KOREA DRUG DEVELOPMENT FUND

BUSINESS MODEL DIAGRAM

GLOBAL BLOCKBUSTER

LICENSE OUT

START UP

Licensing Partnering for Globalization
Establish global business network and support businesses develop and sell products.

Advancing Clinical Trial
Consulting clinical development more effectively and reducing clinical attrition rate with ACT program.

Early-stage license-out opportunity focused program, data validation and bridging translational gap.

Find and support novel and innovative drug candidates from academia, biotech to pharmaceutical companies in Korea.

To increase possibility of licensing, multinational companies and KDDF issue Call for Proposals, select, invest, and manage the selected programs together.

BRIDGE TRACK

INNOVATIVE TRACK

JOINT R&D

KOREA DRUG DEVELOPMENT FUND
R&D PIPELINE

Homepage: http://eng.kddf.org/Main/

KOREA DRUG DEVELOPMENT FUND

KDDF has supported all stage of drug development with brilliant achievements. As of 2017, 20 licenses in different phases of drug development have been successfully transferred to domestic and abroad companies. Licensing deal value totaled more than 3.5 billion USD up to now.

LEAD (27)

CANDIDATE (29)

NON-CLINICAL (31)

PHASE I (116)

PHASE II (153)

FUNDING PROJECT

TOTAL (712)

Funded Project

ESTABLISHED YEAR

2011

BUDGET

Korean 158 dollars for 9 years

41

INTER-MINISTERIAL ORGANIZATION

Ministry of Science, ICT and Future Planning

Ministry of Health and Welfare

Ministry of Trade, Industry and Energy

KDDF HAS

• Top-notch proposal screening system
• Value-focused project management system
• Large pool of excellent domestic and foreign experts in different drug development field
• International and domestic networks in business development field
• More than 112 pipeline in various therapeutic areas from lead stage to clinical trial stage

41

CANCER

INFECTIOUS DISEASE

HERMATOLOGICAL DISEASE

METABOLIC DISEASE

GASTROINTESTINAL DISEASE

RESPIRATORY DISEASE

ONCOLOGY

INFLAMMATION

STROKE

DIABETES

COLON CANCER

TUBERCULOSIS

OSTEOPOROSIS

RHEUMATOID ARTHRITIS

MUCOCILIARY DISEASE

MACULAR DEGENERATION

NEURODEGENERATIVE DISEASE

NEUTROPENIA

COARCTATION OF AORTA

NASH, LIVER CIRRHOSIS

ACUTE HEART FAILURE

COPD

DIABETES

MYOCARDIAL INFARCTION

OSTEOARTHRITIS

PAIN

OSTEOPOROSIS

CORTICAL THINNING

RHEUMATOID ARTHRITIS

NEURODEGENERATIVE DISEASE

OSTEOPOROSIS

DIABETES

PAIN

OSTEOPOROSIS

PAIN

OSTEOPOROSIS

PAIN

OSTEOPOROSIS

PAIN

OSTEOPOROSIS

PAIN
**KOREA DRUG DEVELOPMENT FUND**

- KDDF is the Best Gateway to license-in blockbuster drug candidates from Korea.
- KDDF’s R&D pipeline comes from multi-institutions such as academia, hospitals, research institutions, biotech and pharmaceutical companies.
- The pipeline covers all stage of drug development from lead to clinical stage.
- KDDF’s selection process and project management comply with global standard.

**PROPOSAL**

- Proposal: Every three months, projects from academia to companies are proposed to KDDF.

**APPLICANT PRESENTATION**

- Project Evaluation: Internal and external scientific review committee evaluates proposed projects.

**DUE DILIGENCE**

- On-site due diligence: Internal and external reviewers group visit the site and ensure data integrity.

**INVESTMENT DECISION**

- Investment decision: Investment Committee selects projects with a business point of view.

**MILESTONE AND BUDGET ADJUSTMENT**

- Milestone and Budget: Consulting on research plan including milestone and budget adjustment.

**PROJECT MANAGEMENT**

- Project Management: Ensure project success: Trouble shooting, milestone check, monthly review and consulting.

