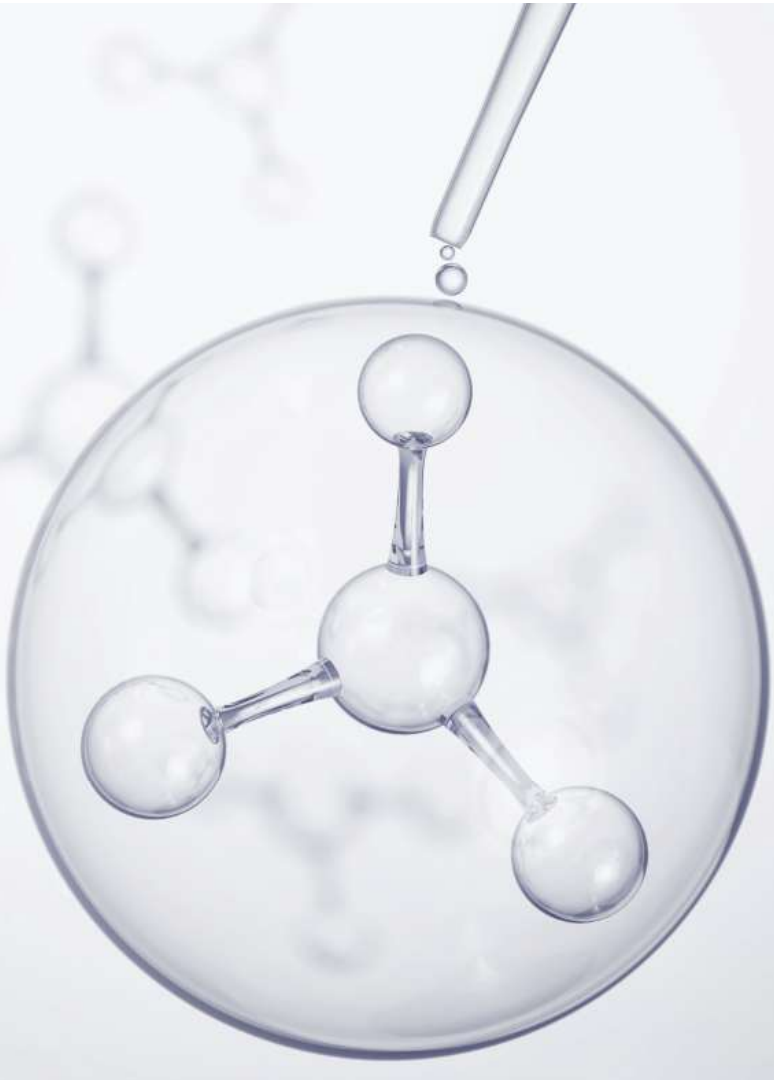
No.1 CRO & the Most Trusted Partner for
Asian Bio Companies

HLB bioStep



HLB bioStep

1 Overview

HLB bioStep,

A leading Korean Non-clinical CRO in Efficacy Studies with a Veterinary Speciality

We are offering CRO services to our clients based on our extensive experience in non-clinical testing and cutting-edge medical imaging equipment.
Since our inception in 2012, fueled by relentless research and a spirit of challenge, we have firmly positioned ourselves as the leading non-clinical CRO in efficacy testing, making significant contributions to the advancement of the bio industry in Korea.

Name	HLB bioStep Co., Ltd.
CEO	MOON Jeong Hwan
Founded	May 1, 2012
Capital	KRW 8.6 billion
Business	Non-clinical Service, Bio-infra
Employees	170+
Location	38, Academy-ro 79beon-gil, Yeonsu-gu, Incheon, Korea

2 History

2012

Registered lab animal facility
Apr. 2012

Founded
Apr. 2012

2013

Licensed for LMO research facility
Feb. 2013

2015

Certified R&D center
May 2015.

2016

Acquired Saeron Bio and VS Pharm
Dec. 2016

Created Lab Consulting Dept.
May 2016

Changed company name (KAMSI → KNOTUS)
May 2016

2019

Listed on KOSDAQ
Nov. 2019

Opened Lab in Songdo
Mar. 2019

2020-2021

Designated as an institution for dinical trials of animal drugs
Dec. 2021

Opened Medical Training Center
Oct. 2021

Designated as an institution for non-dinical trials of animal drugs
Sep. 2020

2022

Designated Domestic medical device training center by Govn't
June 2022

Acquired by HLB Group
Mar. 2022.

