Investor Relations 2023

Global R&BD Group

iNtRON Biotechnology

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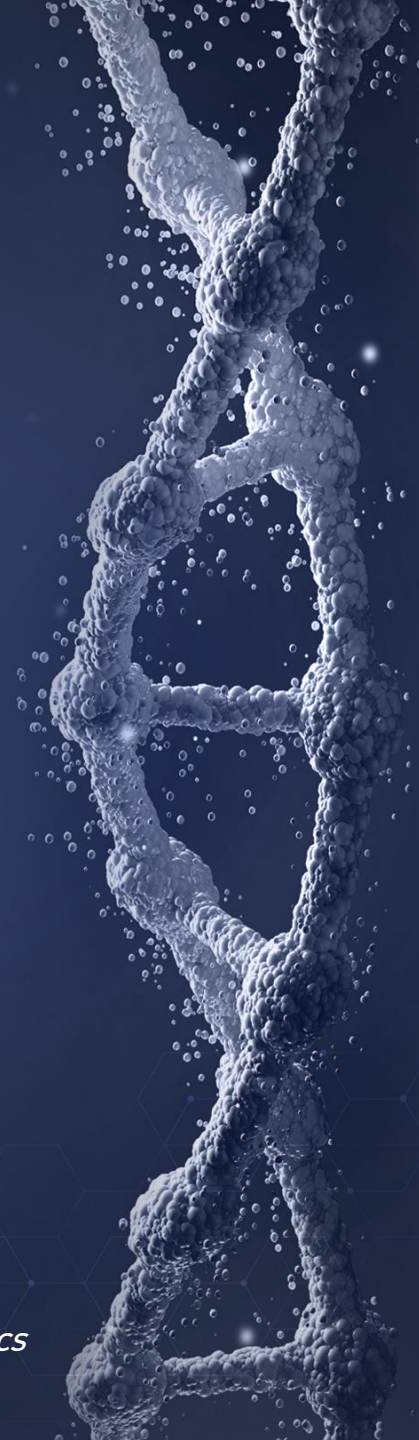
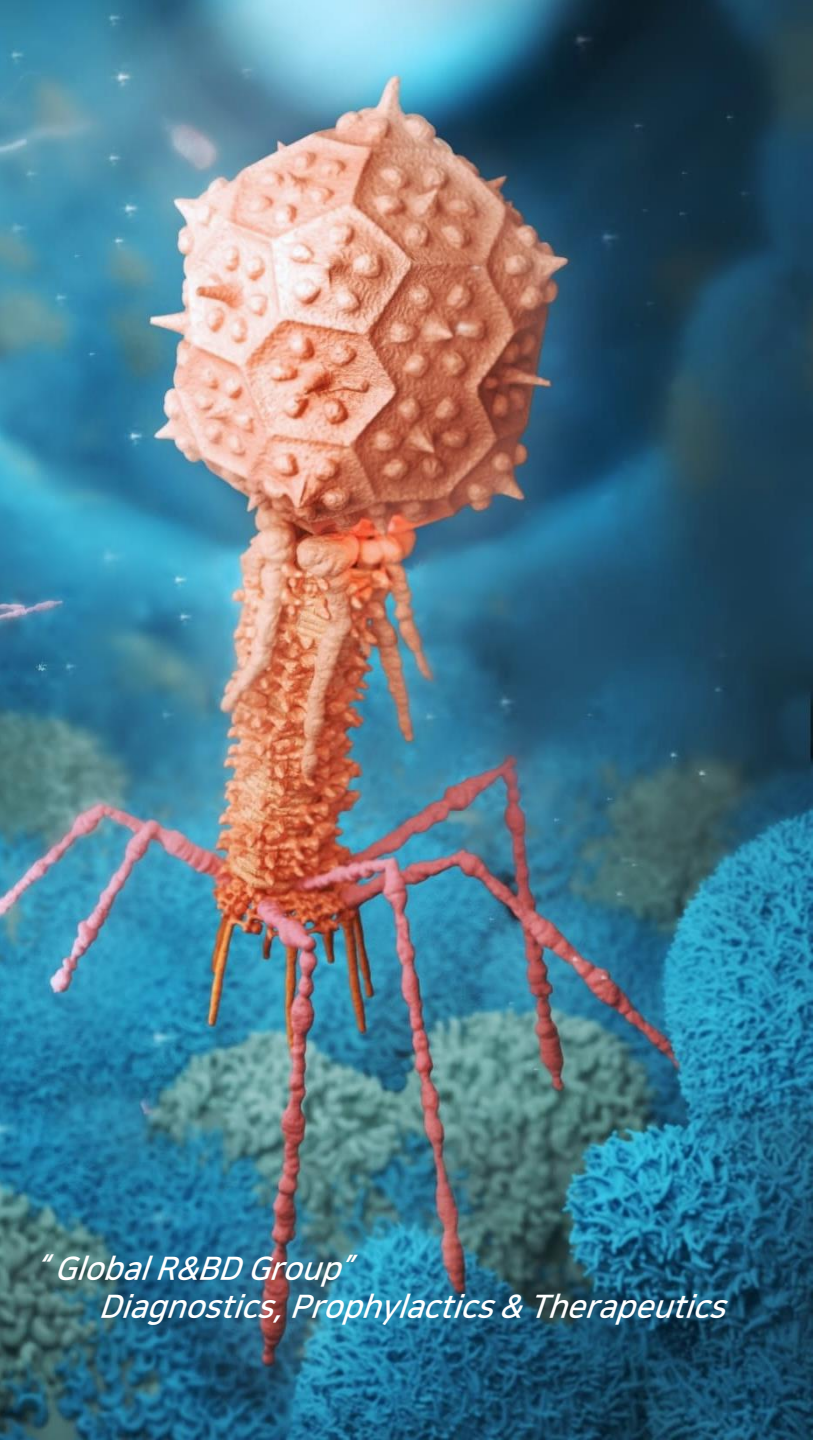
" Global R&BD Group"
Diagnostics, Prophylactics & Therapeutics





OVERVIEW

- 인트론바이오 Mission
- Biz Outlines (사업구조)
- 신약개발 R&BD Mission & Goal
- Infectious Diseases Threat

㈜인트론바이오 Mission

GLOBAL R&BD GROUP

"진단•예방•치료의 세계적 기업"

First-in-Class 신약개발 → First-in-Concept 신약개발

㈜인트론바이오는 감염성 생물체 분야의 특화된 기술 Full-lineup을 통해
박테리오파지 (Bacteriophage) 전문 기업으로 성장해 왔으며, 이제
또 다른 새로운 변화 · 새로운 도약을 모색하고 있습니다.

Main Business

진단•예방•치료의 바이오 3대 축 사업 영위

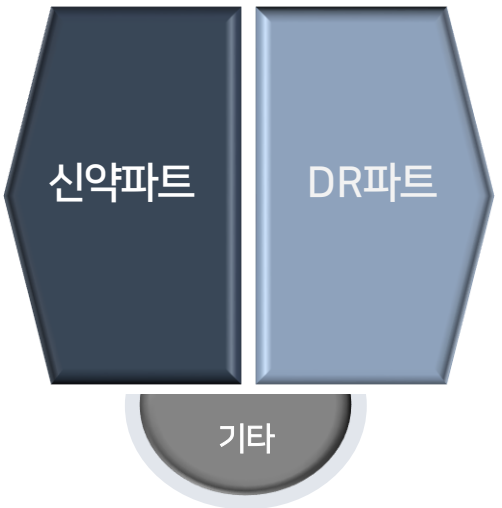
Biz Outlines (사업구조)

㈜인트론바이오 사업구조

▣ 플랫폼 기술 : 박테리오파지 기술

- 잇트리신 (itLysin®) : 세균
- 파지리아 (PHAGERIA®) : 세균
- 파지러스 (PHAGERUS®) : 바이러스
- 파지리아러스 (PHAGERIARUS®) : 면역

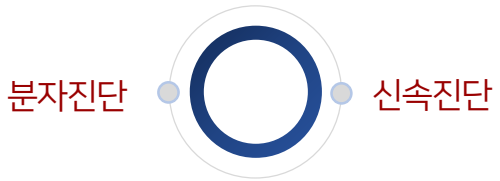
First-in-Class → First-in-Concept



위성기업 네트워크
(Satellite Company Network)