**LICENSE OUT**

- Global: 7
- Domestic: 13

**LICENSE DEAL VALUE**

- $3.5 Billion

**LICENSED OUT PROJECTS**

- Global: 7
- Domestic: 13

**REVIEWED PROPOSAL**

- 401

**FUNDING PROJECT**

- 112

**FUNDED PROJECT**

- 20

**KDDF’S PERFORMANCE**

- As of May 2017

- Patents: Global: 360, Domestic: 17, SCI Journal: 61

- Reviewed Proposal: 401

- Funding Project: 112

- Funded Project: 20

**KDDF’S PERFORMANCE (AS OF MAY 2017)**

- License Out: Global: 7, Domestic: 13

- Milestone Achievement: 59

- License deal value: $3.5 Billion

**ONCOLOGY**

- 06 Chodang Pharmaceuticals
- 07 Yonsei University
- 08 Wellmarkerbio Co., Ltd.
- 09 Eutilex Co., Ltd.
- 10 Abion. Inc
- 11 UNIST
- 12 Scripps Korea Antbody Institute
- 13 JW Pharmaceutical
- 14 Green Cross Corporation
- 15 PharmAbcine Inc.

**GASTROINTESTINAL DISEASE**

- 29 CJ HealthCare

**HEMATOLOGY**

- 30 Alteogen, Inc.
- 31 ENZYCHEM LIFESCENCES

**IMMUNOLOGY**

- 32 Ewha Womans University
- 33 HanAll BioPharma
- 34 Y-Biologics
- 35 Seoul Women’s University
- 36 Oscotec Inc.
- 37 Chong Kun Dang

**INFECTIOUS DISEASE**

- 38 ImmuneMed, Inc.
- 39 Qurient

**RESPIRATORY**

- 40 Dong-wha Pharm. Co.
- 41 YUNGJIN PHARM. CO., LTD.

**CARIOVASCULAR DISEASE**

- 22 LG Chem
- 23 Ulsan University

**OPHTHALMOLOGY**

- 42 Taejoon Pharmaceutical Co., Ltd

**METABOLIC DISEASE**

- 24 GIST
- 25 Ewha Womans University
- 26 Aptamer Sciences Inc.
- 27 Genexine, Inc.
- 28 Genexine, Inc.
**KDDF-201512-06**  
**Chodang pharmaceuticals**

### Asset Overview

**Product Type**  
New Chemical Entity

**Therapeutic Area**  
Human colon cancer

**Target**  
PTEN

**Concept**  
Inhibition of binding p34 to WW1 domain of NEDD4-1  
→ PTEN restoration/re-expression

**Development status**  
Lead generation

**Route of Administration**  
Oral

**Competition**  
Other colon cancer medicine

**Differentiation**  
Novel Target (First In Class potential) for colon cancer patients exhibiting the mutant KRAS (about 40%) or the wild KRAS not responsive to Erbitux treatment (about 30%)

**Intellectual Property**  
Undisclosed (preparation)

**Data**

 ![In vitro data](image1)  
 ![In vivo data](image2)

**Project Milestone**

- Milestone 1: Lead generation (2017.05.31.)
- Milestone 2: Lead optimization (2019.12.31.)

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**KDDF-201606-17**  
**Yonsei University**

### Asset Overview

**Product Type**  
Genetics (virus)

**Therapeutic Area**  
Cancer

**Target**  
TGF-β/HSP27

**Concept**  
- Boosting anti-tumor immune responses by GM-CSF, Flt3L transgenes  
- Breakage of immune tolerance in tumor microenvironment and anti-angiogenesis, anti-invasion/metastasis by shTGF-β  
- Enhanced tumor-selective apoptosis by TRAIL  
- Decrease of survival potential acting as a sensitizer by shHSP27

**Development status**  
Lead Generation

**Route of Administration**  
Intratumoral

**Competition**  
T-vec, JX-594

**Differentiation**  
Best-in-class of oncolytic viral therapeutics with both of tumor versatility and selectivity by combining of genes acting co-operatively

**Intellectual Property**  
Priority application for Korea (10-2016-0166171) and PCT (PCT/KR2016/014325)

**Data**

**Project Milestone**

- Milestone 1: Proof of Concept of efficacy of lead compound (2017.06.30.)
- Milestone 2: Optimization of lead compound (2018.08.31.)