2023-2024

Acquired HLB bioCode Inc. (GLP Toxicology firm)
May 2024

Opened Bioanalysis Center
Nov. 2023

Changed company name (KNOTUS → HLB bioStep)
Mar. 2023

Permitted Facility for Non-Human Primates
Nov. 2023

3 Business

HLB bioStep

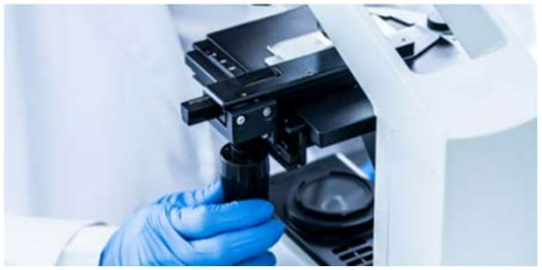
No.1 CRO & the Most Trusted Partner for Asian Bio Companies

Chapter 1. CRO Services

01. Efficacy
02. Toxicology
03. Bioanalysis

1 A Leading Non-clinical CRO in Korea

Maintaining a solid competitive edge through experimental experience, expert personnel, and advanced facility and equipment



Vast Study Experience

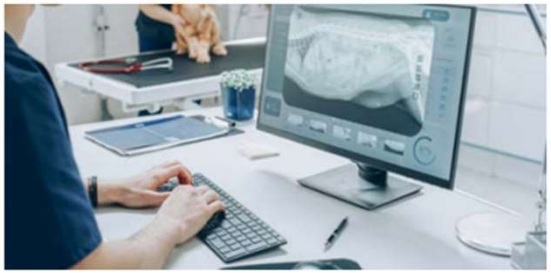
Most extensive domestic experience in efficacy studies

☑ Core competitiveness for non-clinical CRO

Expert Personnel

Largest pool of Veterinarians in Korea

☑ Specializing in veterinary ophthalmology, surgery, pathology etc.



Large Animal Models

Conducting high-difficulty studies

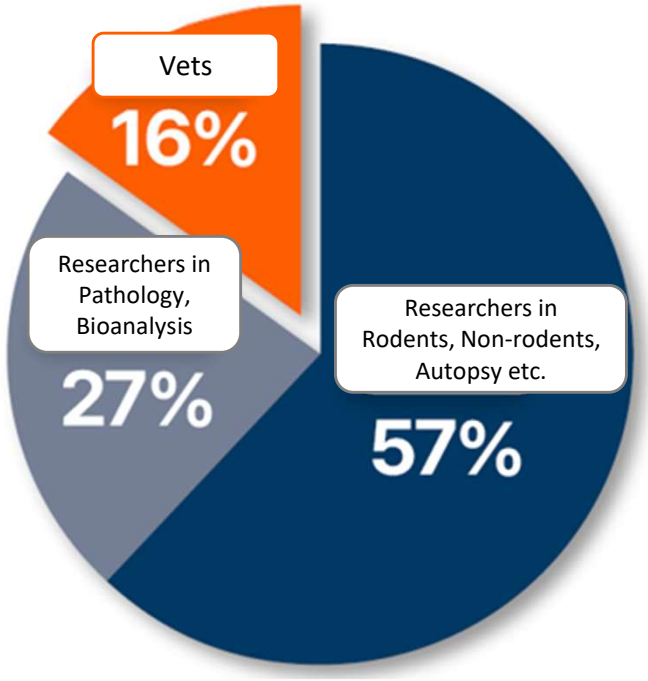
☑ Beagle dogs, pigs, goats etc.

Advanced facility and equipment

Large-scale surgical facilities and diagnostic imaging equipment

☑ Accurate analysis and diagnosis using MRI, CT, X-ray, and IVIS

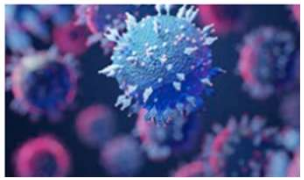
Possess an Overwhelming Number of Efficacy Experts Compared to Competitors



* 111 Researchers (as of May, 2024)

2 High-quality Diagnostic Imaging Equipment

Securing accuracy and reliability of test results through visualizing the results