▣ 플랫폼 기술 : PCR & 크로마토그래피 기술

- 분자진단 (MDx) : 진단 증폭/추출 (DNA/RNA)
- 신속진단 (RDT) : 항원/항체



동물진단 → 인체진단

신약개발 R&BD Mission & Goal

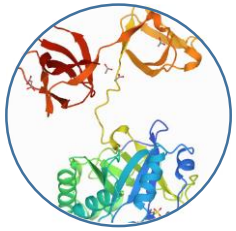
㈜인트론바이오 신약파트

▣ 플랫폼 기술 : 박테리오파지 기술 ▣

생명공학연구소 | First-in-Class → First-in-Concept | BD사업부

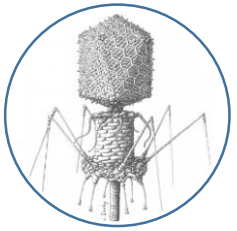
(Bϕ : Bacteriophage)

- ➢ 신규 First-in-Class Endolysin 지속 확보
- ➢ 점막면역 기반의 mRNA 백신
- ➢ 신규 Bϕ 지속 분리·동정
- ➢ Phage & itLysin® 생산시스템
- ➢ Bϕ Genetic Engineering



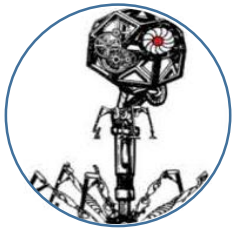
itLysin®
(Endolysin)

MucoDr®
(Mucosal · mRNA)



PHAGERIA®
& PHAGERUS®

Bacteriophage
Endolysin

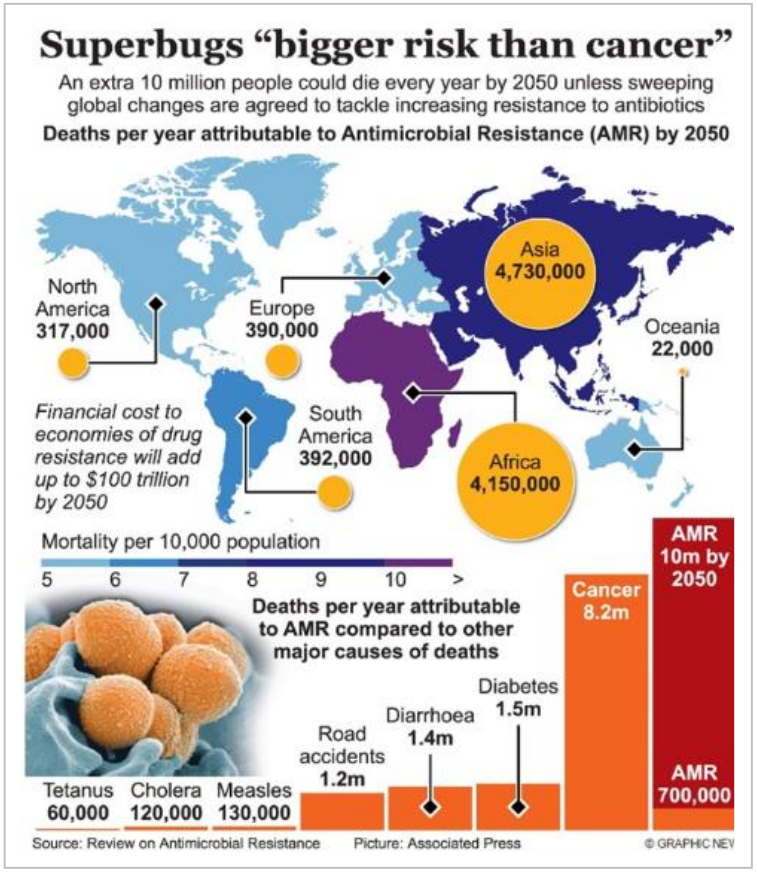


PHAGERUS®
& PHAGERIARUS®

잇트리신 (itlysin®)	파지리아 (PHAGERIA®)	파지러스 (PHAGERUS®)	파지리아러스 (PHAGERIARUS®)

Infectious Diseases Threat

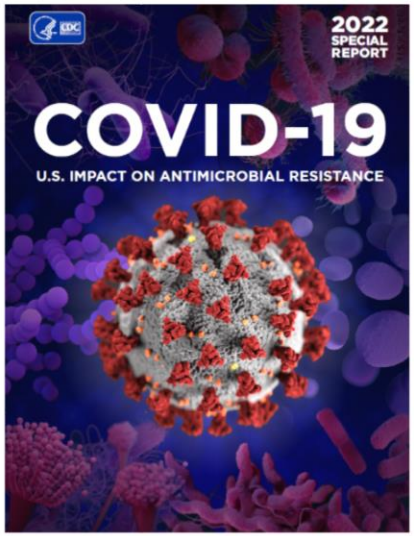
- "세균과 바이러스의 공격 경고" → "Covid-19 Pandemic" → *"What is Next?"*
- 슈퍼박테리아는 여전히 인류에 심각한 위험이 되고 있으며, 2050년에는 매년 천만명 이상의 인류가 슈퍼박테리아로 인해 사망할 것으로 예측.



(Source: "https://amr-review.org" & "VaccinesWork")

Infectious Diseases Threat

2022년도 CDC Special Report : "내성균 문제는 코로나 팬데믹을 거치면서 더 심각해지고 있음"



"Antimicrobial resistance was one of our greatest public health concerns prior to the COVID-19 pandemic, and it remains so."
"코로나 팬데믹 기간에도 내성 문제는 지속되었음"

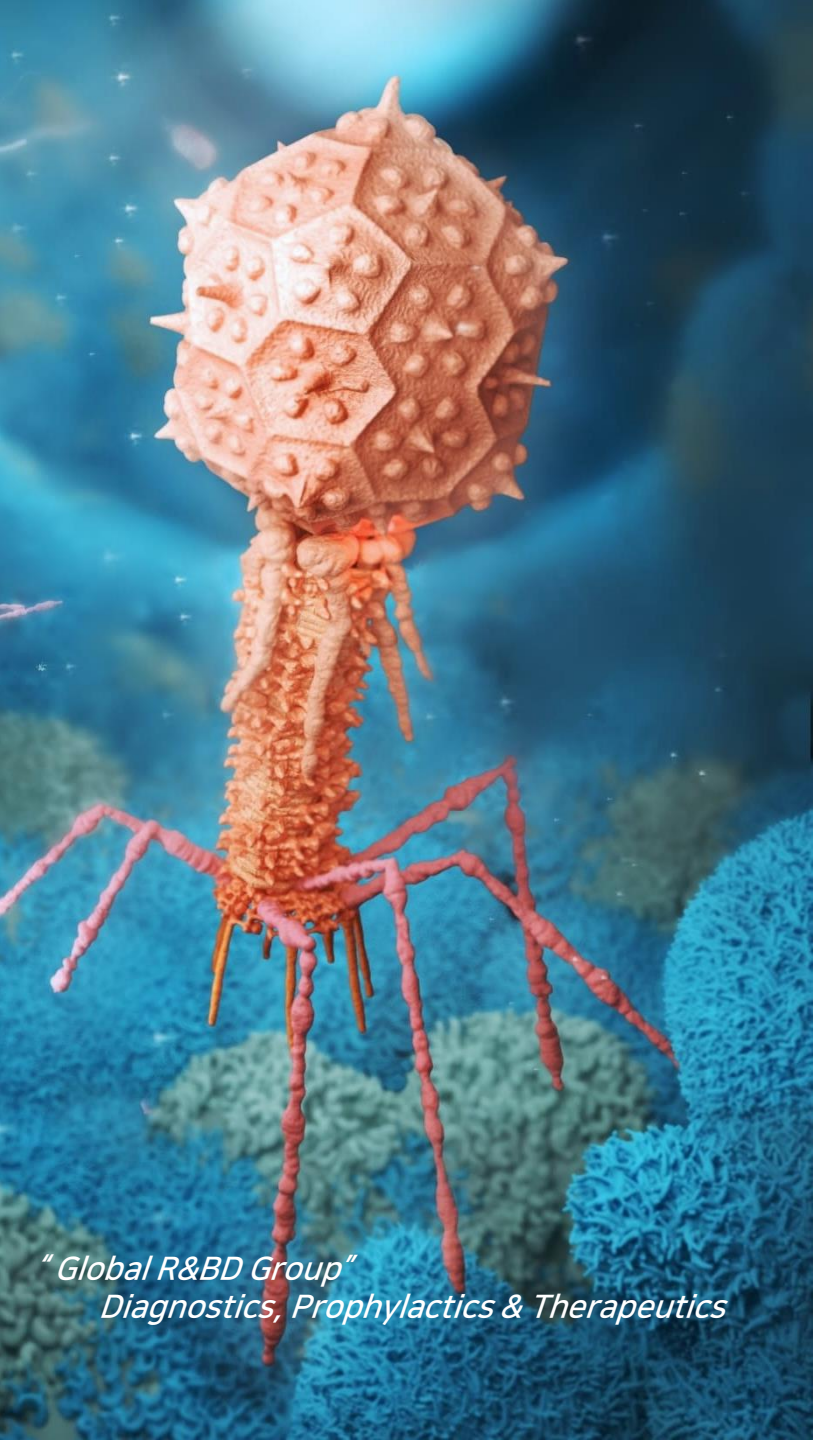
"After more than two years of responding to COVID-19, the threat of antimicrobial resistance is not only still present but has become an even more prominent threat."
"코로나 팬데믹을 거치면서 내성 문제는 훨씬 더 큰 위협이 되고 있음"