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  - Jae J. Song  
  - jjs109@yuhs.ac  
  - +82-2-2228-8037
**KDDF-201612-12**
**Wellmarkerbio Co., Ltd.**

**Asset Overview**

**Product Type**
New Chemical Entity

**Therapeutic Area**
Colon Cancer (Oncology)

**Target**
CRG1 [Cetuximab-Resistant Gene 1]

**Concept**
Binding to CRG1

**Development status**
Lead Generation

**Route of Administration**
Oral

**Competition**
Other Cetuximab-resistant colon cancer medicine

**Differentiation**
Predictive biomarker for treatment of colon cancer
Overcoming resistance of Cetuximab in treatment of colon cancer
(First In Class potential)

**Intellectual Property**
Product Patent: 3 patents registered in Korea, 2 PCT filed
Bio-Marker Patent: 1 patent filed in Korea, 1 PCT filed

**Data**

**Project Milestone**
Milestone 1: Lead generation / Chemical structure optimization (2018.12.31.)

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**KDDF-201408-11**
**Eutilex Co., Ltd.**

**Asset Overview**

**Product Type**
Protein (Antibody)

**Therapeutic Area**
Solid tumors

**Target**
AITR

**Concept**
AITR agonist > Th1 polarization and convert Treg into Th1
> Suppress cancers

**Development status**
Lead Optimization

**Route of Administration**
IV

**Competition**
Anti-AITR antibody (TOLERx, Merck, BMS)

**Differentiation**
Our AITR human antibody has the ability to convert Treg into Teff and induce IFN-
gamma and can effectively suppress cancers (Best In Class)

**Intellectual Property**
Undisclosed (preparation)

**Data**

**Project Milestone**
Milestone 1: Proof of Concept (2018. 3Q)
Milestone 2: Preclinical study (2019. 3Q)
## KDDF-201603-08
### Abion. Inc

### Asset Overview

<table>
<thead>
<tr>
<th>Product Type</th>
<th>New Chemical Entity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapeutic Area</td>
<td>Gastric Cancer</td>
</tr>
<tr>
<td>Target</td>
<td>c-MET</td>
</tr>
<tr>
<td>Concept</td>
<td>Inhibition of the enzymatic activity of the c-MET tyrosine kinase &gt; Dephosphorylation of the multiple docking site &gt; Dephosphorylation of the downstream proteins</td>
</tr>
<tr>
<td>Development status</td>
<td>Lead Optimization / Preclinical</td>
</tr>
<tr>
<td>Route of Administration</td>
<td>Oral</td>
</tr>
<tr>
<td>Competition</td>
<td>Other c-MET inhibitor</td>
</tr>
<tr>
<td>Differentiation</td>
<td>Personalized Medicine (Best In Class potential)</td>
</tr>
<tr>
<td>Intellectual Property</td>
<td>PCT application: Korea, China, Europe, Japan, India and USA (Registrations of patents are submitted)</td>
</tr>
</tbody>
</table>

### Data

**Fig.1** SNUS Cell-line Derived Xenograft data  
**Fig.2** Patient Derived Xenograft data

**Project Milestone**  
U. S. Food and Drug Administration (FDA) IND Approval (2018)

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## KDDF-201312-06
### UNIST

### Asset Overview

<table>
<thead>
<tr>
<th>Product Type</th>
<th>New Chemical Entity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapeutic Area</td>
<td>Cancer</td>
</tr>
<tr>
<td>Target</td>
<td>TRAP1</td>
</tr>
<tr>
<td>Concept</td>
<td>TRAP1 inhibition &gt; Mitochondrial death program/metabolic dysfunction/ROS overproduction &gt; Cell death</td>
</tr>
<tr>
<td>Development status</td>
<td>Preclinical</td>
</tr>
<tr>
<td>Route of Administration</td>
<td>Oral or IV</td>
</tr>
<tr>
<td>Competition</td>
<td>No drug with similar MDA</td>
</tr>
<tr>
<td>Differentiation</td>
<td>Novel Target, Novel MDA (First In Class)</td>
</tr>
<tr>
<td>Intellectual Property</td>
<td>Partially disclosed (preparation)</td>
</tr>
</tbody>
</table>