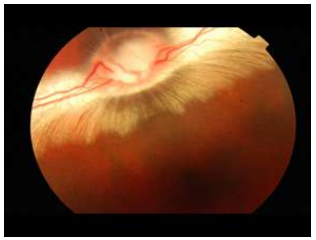


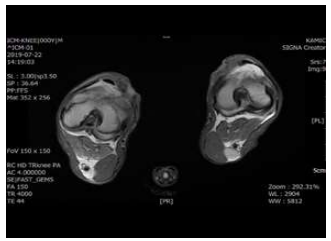
Ability to produce animal disease models

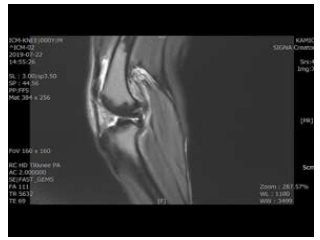
Veterinary management of animal disease models

Differentiated services based on diagnostic imaging equipment

Having diverse and comprehensive experimental capabilities ranging from rodents to large animals







3 Efficacy Services

Efficacy Study

Cancer	• Xenograft • Syngeneic • Orthotopic
In-vitro	• Oncology • Immunology Research • Metabolic Health • Skin care • Neurology • Customized in-vitro experiment service
Endocrine & Metabolic Disease	• Ovariectomy (OVX)-induced climacterium • db/db mouse (DM type II), STZ (Streptozotocin) (DM typeI) • HFD (High fat diet)/HCD (High cholesterol diet)induced hyperlipidemia • Sodium taurocholate induced pancreatitis
Neurologic Disorder	• Stroke (Middle cerebral artery occlusion) • Thomboembolic infraction • Alzheimer's disease (APP/PS1 TG, 3xTg, 5xFAD mouse) • Charcot-Marie-Tooth disease (CMT)
Dental Disease	• Ligation (w/LPS) induced periodontitis • Beagle mandibular defect
Ocular Disease	• Dry AMD (Sodium iodate induced AMD) • Wet AMD (Laser-induced choroidal neovascularization) • Benzalkonium-induced dry eye • LPS induced uveitis • STZ induced diabetic retinopathy • Dexamethasone induced glaucomal
Gastrointestinal Disease	• EtOH or NSAID induced gastritis • Reflux esophagitis • Shay rat • Lumen perforated rat (LPR) • Heidenhain pouch dog (HPD) • DSS induced IBD
Liver Disease	• CCl_4-induced liver fibrosis • MCD or CDAHFD-induced MASLD/MASH • MDR2 knockout mouse liver disease (Fibrosis, MASLD) • Bild duct ligation induced liver cirrhosis
Bone Disease	• Monosodium Iodoacetate-induced OA (Osteoarthritis) • Collagen-induced OA • ACLT (Anterior cruciate ligament transection) +meniscectomy OA • OVX (Ovariectomy)-induced osteoporosis

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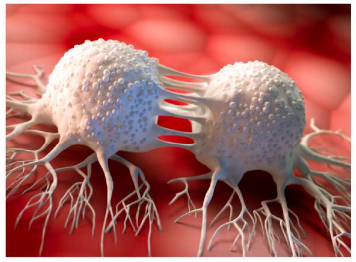
3 Efficacy Services

Efficacy Study

Kidney Disease	• Cisplatin induced acute renal failure • Adenine induced chronic kidney disease • Unilateral ureteral obstruction
Cardiovascular Disease	• Hepatectomy or splenectomy induced hemorrhage • TAC (Transverse aortic constriction) • Myocardial infarction • Apolipoprotein E knockout ($ApoE^{-/-}$ KO) mouse arteriosclerosis • Tail bleeding mouse
Skin Disease	• AD cream induced atopic dermatitis in NcNga mouse • Wound healing • Psoriasis
Respiratory Disease	• Idiopathic pulmonary fibrosis (IPF) • Asthma • LPS induced ARDS • Mouse expectorant • Guinea pig antitussive
Pain	• Chronic constriction injury (CCI) • STZ induced diabetic peripheral neuropathy • PBQ induced systemic pain • Spinal cord injury (SCI) • Carrageenan induced paw edema
Hair Growth	• Catagen phase (Dexamethasone, DHT, corticosterone, testosterone) • Anagen phase