"Germs continue to spread and develop new types of resistance. More investments are needed to continue addressing antimicrobial resistance while simultaneously responding to COVID-19 and other health threats."
"이런 내성 문제에 대응하기 위해 더 많은 투자가 필요함 "

"*itLysin*® 플랫폼은 이런 내성 문제를 근본적으로 해결할 수 있는 Bio Technology임 "

✓ ***itLysin***® has total different bactericidal ability than conventional antibiotics and is able to solve a fundamental problem of Antibiotic Resistance.

(Source : CDC. COVID-19: U.S. Impact on Antimicrobial Resistance, Special Report, 2022)



감염성 질환 대응 Platform

- itLysin®

잇트리신 (itLysin®)

itLysin® Platform Technology : Overview

iNtRON Biotechnology

A. Bacteriophage

- 세균의 천적 'Bacteriophage'
- 자연친화적 세균 바이러스 대응 기술

Endolysin vs itLysin®

B. Endolysin

- 살균항생제
- 인트론바이오 Endolysin Pipelines 확보

C. itLysin®

- itLysin® vs Endolysin
- Engineered Endolysin
- 그람양성균
- 그람음성균

GOAL

높은 치료효과 및 안전성

- 내부환경요소에 저항성이 없도록
- 보다 안전할 수 있도록
- 치료 효과가 높아질 수 있도록

itLysin® Platform Technology : Formulation

"Endolysin/itLysin 바이오신약의 다양한 목적으로의 활용을 위해 여러 가지의 **제형 (Formulation) 개발 성공** "

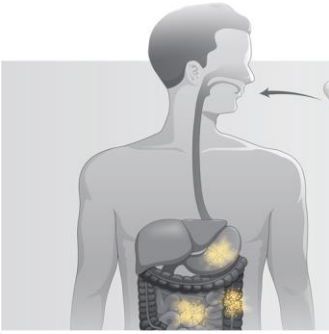
- 적응증 확장 등 활용 목적 확대 가능
- (1) 주사제형 (IV), (2) 경구투여 제형 (Oral Capsule), (3) 외용제 제형 (Topical Medication), (4) 요관투여용 (Urinary Tract) 제형 등

1

Solution Formulation for IV INJECTION
SAL200, SPL200, BAL200, GN200

- **Bacteremia**
  VRE infection in bloodstream, blood poisoning
- **Endocarditis**
  Infection in heart chambers and heart valves
- **Neonatal Sepsis**
  Bacterial bloodstream infection in a newborn baby
- **Meningitis**
  Inflammation of the fluid and membranes in brain/spinal cord

2



Capsule Formulation for
ORAL DRUG CDL200, EFL200

- **Antibiotic-Associated Diarrhea (AAD)**
  C. difficile diarrhea and coilitis
- **VRE Colonization**
  Hospital-acquired VRE colonization. Cohort Isolation

3

Topical Formulation for SKIN
TM_SAL200, SBL200, CAL200

- Acne
- Dermatitis
- Psoriasis
- Sebaceous cyst
- Rash

4

itLysin® : Pipelines

"Global leader in Endolysin/itLysin® based drug"

Category	Pipeline	Target Clinical Needs	Remark/Potential
Endolysin	 SAL200	Drug for Staphylococcal Endocarditis/Bacteremia	• WHO INN 성분명 TONAbacase 등록 • 2022년 미국 FDA 임상 2b IND 승인
	 TM_SAL200	Drug for Staph 2nd infection in atopic dermatitis	• Topical Medication
itLysin® 그람양성균	 BAL200	Drug for anthrax	• US FDA ODD (Orphan Drug Designation) 획득
	 CDL200	Drug for *C. difficile* infections (CDI) incld. antibiotic-associated diarrhea (AAD)	• Capsule type (Oral Drug)
	 EFL200	VRE decolonization	• Capsule type (Oral Drug) • Sepsis 예방제제
itLysin® 그람음성균	 GN200 Series	Drug for Gram-negative bacterial infections (*Acinetobacter, Pseudomonas, Klebsiella*)	• Carbapenem-resistant Gram negative bacterial infections • Urinary tract infections • Bone and joint infections • Infections in patients with severe burns and in cancer and AIDS patients

Unlisted development programs:

- Candidate drug SBL200 (against *Streptococcus ß-hemolytic* infections)
- Candidate drug CAL200 (against *Cutibacterium acnes* infections), etc.
- Candidate drug SPL200 (against *S. pneumoniae* infections), etc.

itLysin® : Pipelines

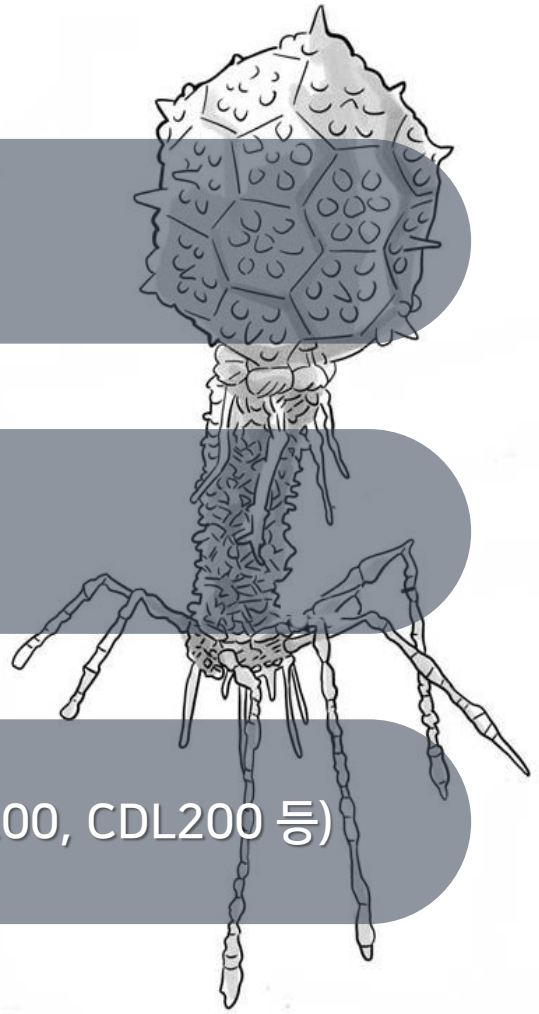
"미국 질병통제국이 위험을 경고한 주요 내성 세균 중에 많은 것들에 대하여 대응 파이프라인을 보유"