### Data

**Project Milestone**  
Milestone 1: ADME optimization [2018.03.31.]

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+82-2-6006-7615

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**https://sites.google.com/site/mitomed/**  
Byoung Heon Kang  
kangbh@unist.ac.kr  
+82-52-217-2521
## KDDF-201606-15
### Scripps Korea Antibody Institute

### Asset Overview

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Protein (Therapeutic Antibody)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapeutic Area</td>
<td>Metastatic Non-Small Cell Lung Cancer</td>
</tr>
<tr>
<td>Target</td>
<td>PD-L1</td>
</tr>
<tr>
<td>Concept</td>
<td>Various cancers have developed a unique mechanism to survive against our body’s immune surveillance, one of which is based on the suppression of immune cell activities through immune checkpoints interaction, such as PD-1 and PD-L1 interaction between T cells and cancer cells respectively. By abrogating this PD-1 and PD-L1 interaction through anti-PD-L1 antibody, such as ‘KL001’, body’s anti-cancer immune activity can be efficaciously re-activated and eradicate cancers even at very late stages. This therapeutic antibody can show such anti-cancer activity against diverse cancers, such as NSCLC, melanoma, H&amp;N cancer, stomach cancer, etc.</td>
</tr>
<tr>
<td>Development status</td>
<td>Lead optimization and Cell-line development</td>
</tr>
<tr>
<td>Route of Administration</td>
<td>IV</td>
</tr>
<tr>
<td>Competition</td>
<td>Atezolizumab (Roche), Durvalumab (AstraZeneca), Avelumab (Merck Serono)</td>
</tr>
<tr>
<td>Differentiation</td>
<td>‘KL001’ has an unique binding epitope on PD-L1 and PD-L2</td>
</tr>
<tr>
<td>Intellectual Property</td>
<td>Undisclosed (in preparation)</td>
</tr>
</tbody>
</table>

### Data

1. ‘KL001’, anti-PD-L1 I/O therapeutic antibody was isolated through proprietary phage display screening from fully human antibody libraries
2. ‘KL001’ showed good PD-1/PD-L1 interaction blockade in SPR assay and in vitro cell-based assay
3. In vivo study using murine colon cancer MC38 & C57BL/6 syngeneic mouse model showed strong anti-cancer efficacy of ‘KL001’
4. Physico-chemical druggable properties, Biodistribution, epitope mapping analysis and rodent tox study (multiple injection) also showed unique characteristics of ‘KL001’
5. Affinity maturation study is at its final stage

### Project Milestone

1. Finalization of preclinical candidate (2017.06.30.)
2. Production cell-line development

## KDDF-201408-09
### JW Pharmaceutical

### Asset Overview

<table>
<thead>
<tr>
<th>Product Type</th>
<th>New Chemical Entity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapeutic Area</td>
<td>Cancer (AML, MM)</td>
</tr>
<tr>
<td>Target</td>
<td>Wnt pathway</td>
</tr>
<tr>
<td>Concept</td>
<td>Wnt pathway inhibition by disrupting the unfolded protein response and inducing endoplasmic reticulum stress</td>
</tr>
<tr>
<td>Development status</td>
<td>Phase I</td>
</tr>
<tr>
<td>Route of Administration</td>
<td>IV</td>
</tr>
<tr>
<td>Competition</td>
<td>Other AML, MM drug</td>
</tr>
<tr>
<td>Differentiation</td>
<td>Novel target (First-in-class)</td>
</tr>
<tr>
<td>Intellectual Property</td>
<td>Worldwide IP 2028-2032</td>
</tr>
</tbody>
</table>

### Data

### Project Milestone

AML P1 combo (+cytarabine) trial 2018. 2Q
MM P1 mono, combo (+lenalidomide, dexamethasone) trial 2018. 2Q
KDDF-201412-08
Green Cross Corporation

Asset Overview

Product Type: Protein (Antibody)
Therapeutic Area: Cancer
Target: EGFR
Concept: Different binding epitope/More efficient inhibition of EGFR ligand binding to EGFR esp. high-affinity ligands
Development status: Phase I (data clearing)
Route of Administration: IV
Competition: Mixtures of EGFR antibodies (Sym004, MM151)
Differentiation: Different (best in class potential)

Data

Project Milestone
Milestone 1: Safety, Tolerability, RP2D (2017.07.31.)
Milestone 2: Proof of Concept (2020.06.30.)