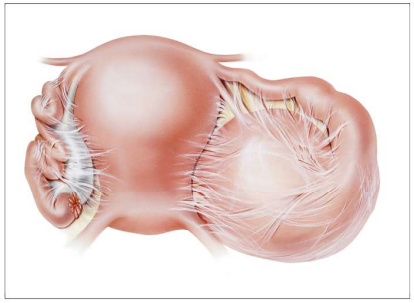





3 Efficacy Services

Medical Device

Bone Graft Materials	• Beagle mandibular defect • Rat calvarial defect	**Skin Care Medical Devices**	• HIFU (High intensive focused ultrasound) • Filler
Anti-adhesion Agent	• Rabbit laminectomy • Intra-abdominal blunt trauma • Operative incision	**Operation / Intervention Medical Devices**	• Laparoscope • Robotic medical device • Vascular sealing device
Wound Dressing Materials	• Rabbit laminectomy • Intra-abdominal blunt trauma • Operative incision	**Biodegradation / Residual Study**	• Suture • Anti-adhesion agent • Filler
Hemostatic Agent	• Mini-pig ESD, EMR • Operative perforation	**ETC**	• Evaluation requiring surgical procedure • Customized consultation services

4 GLP Toxicology Services

Acquired a CRO with GLP Facility to expand market-leading capabilities and non-clinical CRO services

GLP certifications for various test items from KFDA, Ministry of Environment, Animal & Plant Quarantine Agency

Single Dose Toxicity(non-rodents), Repeated Dose Toxicity (non-rodents), Local toxicity (Eye Irritation Test), Repeated Dose 90-day Oral/Dermal Toxicity Study, Repeated Dose Toxicity (rodents), Genotoxicity study etc.

Entire process of non-clinical studies, including Clinical trial IND support

[HLB bioStep] Efficacy studies + **[HLB bioCode]** GLP Toxicology studies → **One-stop Service**

Able to conduct non-clinical studies from efficacy to GLP toxicology studies with the highest quality, expertise and speed

4 GLP Toxicology Services

HLB바이오코드와 유기적인 Co-work 통한 비임상 시험 퀄리티 극대화

- 양사 간 시험데이터 공유로 정확한 독성 시험디자인 설계

GLP 인증현황

환경부

인증 항목 (9개)

- 피부자극성 및 부식성 시험
- 눈 자극성 및 심한 눈 손상시험
- 급성 경구 독성 시험
- 급성 경피 독성 시험
- 박테리아를 이용하는 복귀돌연변이시험
- 포유류 배양세포를 이용하는 염색체이상시험
- 포유류 골수세포를 이용하는 소핵시험
- 90일 반복 경구투여 독성 시험
- 90일 반복 경피투여 독성 시험

식품의약품안전처

인증 항목 (8개)

- 단회 투여 독성시험 (설치류 및 비설치류)
- 반복 투여 독성시험 (설치류 및 비설치류)
- 체내 염색체 이상 및 소핵시험
- 체외 염색체 이상 및 소핵시험
- 복귀돌연변이시험
- 안점막 자극시험

농림축산검역본부

인증 항목 (11개)

- 급성독성시험 (설치류 및 비설치류)
- 아급성독성시험 (설치류 및 비설치류)
- 만성독성시험 (설치류 및 비설치류)
- 세균을 이용하는 복귀변이시험
- 포유류 배양세포를 이용하는 염색체이상시험
- 설치류를 이용하는 소핵시험
- 피부자극성 시험
- 안점막자극시험

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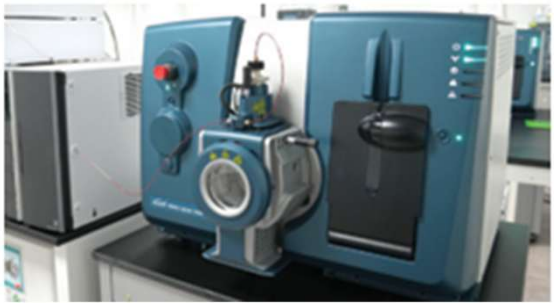
5

Bioanalysis Services

Providing differentiated analytical services through advanced analytical equipment and analytical methods

Items	Techniques
Absorption, Distribution, Metabolism, Excretion (ADME)	LC-MS/MS
Drug Metabolism and Pharmacokinetics (DMPK)	HPLC-UV
Toxicokinetics	Real Time PCR
Dose Formulation Analysis	Ligand Binding Assay
Biomarkers	Flow Cytometry