내성균	2017 Threat Estimates	2018 Threat Estimates	2019 Threat Estimates	2020 Threat Estimate and 2019-2020 Change	Our Pipelines
Carbapenem-resistant *Acinetobacter*	8,500 cases 700 deaths	6,300 cases 500 deaths	6,000 cases 500 deaths	7,500 cases 700 deaths Hospital-onset : 78% increase	**GN200 Series**
Clostridioicles *difficile*	223,900 infections 12,800 deaths	221,200 infections 12,600 deaths	202,600 infections 11,500 deaths	-	**CDL200**
Vancomycin-resistant Enterococcus	54,500 cases 5,400 deaths	46,800 cases 4,700 deaths	47,000 cases 4,700 deaths	50,300 cases 5,000 deaths Hospital-onset : 14% increase	**EFL200**
Multidrug-resistant *Pseudomonas aeruginosa*	32,600 cases 2,700 deaths	29,500 cases 2,500 deaths	28,200 cases 2,400 deaths	28,800 cases 2,500 deaths Hospital-onset : 32% increase	**GN200 Series**
Methicillin-resistant *Staphylococcus aureus*	323,700 cases 10,600 deaths	298,700 cases 10,000 deaths	306,600 cases 10,200 deaths	273,300 cases 9,800 deaths Hospital-onset : 13% increase	**SAL200**
Drug-resistant *Streptococcus pneumoniae*	12,100 infections 1,500 deaths	-	12,000 infections 1,200 deaths	-	**SPL200**

(Source : CDC. COVID-19: U.S. Impact on Antimicrobial Resistance, Special Report, 2022)

itLysin® : itLysin 부문 2023년 주요 Focus

- SAL200 Out-licensing
- BAL200 Out-licensing
- API 관련한 Technical 측면에서의 강화 (GN200, EFL200, CDL200 등)



itLysin® : SAL200

- SAL200 – Key Features to resolve the problem

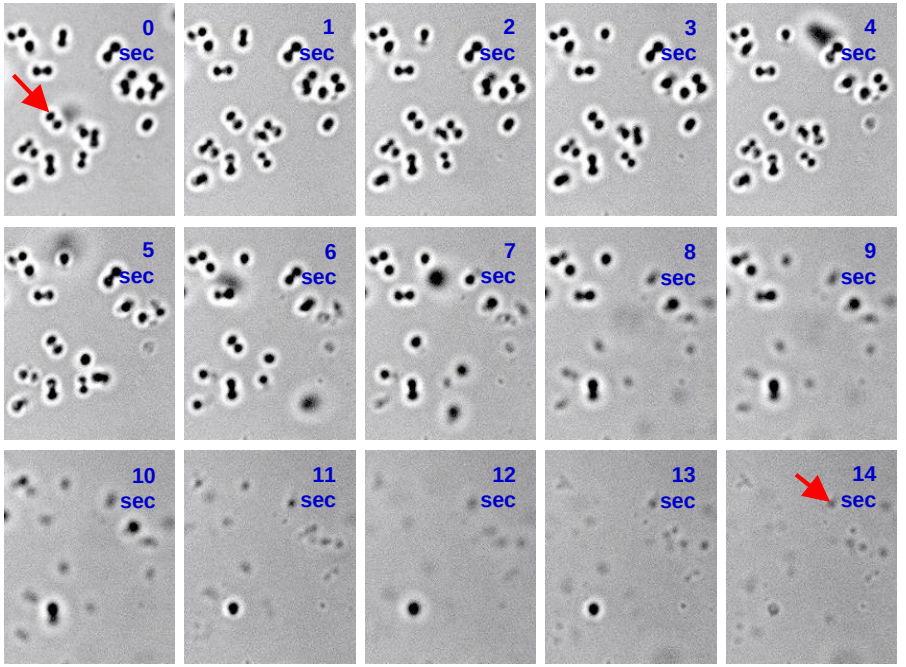
Rapid Bactericidal Activity
(No time to develop resistance)

Species Specificity
(No harm to unwanted strains)

Target Highly Conserved Sites
(Where essential to bacteria viability)

Effective against MDR Strains
(Novel MOA effective against conventional antibiotics resistance strains)

SAL200 is a potentially **First-in-Class anti-Staphylococcal biologic** with a **Novel Mode of Action**, bactericidal anti-staphylococcal activity via **cell wall hydrolysis**



itLysin® : SAL200

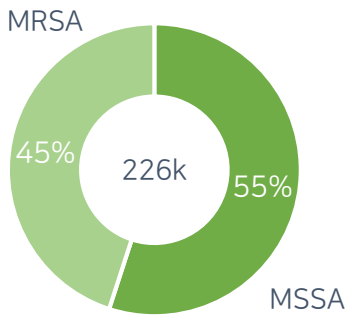
- Supported by the preclinical and clinical study results, **aspired US phase 2b indication is *Staph aureus* bacteremia including left and right sided infective endocarditis**
- A high-priority unmet medical need, provides the **quickest pathway to approval and the most attractive commercial market**
- SAL200 has significant potential **to be developed for variety of adjacent clinical areas**

Aspired SAL200 US Label Indication

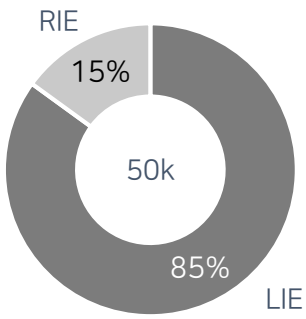
S. aureus bloodstream infections (**bacteremia**), including those with **left- and right-sided infective endocarditis**, caused by m ethicillin-sensitive and methicillin-resistant (**MSSA, MRSA**) isolates on top of standard-of-care antibiotics

Exploration of Adjacent High Medical Need Indications

Has potential to treat **opportunistic infections** (CoNS) and **adjacent SA indications**, e.g., CDI, PVE, PJI, chronic wounds, an d Cystic Fibrosis associated with S. aureus infection
Additional formulation development will be required beyond IV



SAB



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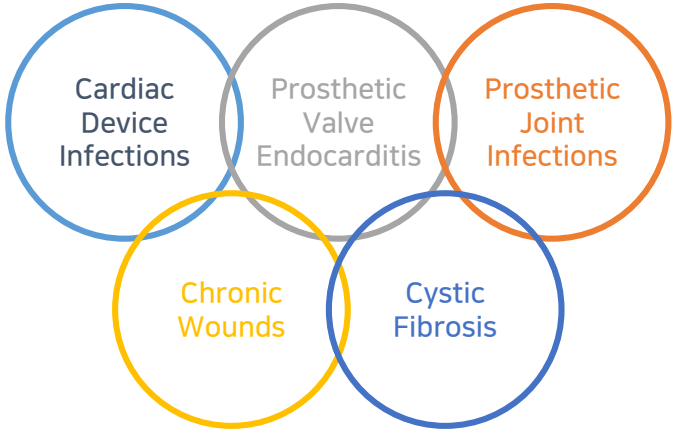
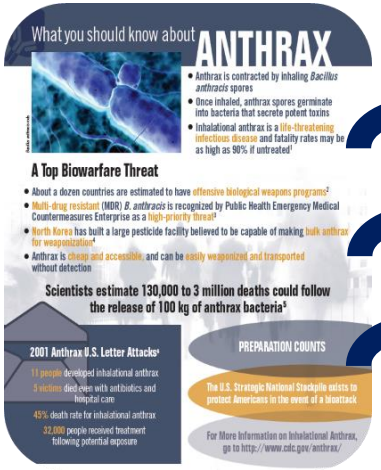


Anthrax is Ongoing Threat



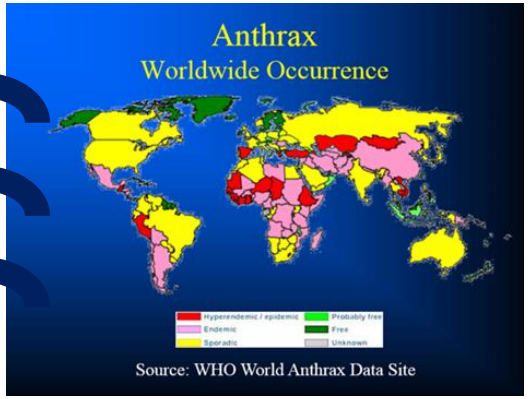
Bioterrorism

According to the Centers for Disease Control and Prevention (CDC), anthrax is "one of the most likely pathogens" in the event of a biological attack.