KDDF-201509-07
PharmAbcine Inc.

Asset Overview

Product Type: Protein (Antibody)
Therapeutic Area: Glioblastoma Multiform (GBM)
Target: VEGFR-2 (KDR)
Concept: VEGF/VEGFR-2 signal inhibition > Inhibition of Cell Proliferation and Migration > Apoptosis of Tumor cells
Development status: Phase IIa in Australia
Route of Administration: IV
Competition: • Other VEGF or VEGFR-2 targeting medicines
• Safe in use - No side effects like hypertension, hemorrhage which are mostly common side effects in vascular targeting therapeutics
• Interspecies cross reactivity: The only antibody therapeutics holding murine cross reactivity among VEGFR-2 targeting antibody
• BIC mAb
Differentiation: Registered in 23 countries, including KR, US, JP, CN, EP, CA, AU etc.

Data

Project Milestone
Milestone 1: Safety Evaluation in GBM Phase IIa patients (2016.12.)
Milestone 2: Preliminary Efficacy Evaluation in GBM Phase IIa patients (2018.12.)

ENTOLOGY
KDDF-201603-02
Neuracle Science, Co., Ltd.

Asset Overview

Product Type: Protein (Therapeutic Antibody)
Therapeutic Area: Alzheimer’s disease
Target: Confidential
Concept: Inhibition of reactive gliosis
Development status: Lead Generation
Route of Administration: IV
Competition: Other AD medicine
Differentiation: Novel target (First-in-class)
Intellectual Property: Undisclosed

Data

Project Milestone
- Lead generation (2017.09.31.)
- Lead optimization (2018.09.31.)

KDDF-201512-08
Bio-Pharm Solutions

Asset Overview

Product Type: New Chemical Entity
Therapeutic Area: Infantile Spasms (pediatric epilepsy)
Target: Metabotropic glutamate receptor family I & III
Concept: Inhibit glutamate release and de-inhibit GABA signaling

Development status: Preparing for Phase I/II
Route of Administration: Oral
Competition: Vigabatrin/ACTH
Differentiation: Novel MoA with anticonvulsant, anti-epileptogenesis and Neuroprotection (Best in Class potential)
PCT: KR2014-001903

Data

- A) Efficacy in Symptomatic infantile spasms rat pup model
- B) Protect hippocampal neurons against benzodiazepine-resistant status epilepticus in adult rats

Project Milestone
- Milestone 1: Update nonclinical data, (2016.04-2017.06.)

Preparation: Yongho Kwak
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+82-31-888-9636
KDDF-20160603-03
Dong-A ST

Asset Overview

Product Type: Botanical drug
Therapeutic Area: Alzheimer’s Disease
Target: Multi-Target (Aβ, Tau, AChE)
Concept:
1) Disease-treating via removal of disease-causing source (Aβ [Neprilysin] ptau[GSK-3β])
2) Improving cognitive ability via AChE inhibition
3) Neuroprotection via NGF

Development status: Pre-Clinical
Route of Administration: Oral
Competition: Aβ antibody and/or AChE inhibitor
Differentiation: Multi-function (Disease modifying and symptomatic effects)


Data

Project Milestones:
1. FDA Phase 1b or 2a IND filing & submission (2017. 4Q)
2. US clinical initiation and clinical completion (2018. 2Q ~ 2019. 4Q)

KDDF-20160618
OliPass Corporation

Asset Overview

Product Type: Chemical (OliPass Oligonucleotide)
Therapeutic Area: Neuropathic Pain
Target: SCN9A / Nav1.7
Concept: OLP-1002 selectively binds to SCN9A pre-mRNA → Induce Exon Skipping of SCN9A pre-mRNA → Inhibition of Translation of Nav1.7 → Inhibition of Nav1.7 Expression → Reproduce Pharmacological Phenotypes of SCN9A Channelopathy

Development status: Preclinical
Route of Administration: Subcutaneous
Competition: Small molecule Nav1.7 selective inhibitors—Found to show poor analgesic activity in human subjects.
Differentiation: Novel Target (First In Class Potential)
- OLP-1002 possesses an extremely high selectivity for Nav1.7 over Nav1.5, and distributes well to CNS tissues.
- Therapeutic dose of OLP-1002 is predicted to be as small as 10 to 20 mg per week in patients with chronic neuropathic pains, which may be developed for an readily affordable annual treatment cost.