Regulatory Bioanalysis Meet the Experts



LC-MS/MS

Automated liquid Handler

Flow Cytometry

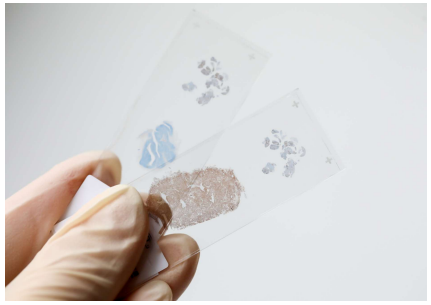
6 Bioanalysis Services

Pathology

Pathology	• Necropsy (Rodent, Non-Rodent) • Slide Preparation (Tissue Trimming, Tissue Processing, Tissue Embedding, Tissue Sectioning) • Staining (Routine H&E Stain, Special Stain, Immunohistochemistry) • Microscopic Observation (Pathology Report, Peer Review) • Digital Imaging Service (Scanning, Image analysis) • Confocal Laser Scanning Microscopy (CLSM) Services	**Clinical Pathology**	• Hematology and differential counts (Measure CBC, WBC, PLT and Reticulocyte count, etc.) • Coagulation tests (PT, APTT, Fibrinogen) • Blood chemistry test (General List : TP, AL, B, AST, ALT and other parameters related to efficacy (e.g., HbA1c)) • Urinalysis • Hormone tests

Pharmacokinetics / Toxicokinetics

Pharmacokinetics Study	• In vivo ADME studies : Various species (Dog, Rat, Mouse, Rabbit, Miniature pig, etc.) • Customized study design as per client's needs • Analysis service of substances and metabolites in plasma, urine, feces • Analysis service of biological samples including method development and validation



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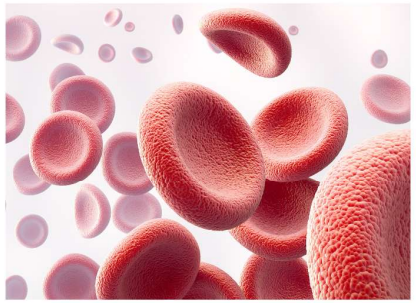
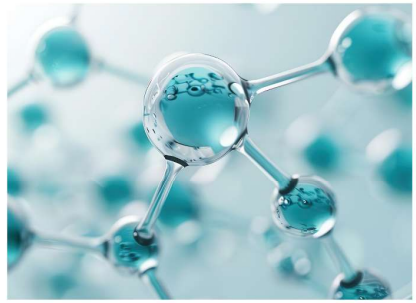
6 Bioanalysis Services

Biological Analysis

Mass Spectrometry	• Small molecules • Biotherapeutics • Peptide • Fusion peptide • Biomarkers	**Flow Cytometry**	• Immune cell phenotyping • Immune cell functional assay • Cell cycle analysis • Cell apoptosis assay • ROS assay • Cytometric bead array • Biomarker quantification • Nuclear antigen quantification
Bioanalysis Service	• DMPK Studies • Non-GLP TK (Toxicokinetics) Studies • Analytical Method Development and Validation Studies	**Molecular Biology**	• Protein : Ligand binding assay, ELISpot • Gene (DNA & RNA) : Real time PCR (Gene expression & Biodistribution)



Chapter 2. Bio-infra

Optimizing Lab for Efficiency & Productivity

Securing a sustainable revenue structure through consulting, construction, maintenance, and supply of equipment and consumables

Consulting

Design

Construction

T.A.B

Testing, Adjusting &Balancing

Fumigation

Maintenance

Equipment

Validation

Chapter 3. New Growth Engine

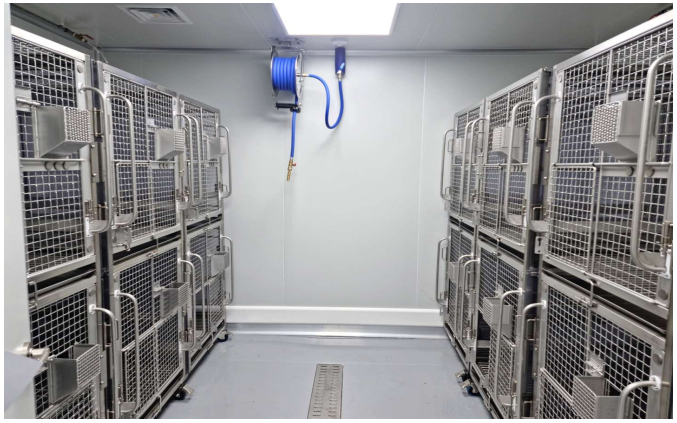
1 Non-human Primate Study (NHP)