- Anthrax is easy to find in nature and easy to grow in the labs
- Attacks would be hard to detect
- Previously used as a weapon

Anthrax Natural Occurrences

- Approximately 2,000 ~ 20,000 cases of anthrax occur each year.
- Anthrax is considered a rare disease, but that may not be the case anymore. According to recent BBC news, long-frozen anthrax is being discovered as the Arctic ice melts. This poses a potential risk.



The Limitations of Current Available PEP Antibiotics

- **Post-exposure prophylaxis (PEP)** can be provided to prevent inhalational anthrax after a known exposure to *B. anthracis* spores. Four **antibiotics** approved by the FDA : doxycycline, ciprofloxacin, levofloxacin, and parenteral procaine penicillin G
- The current PEPs are small molecule-based antibiotics
- The MoA of small molecule antibiotics is dependent on **bacterial metabolism** and is **inhibitory**. Therefore, the **development of resistance** to these antibiotics is rather easy
- Additionally, the activity of these antibiotics are bacteriostatic or pseudo-bactericidal, making them **very ineffective at removing infecting bacteria** from the body
- More seriously, these antibiotics **don't work effectively** against **PEP-resistant strains** and **don't work at all** against **artificial resistant strains**
- These characteristics of current small-molecule PEP antibiotics are undesirable

itLysin® : BAL200

- BAL200 is a **bacteriophage-derived biologic** and the API of BAL200 is an **engineered endolysin** (26.5 kDa) that can lyse the *B. anthracis* cells

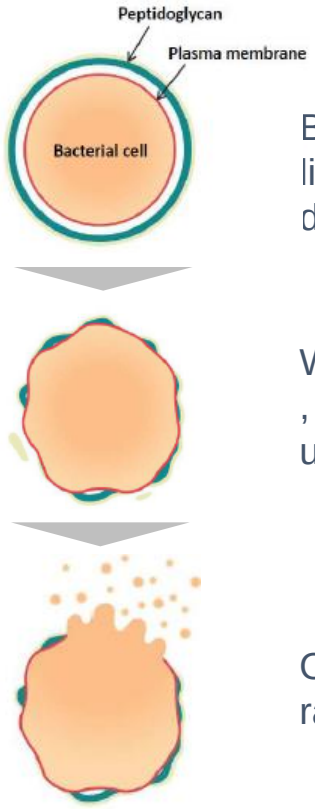
- Thus, BAL200 is effective for the treatment of Bacillus infections including anthrax (i.e., *B. anthracis* infection) and can provide **rapid and potent bactericidal (i.e., bacteriolytic) activity** *via* cell wall hydrolysis against PEP-sensitive and - resistant *B. anthracis* strains

Differentiated Features of BAL200 over Current PEP Antibiotics

	BAL200	PEP Antibiotics
Drug Type	Biologics	Chemical
Mode of Action	Lysis of cell wall (Strong bactericidal)	Inhibition of biological cellular action
Targeting Ability	Non-stoichiometric	Stoichiometric
Harm on Eukaryotic Cell	No effect	Effect
Against Antibiotic-resistant Strains	Effective	Not Effective
Time to be Effective	Rapid	Slow
Rapid Clearance of Infecting Bacteria from the Body	**Yes**	**No**
Resistance Development	**Significantly Low**	**High**

Rapid Clearance of Infecting Bacteria from the Body

- **Novel Mode of Action** provides strong bacteriolytic activity against a various strains of B. anthracis and could rapidly kill the B. anthracis cells **within minutes**

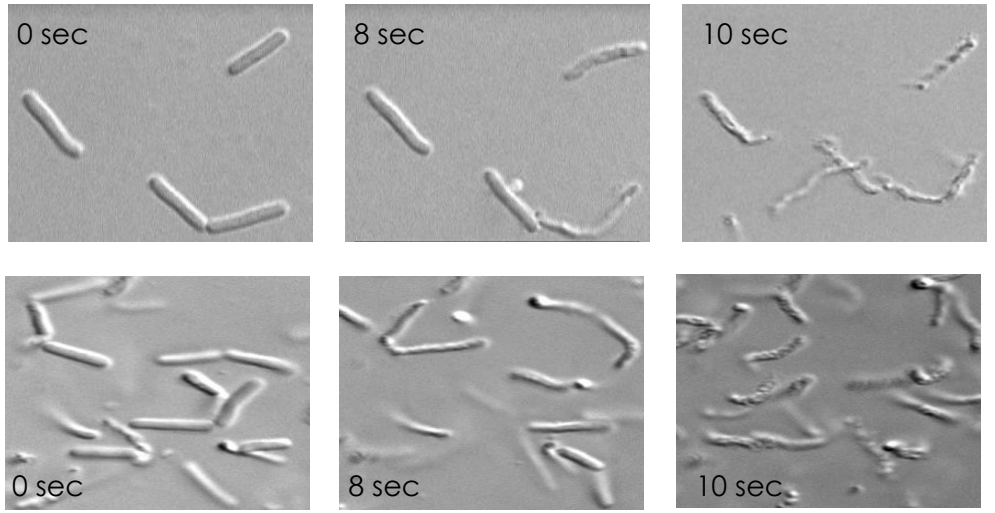


BAL200 breaks down the linkages in bacterial peptidoglycan

Without an intact cell wall, the rigid bacterial structure is lost

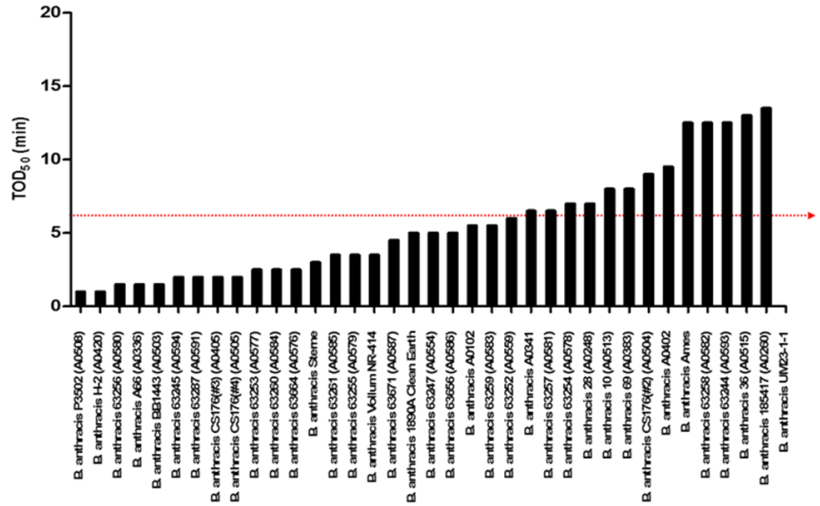
Osmotic pressure causes rapid bacterial cell lysis

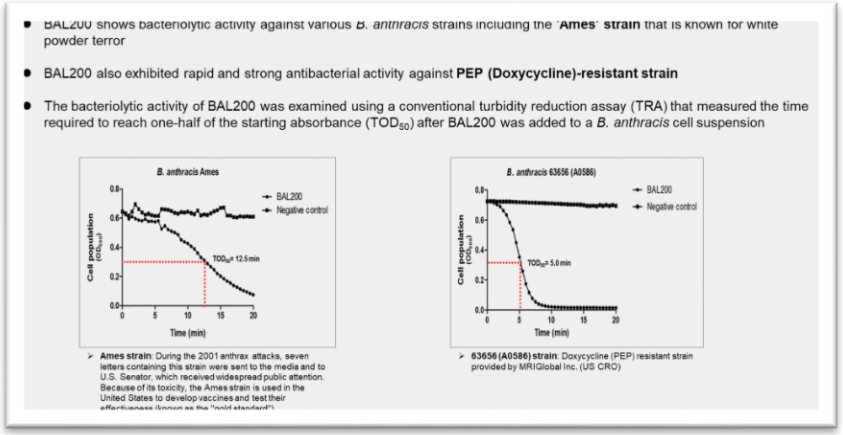
Potent and complete lysis



"Efficacy Test 완료"