OLP-1002 is a derivative of OliPass Oligonucleotide, a novel class of oligonucleotide which was developed by rationally modifying PNA to possess good membrane permeability as well as ultra strong affinity for nucleic acid.

Data

Project Milestone: IND approval in Europe (2018. 03.)
KDDF-201502-07
Abion. Inc

Asset Overview

Product Type: Protein
Therapeutic Area: Multiple Sclerosis
Target: The next generation Biobetter version of the human Interferon-beta through glycoengineering
Concept: Immune modulation
Development status: Process Development / Preclinical
Route of Administration: SC
Competition: Merck Seronex (Rebif), Biogen Idec (Avonex)
Differentiation:
- Decrease of aggregation tendency with additional glycosylation
- Improvement of solubility and stability
- Price rationalization through improved productivity
- Increase of in-vivo half-life and activity
- Possibility of use in the off-label market, such as to treat viral disease

Intellectual Property:
- Modified Interferon-beta Conjugated with Polyethylene Glycol (KR, PCT)
- Stabilized Formulations of Interferon beta Mutant (KR, PCT)
- Immunocytokine Conjugated with Human Interferon Beta-mutein and Method for Preparing Thereof (KR, PCT)

Data

Project Milestone: European Medicines Agency (EMA) approved [2023]

KDDF-201512-08
JEIL Pharmaceutical Co., Ltd.

Asset Overview

Product Type: New Chemical Entity
Therapeutic Area: Acute Ischemic Stroke
Target: PARP-1
Concept: Reperfusion of stroke patient → PARP-1 over-activation → PARP-1 inhibition → Reducing damages caused by necrosis and apoptosis → Neuroprotective effect
Development status: Phase II
Route of Administration: IV bolus + Infusion
Competition: MP-124 of Mitsubishi Tanabe
Differentiation:
- Novel Target (First in Class and Best in Class potential)
- Patent applications covering materials and preparation methods were submitted in 2009, and the registration was approved in 2010 in Korea (10-0968175), as well as in the US, Europe, China, Japan, Australia, Canada, Russia, Mexico, and Hong Kong.
  - PCT: WO 2010/056038
- Application for the JPI-289 crystalline structure patent was submitted in 2012, and the registration was approved in the US and Russia.
- In summary, one application in Korea and 12 international applications have been registered, and review processes for registration of another application in Korea and 4 international applications are currently underway.

Data

Project Milestone: European Medicines Agency (EMA) approved (2023)
KDDF-201210-07
LG Chem

Asset Overview

Product Type: New Chemical Entity
Therapeutic Area:
1. Cardiac ischemia-reperfusion injury (i.e. AMI)
2. Autoimmune & inflammatory diseases
3. Mitochondrial (rare) diseases
Target: Mitochondrial ROS
Concept:
1. A mitochondria-targeted ROS scavenger
2. A novel necrosis inhibitor
3. A mPTP modulator (indirect)
Development status: Phase II (STEMI patients with AMI)
Route of Administration: IV (orally available)
Competition: No competition (all clinical trials failed)
Differentiation:
1. A novel necrosis inhibitor (First In Class potential)
2. Downregulation of RIP-1 & -3 expression (necroptosis inhibition)

Intellectual Property: 10 PCTs

Data

Project Milestone: The interim data of Phase 2a will be available at the end of 2017

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KDDF-201609-12
Ulsan University

Asset Overview

Product Type: New Chemical Entity
Therapeutic Area: Calcific aortic valve disease (CAVD)
Target: Dipeptidyl peptidase-4 (DPP-4)
Concept:
DPP-4 inhibition → Reduction of aortic valve calcification → Attenuation of CAVD development
Development status: Lead Optimization
Route of Administration: Oral
Competition: None
Differentiation: Novel Target (First In Class potential)

Intellectual Property: Undisclosed (preparation)

Data

Project Milestone: Milestone 1: Drug Repositioning of DPP-4 inhibitor for CAVD treatment (2019.01.31.)