Building an efficacy study portfolio covering all ranges from small animals to primates

- ☑ **Approved NHP research facility** (by Ministry of Environment, 2023)
- ☑ **Capacity of housing to 24 Cynomolgus monkeys**
- ☑ **Hired experts in NHPs** (vets etc.)
- ☑ **Established system of Pharmacokinetics(PK) study on NHPs**

Development of various disease models → **Expanding the range of NHP study service**

NHP Facility



2 Nonclinical Studies in line with the latest trends in pharmaceutical development

50+

mRNA

Vaccines, Therapeutics, Delivery Platforms etc.

100+

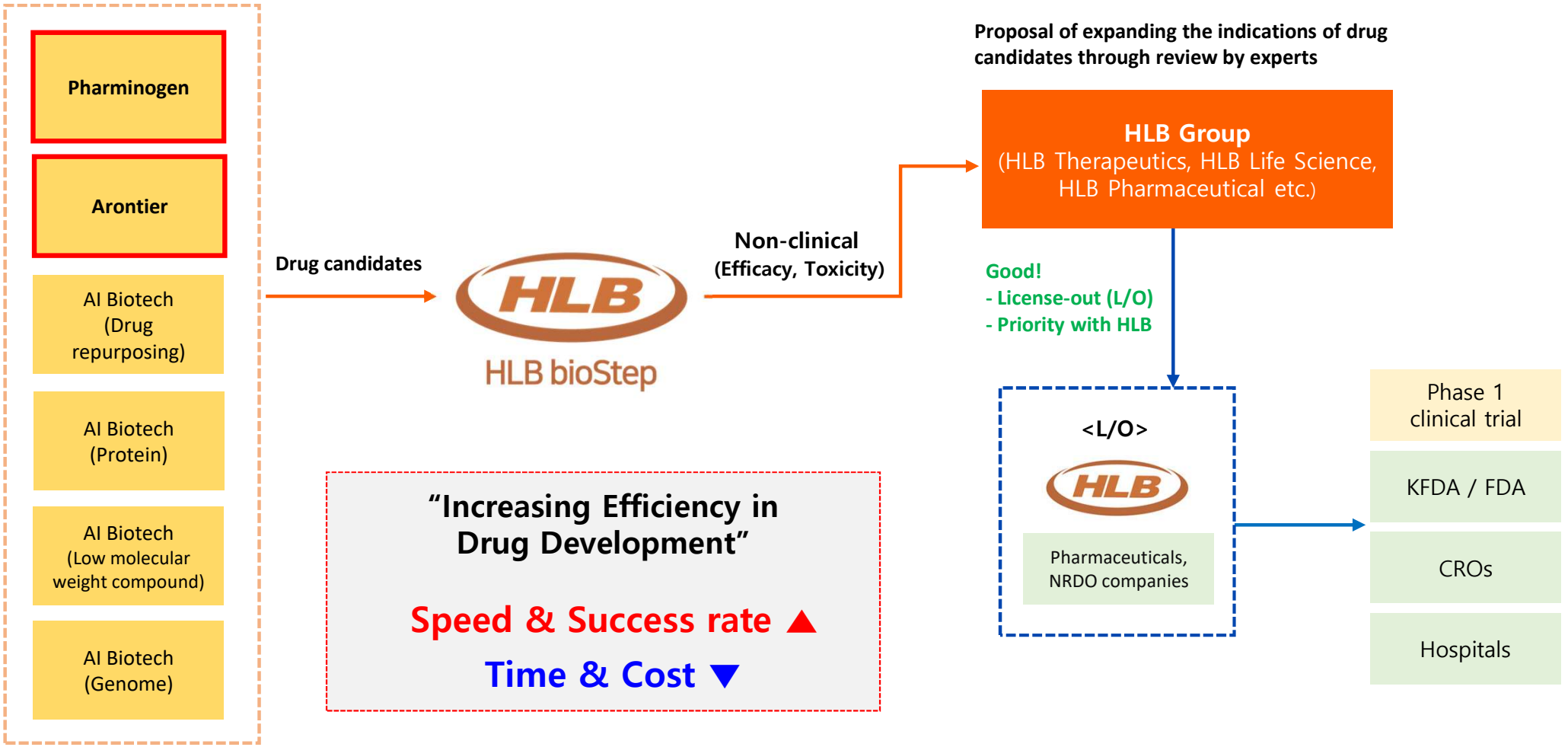
Vaccine & Influenza

Dengue, Influenza, Respiratory Infections etc.