- **The efficacy of BAL200 against broad types of anthrax strains is confirmed**
- The TOD_{50} values were determined with 39 *B. anthracis* strains and average value is 5.7 minutes



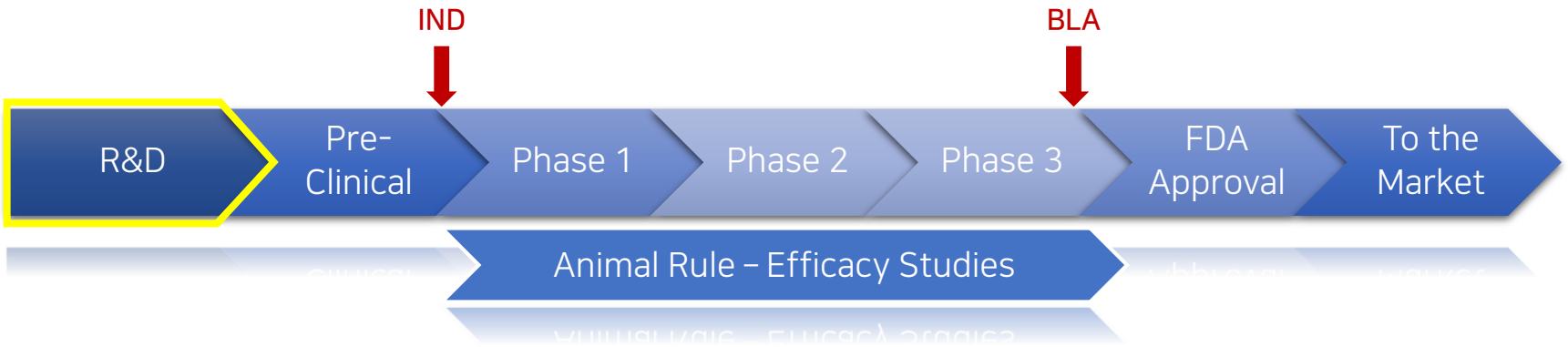


GLP-Package Done → BAL200 Efficacy Test Done → L/O 추진

itLysin® : BAL200

Under the Benefits of Animal Efficacy Rule for BLA

- **BAL200 is eligible to expedite it's development**
- In the aftermath of 9/11 in 2001, FDA enacted "Animal Efficacy Rule" to expedite the approval of anti-terrorist countermeasures



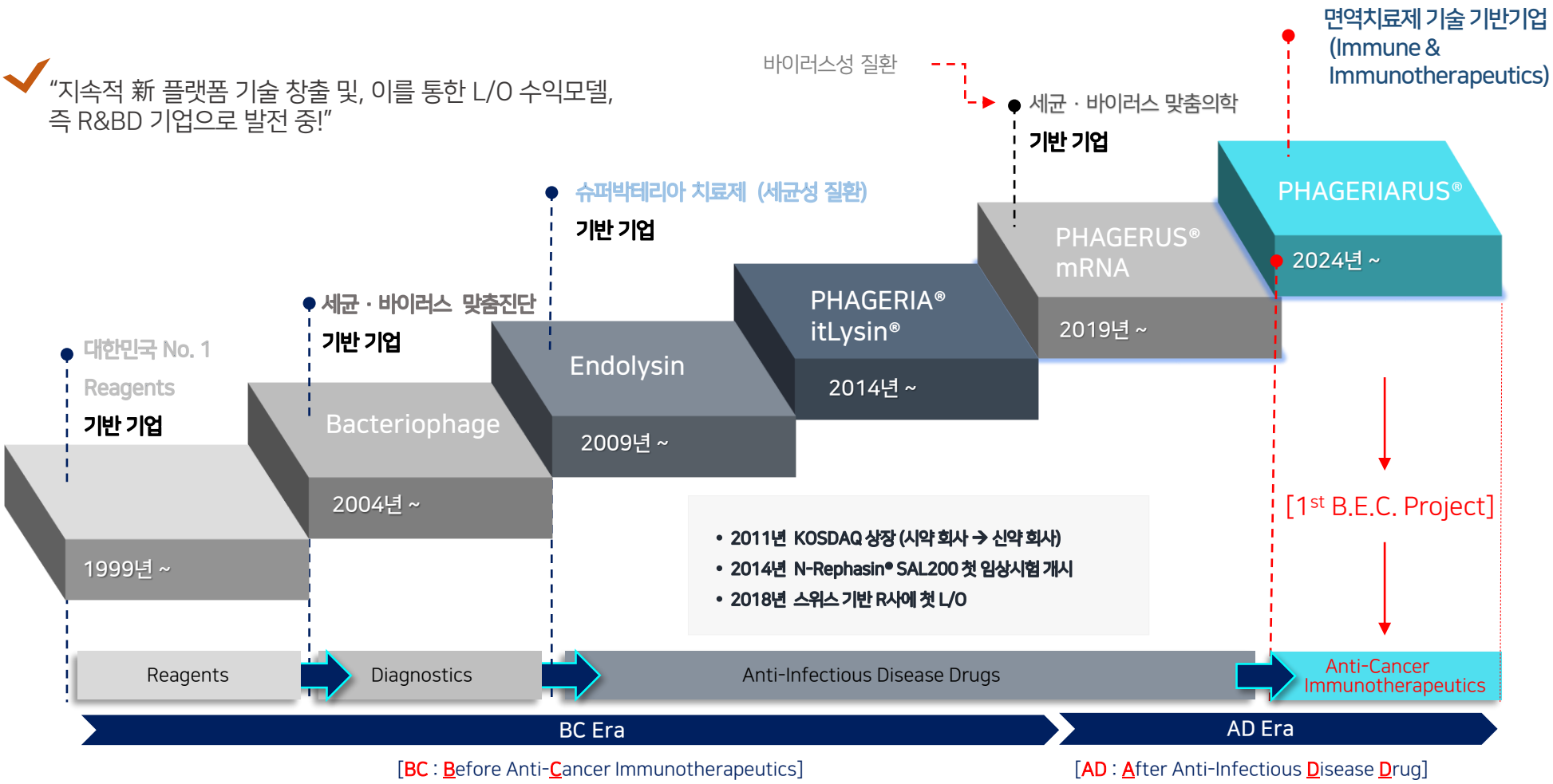
Orphan Drug Designation Granted by US FDA

- BAL200 is expected to have various benefits from Orphan Drug Designation (ODD) in the regulatory pathway for the final approval
- The US FDA has granted **ODD** to BAL200 for the treatment of inhalational anthrax in Jun. 2018.
- The ODD status grants sponsor of the drug for various **development incentives including tax credits for qualified clinical trials**

신약개발 R&BD Platform Roadmap

5년 주기로 지속적 신약 개발 Platform 확장

"지속적 新 플랫폼 기술 창출 및, 이를 통한 L/O 수익모델,
즉 R&BD 기업으로 발전 중!"



[BC : Before Anti-Cancer Immunotherapeutics]

[AD : After Anti-Infectious Disease Drug]

요약 재무제표

Company Profile (개별 기준)