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KDDF-201601-03
Gwangju Institute of Science and Technology

Asset Overview

Product Type: New Chemical Entity
Therapeutic Area: Diabetes Mellitus, Type 2 (Metabolic Disease)
Target: Gut-restricted Farnesoid X Receptor (FXR)
Concept: Gut-restricted FXR agonism > Enhancing GLP-1 signaling & energy expenditure, reducing serum inflammatory cytokines, altering serum bile acid composition & gut microbiome > Reducing blood glucose levels & diet-induced weight gain, improving metabolic syndromes
Development status: Lead Generation
Route of Administration: Oral
Competition: Other T2DM medicines
Differentiation: Gut-restricted FXR Modulator (First In Class potential)
Intellectual Property: Undisclosed (preparation)

Data

Project Milestone
Milestone 1: Proof of Concept/Lead Generation (2017.07.15.)
Milestone 2: Chemical structure Optimization (2019.01.15.)

KDDF-201601-01
Ewha Womans University

Asset Overview

Product Type: New Chemical Entity
Therapeutic Area: Diabetes Mellitus, Type 2 (Metabolic Disease)
Target: Gut-restricted Farnesoid X Receptor (FXR)
Concept: Gut-restricted FXR agonism > Enhancing GLP-1 signaling & energy expenditure, reducing serum inflammatory cytokines, altering serum bile acid composition & gut microbiome > Reducing blood glucose levels & diet-induced weight gain, improving metabolic syndromes
Development status: Lead Generation
Route of Administration: Oral
Competition: Other T2DM medicines
Differentiation: Gut-restricted FXR Modulator (First In Class potential)
Intellectual Property: Undisclosed (preparation)

Data

Project Milestone
Milestone 1: Proof of Concept/Lead Generation (2017.07.15.)
Milestone 2: Chemical structure Optimization (2019.01.15.)
Asset Overview

**Product Type**
Chemical (Aptamer)

**Therapeutic Area**
Diabetes Mellitus, Type 2 (Metabolic Disease)

**Target**
Insulin Receptor

**Concept**
Allosteric activation of Insulin Receptor → Biased Function
[Blood glucose control without mitogenic activity]

**Development status**
Lead Optimization

**Route of Administration**
SC

**Competition**
Insulin Analogues (Basal insulin)

**Differentiation**
Novel mechanism of action without side effect [First in class]

**Intellectual Property**
Undisclosed (preparation)

**Data**

**Project Milestone**
Milestone 1: Chemical optimization (2018.06.08.)

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Asset Overview

**Product Type**
GX-H9 (Hybrid Fc fusion human growth hormone)

**Therapeutic Area**
Growth hormone deficiency

**Target**
Growth hormone deficiency in Adult

**Concept**
Developing long-acting growth hormone to ensure compliance, convenience and safety

**Development status**
Global Phase II (In-process of completion)

**Route of Administration**
SC injection (liquid)

**Competition**
Opko (L/O to Pfizer), Versartis, Novo Nordisk, Ascendis

**Differentiation**
Twice-monthly and weekly doses and improved safety profile

**Intellectual Property**
US 8,586,038; US 8,586,048; US 8,586,531; US 8,529,899;
KR 1 380729; KR 1 380732

**Data**

**Project Milestone**
Project ends in 2017.06.
Asset Overview

**Product Type**
GX-H9 (Hybrid Fc fusion human growth hormone)

**Therapeutic Area**
Growth hormone deficiency

**Target**
Growth hormone deficiency in pediatric population

**Concept**
Developing long-acting growth hormone to ensure compliance, convenience and safety

**Development status**
Global Phase II (Complete recruitment)

**Route of Administration**
SC injection (liquid)

**Competition**
Opke IL/D to Pfizer, Versartis, Novo Nordisk, Ascendis

**Differentiation**
Best-in-class P-CAB

**Intellectual Property**
Undisclosed (preparation)

**Data**

<table>
<thead>
<tr>
<th>Assay (Stomach)</th>
<th>'H+/K+-ATPase Human: 0.52</th>
<th>Porcine: 0.47</th>
<th>Canine: 0.29</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assay (Canine)</td>
<td>Na+/K+-ATPase Canine: &gt;100</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Project Milestone**
Milestone 1: 6 month aHV result (2017.04.)
Milestone 2: License out (2017.10.)
**KDDF-201606-02**