- ✓ **Proposing Optimized Evaluation Methods Based on Extensive Testing Experience and Data**
- ✓ **Providing Services Across a Wide Range of Animal Species, from Rodents to Large Animals**

3 HLB Group AI-driven Drug Development Platform

Collaborating on accelerating AI-driven drug development from the exploration of promising candidates to Phase 1 clinical trials



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4 Future Business Plan

Continuous efforts to expand business areas and discover various new growth drivers

New efficacy evaluation model 01

- Preemptive development of evaluation models in line with the latest drug development trends (ex. mRNA, ADC etc.)

☑ **Increase in new experiment orders due to establishment of new models → Revenue growth**

Alternative Test Model Development 02

- Development of human cell-based organoid evaluation system and PDX model through collaboration
- Expansion into areas such as artificial tissues/organs, cell processing, organ-on-a-chip, etc.

☑ **Models to secure the best results by minimizing animal study**

Overseas CRO Collaboration 03

- Receiving cooperation proposals from international non-clinical CRO companies located in various regions (India, Australia, China, etc.)

☑ **Collaborating with overseas non-clinical CRO companies to ensure competitive service offerings.**

Entering Global Market 04

- Commencement of full-scale global marketing based at the Boston Cambridge Innovation Center (CIC)
- Utilization of overseas subsidiary networks
- Expansion of overseas CRO partnerships

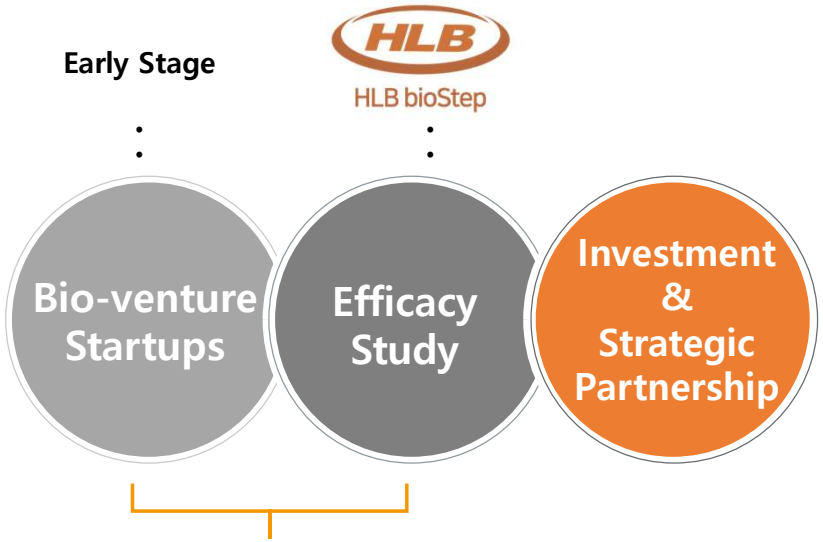
☑ **Securing recognition and acquiring clients in the global market**

Chapter 4.
Investment & Cooperation

1 Discovery of Future Growth Engines through Investment

Investment in various companies developing medicines, vaccines, diagnostic instrument, veterinary drugs etc.

Investment strategy based on CRO service



Early-stage investment in high-tech and marketable startups

Assessing growth potential through efficacy study

Offering CRO service, Direct investment

Exploring and jointly planning for exclusivity of new drugs and medical devices

Investment Status

20 Bioventures, 7 Investment consortiums
KRW 41.7 bilion in total

Company	Business
NextBioMedical	Development of powder-form endoscopic hemostatic agents
Inventage Lab	Development of long-lasting injection
LISCure Biosciences	Development of a microbial-based immunotherapies
Mepsgen	Drug development through human organ chip platform technology
Moogene Medi	Development of gene editing and drug delivery technologies
HLB Science	Development of sepsis and dementia treatments
HLB Innovation	Semiconductor and CAR-T research and development
HLB Panagene	Development, manufacturing, and sales of PNA genetic diagnostic products
Progeneer	Development of immune-enhancing agents