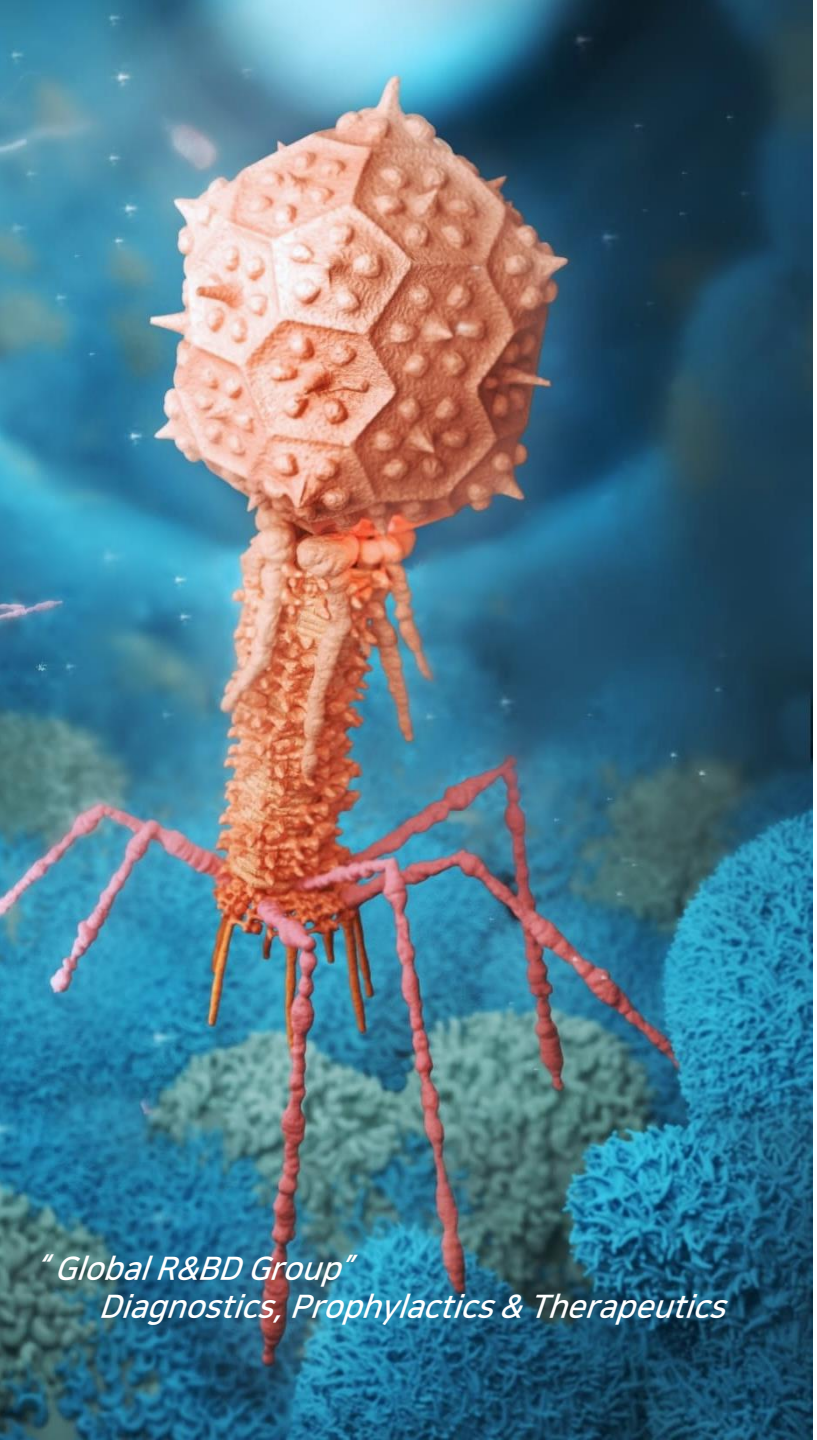
단위: 백만원

구분	2019	2020	2021	2022 3Q
유동자산	73,487	79,982	124,268	121,446
비유동자산	15,769	21,249	29,868	26,171
자산총계	89,256	101,231	154,135	147,617
유동부채	4,671	12,700	33,251	31,491
비유동부채	19,338	2,453	18,762	2,916
부채총계	24,009	15,153	52,014	34,408
자본금	15,989	16,574	16,898	17,075
자본잉여금	62,622	67,737	73,603	80,978
기타자본구성요소	(1,967)	(1,967)	(1,967)	(6,857)
이익잉여금(결손금)	(11,398)	3,734	13,586	22,012
자본총계	65,246	86,078	102,121	113,209

손익계산서 (개별 기준)

단위: 백만원

구분	2019	2020	2021	2022 3Q
매출액	8,347	45,433	29,308	11,572
매출원가	4,548	18,900	7,536	3,358
매출총이익	3,800	26,533	21,772	8,214
판매비와관리비	7,952	10,479	11,478	8,577
영업이익(손실)	(4,153)	16,054	10,294	(363)
금융수익	4,636	8,768	3,631	18,968
금융비용	2,349	5,926	3,135	6,741
영업외수익	205	428	97	125
영업외비용	153	1,923	96	70
법인세비용차감전 순이익	(1,814)	17,402	10,791	11,920
법인세비용(이익)	1,273	2,103	847	2,641
당기순이익(손실)	(3,087)	15,299	9,944	9,279


" Global R&BD Group"
Diagnostics, Prophylactics & Therapeutics

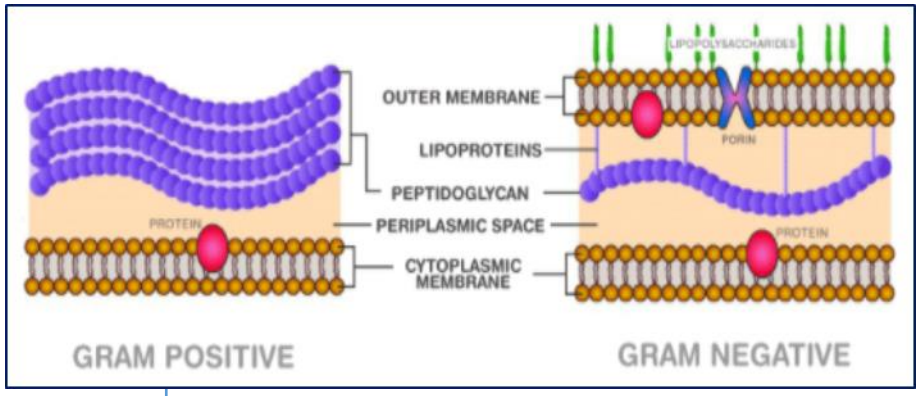
APPENDIX

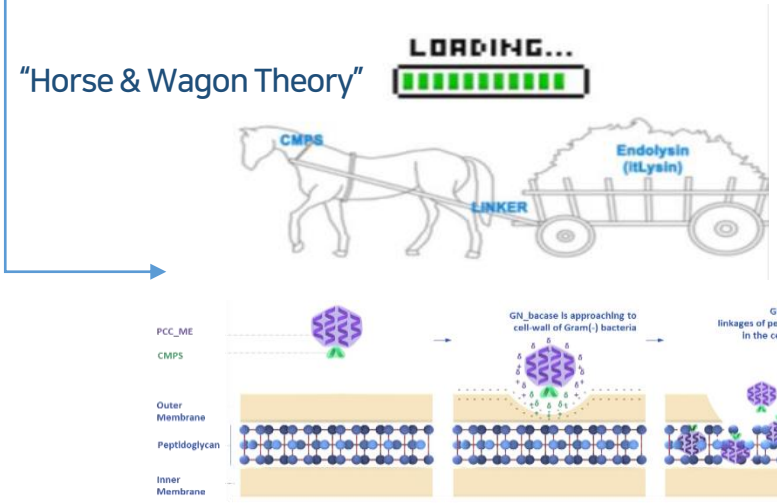
itLysin® Platform Technology : Case1 (GN200 Series)

GN200 Series Gram(-) itLysin®

Horse & Wagon Theroy

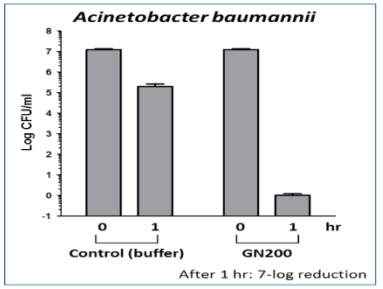
기존의 정설 "Endolysin → Gram(-) No Activity"를 깨는 획기적 플랫폼

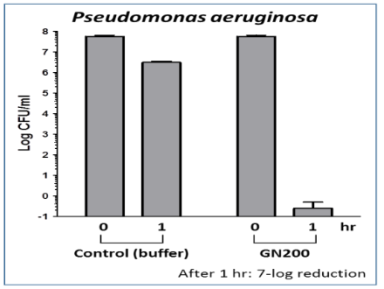




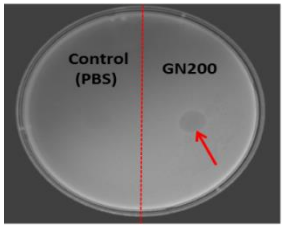
Major GN200 Series Target

- *Acinetobacter baumannii*
- *Pseudomonas aeruginosa*
- *Klebsiella sp.*

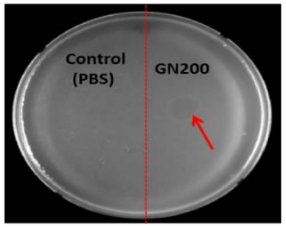




Acinetobacter baumannii (CCARM 12226)

