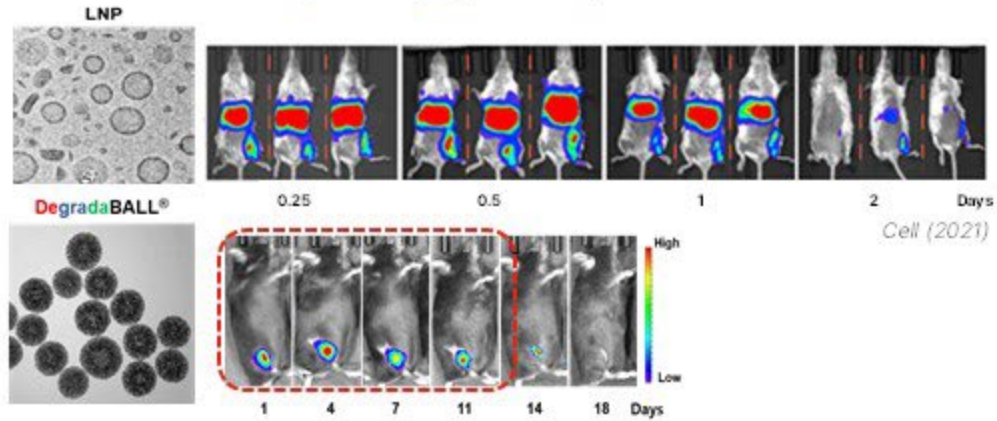
[3S] Stability, Safety, Speed



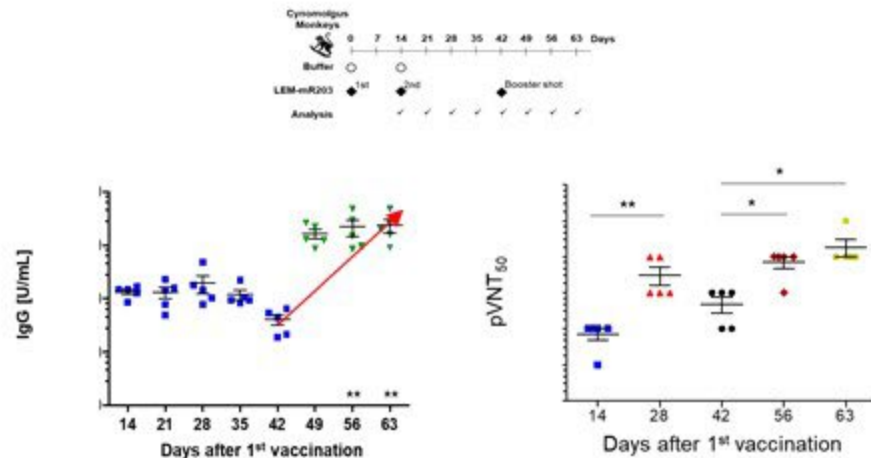
LEM-mR203 elicited immune response in NHP similar to the existing mRNA-LNP vaccine

PK study (monkey & mouse model)

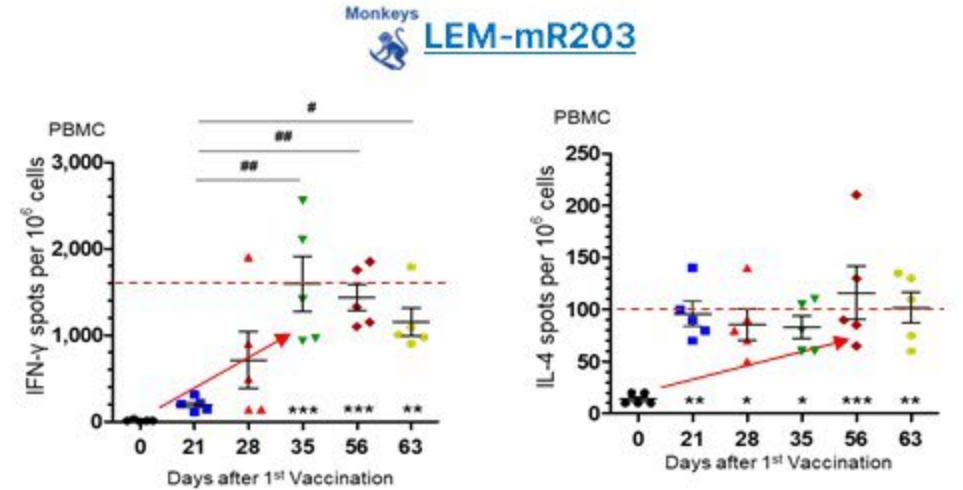
Minimized side effects by avoiding systemic exposure



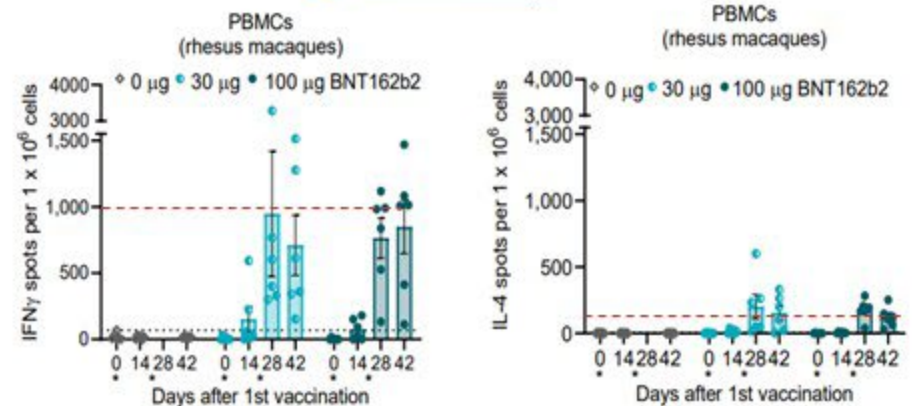
Binding antibody & neutralizing antibody formation in monkeys



T cell response in monkeys



Monkeys BNT162b2



Nature 592, 283-289 (2021)

4-1. Conclusion:

Lemonex's strategy to prepare for disease X: 100 days mission

1. LEM-mR203 clinical trial for fast track approval of Disease X



2. International Network

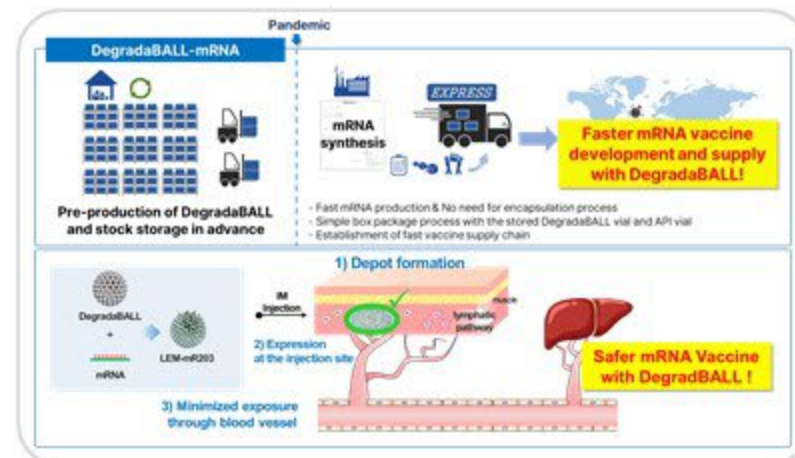


"100 days mission for Next Pandemic"

3. Manufacturing Infrastructure



4. Faster and Safer Vaccine



Lem  nex Inc.

Thank You



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