2 Key Contribution Achievement

FDA Approval

FDA clears Medtronic Nexpowder endoscopic hemostasis system (2022.09)

NEXT BIOMEDICAL

혁신형 치료제품 전문기업인 ㈜넥스트바이오메디컬(대표이사 이돈형)은 최근 내시경용 지혈재 제품인 Nexpowder(넥스파우더)의 미국 판매를 위한 FDA승인을 취득했다고 20일 밝혔다

Nexpowder(넥스파우더)는 위장관 내 출혈 시 내시경을 통해 출혈부위에 분말 형태로 도포되는 지혈재로 국내 신의료기술 인증을 받은 넥스트바이오메디컬의 독자적 개발 제품이다. Nexpowder는 기존 제품과 달리 신규 물질로 이루어진 신규개발 제품이다.

지난 2020년 9월 FDA허가 신청 후 2년여만에 승인을 완료함으로써 그 의미가 남다르다고 할 수 있다. 2년여 동안 한국과 유럽 임상 결과 (총 365명 환자의 임상), 대규모 고난이도 대동물 전임상(㈜노터스에서 진행) 결과, 생물학적 안전성 시험(GLP) 등과 같은 140여건의 자료를 제출했다.

회사관계자에 따르면 "분말형 내시경 지혈재는 현재 주로 사용되고 있는 지혈 기구를 대체 및 보완할 수 있는 혁신형 제품으로, 경쟁 제품 대비 우수한 지혈 효과와 사용자 편의성으로 인해 독점적 시장 점유율을 기대하고 있으며, 혈액이 있어야 작용하는 타사 제품과 달리 Nexpowder는 수분에 의해 점착성 하이드로겔을 형성함으로 출혈이 예상되는 병변에 선제적으로 사용할 수 있어 '출혈 예방 치료'라는 새로운 시장을 구축할 수 있다"고 밝혔다.

FDA approves ICM's IND for Phase 1/2a trial of Osteoarthritis treatment (2022.10)

ICM 아이엠

[이데일리 송영두 기자] 퇴행성 질환 유전자치료제를 개발하는 아이씨엠은 미국 식품의약국(FDA)으로부터 'ICM-203'의 임상 1/2a상 시험계획(IND)을 승인받았다고 18일 밝혔다.

아이씨엠은 지난 9월 15일 IND 패키지를 FDA에 제출했다. 이후 임상 프로토콜에 대한 일부 보완 요청을 제외하고, 전 임상 효능/독성 및 AAV 벡터 임상시료 생산공정 부분의 자료들에 대해 FDA가 수정요청 없이 그대로 승인했다는 점은 매우 이례적이라는 평가다.

김대원 아이씨엠 대표는 "이번 IND 승인은 FDA가 ICM-203의 중대형 동물에서의 골관절염 치료효능을 공식적으로 인정했다는 큰 의미가 있다"며 "AAV 벡터 임상약 생산에 필요한 고난이도 기술력을 아이씨엠이 보유하고 있음을 FDA가 확인해 준 것"이라고 평가했다.

아이씨엠의 리드 파이프라인 'ICM-203'은 AAV(아데노부속바이러스)에 치료유전자를 탑재한 유전자치료제다. 무릎 관절강에 주사해 연골 생성을 촉진하고 활막 염증을 억제함으로써 골관절염을 근본적으로 치료하는 DMOAD (Disease Modifying OsteoArthritis Drug) 후보물질이다.

한국에서 개발된 AAV 유전자치료제로서는 최초로, 지난 3월 호주에서 환자를 대상으로 임상 투여가 개시됐다. 현재까지 특별한 부작용에 대한 보고 없이 순조롭게 투약이 진행되고 있다.

Business Expansion Platform

Biotech and medtech companies

▶Process

Establishment → Discovery → Attracting Investment → Building of Lab Infrastructure → Efficacy Study → Toxicity Study → Clinical Trial

HLB bioStep

- Attracting Investment: Direct investment or connecting potential investors
- Building of Lab Infrastructure: Lab Consulting · Supply of lab animals and apparatus
- Efficacy Study / Toxicity Study: Exploring the possibility of new drug development and joint R&D

Overseas clients

Full spectrum
Non-clinical service
(Efficacy, GLP toxicology, Pathology, Bioanalysis)

HLB Bio-eco System

HLB bioStep