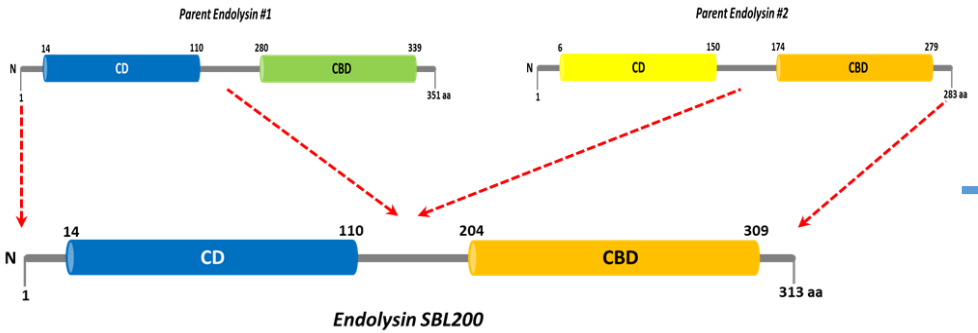


Pseudomonas aeruginosa (PA01)

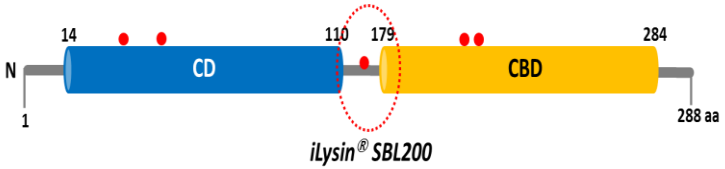


itLysin® Platform Technology : Case2 (SBL200)

Native Endolysin

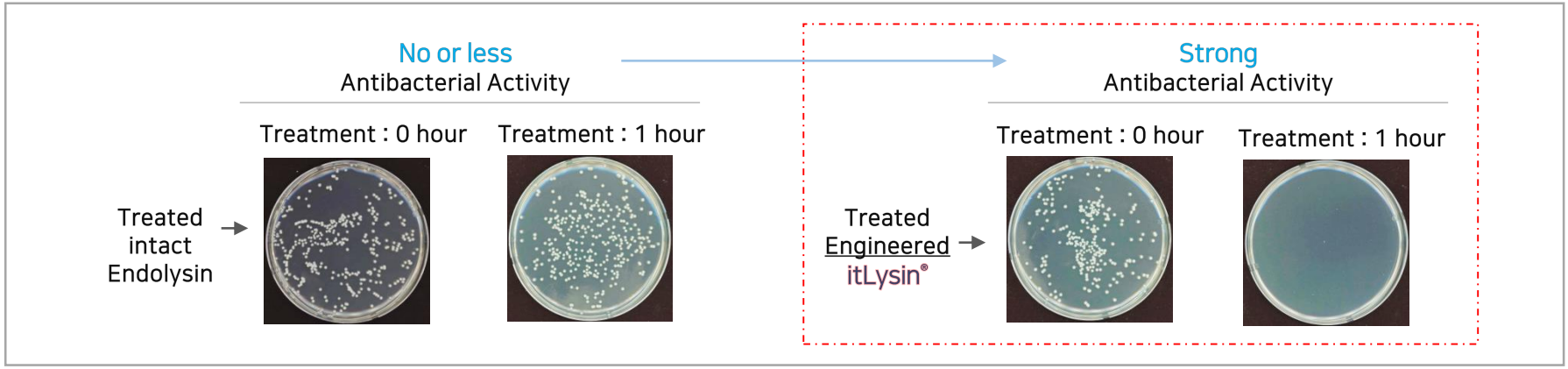


Engineered itLysin®

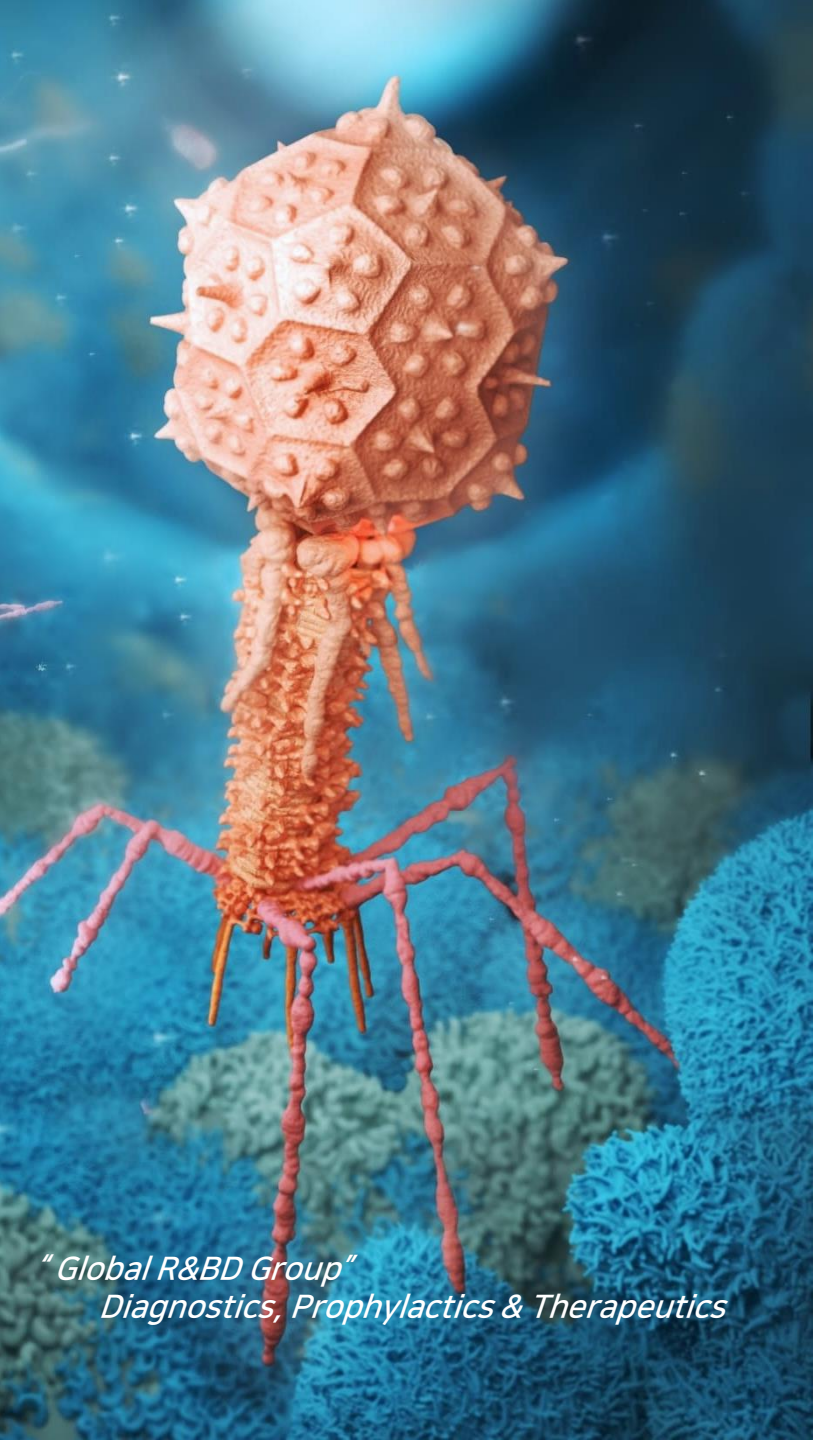


Example of itLysin® technology

◆ Strengthen the Natural Property of Endolysin



Milk 속에서 활성이 유지되지않았던 Endolysin → 높은 활성의 Engineered itLysin®으로 재탄생



Thank you!
it is iNtRON.

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