**Alteogen, Inc.**

**Asset Overview**

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Protein</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapeutic Area</td>
<td>Hemophilia</td>
</tr>
<tr>
<td>Target</td>
<td>Coagulation Factor VIIa</td>
</tr>
<tr>
<td>Concept</td>
<td>Recombinant FVIIa + NexP&lt;sup&gt;TM&lt;/sup&gt; → Long-acting FVIIa</td>
</tr>
<tr>
<td>Development status</td>
<td>Lead Optimization</td>
</tr>
<tr>
<td>Route of Administration</td>
<td>IV</td>
</tr>
<tr>
<td>Competition</td>
<td>FVIIa-FP (albumin fusion), FVIIa-CTP (CTP fusion)</td>
</tr>
<tr>
<td>Differentiation</td>
<td>Prolonged half-life with equivalent effects (Best In Class potential)</td>
</tr>
<tr>
<td>Intellectual Property</td>
<td>US patent No. 9012606 (registered; application date: 2011.10.21)</td>
</tr>
</tbody>
</table>

**Data**

**Project Milestone**

- Milestone 1: Proof of concept in hemophilia mice (2017.09.30.)
- Milestone 2: Starting of preclinical study (2017.12.31.)

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**KDDF-201606-08**

**ENZYCHEM LIFESCIENCES**

**Asset Overview**

<table>
<thead>
<tr>
<th>Product Type</th>
<th>New Chemical Entity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapeutic Area</td>
<td>Neutropenia (Febrile)</td>
</tr>
<tr>
<td>Target</td>
<td>STAT3</td>
</tr>
<tr>
<td>Concept</td>
<td>Inhibition of phosphorylation of STAT3 → Decrease of production of CXCL8 → Decrease of neutrophils mobility → Decrease of neutrophils extravasation</td>
</tr>
<tr>
<td>Development status</td>
<td>Phase II</td>
</tr>
<tr>
<td>Route of Administration</td>
<td>Oral</td>
</tr>
<tr>
<td>Competition</td>
<td>IV-infusible/SC-injectable recombinant myeloid growth factors</td>
</tr>
<tr>
<td>Differentiation</td>
<td>Novel MOA/Oral route (FIC)</td>
</tr>
<tr>
<td>Intellectual Property</td>
<td>Undisclosed (preparation)</td>
</tr>
</tbody>
</table>

**Data**

**Project Milestone**

- Milestone 1: Clinical Proof of Concept (2018.10.)
### KDDF-201609-01
**Ewha Womans University**

**Asset Overview**

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Peptide</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapeutic Area</td>
<td>Atopic dermatitis</td>
</tr>
<tr>
<td>Target</td>
<td>Histamine Releasing Factor (HRF)</td>
</tr>
<tr>
<td>Concept</td>
<td>HRF inhibiting peptide [dTBP2] → HRF inhibition → Targeted therapy for atopic dermatitis</td>
</tr>
<tr>
<td>Development status</td>
<td>Lead Generation</td>
</tr>
<tr>
<td>Route of Administration</td>
<td>Subcutaneous</td>
</tr>
<tr>
<td>Competition</td>
<td>Dexamethasone (a corticosteroid)</td>
</tr>
<tr>
<td>Differentiation</td>
<td>Novel Target (First In Class potential)</td>
</tr>
<tr>
<td>Intellectual Property</td>
<td>Undisclosed (preparation)</td>
</tr>
</tbody>
</table>

**Data**

**Project Milestone**

Milestone 1: Proof of Concept (2018.04.15.)

---

### KDDF-201410-02
**HanAll BioPharma**

**Asset Overview**

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Protein (Fully Human Monoclonal Antibody)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapeutic Area</td>
<td>Pathogenic IgG-Mediated Autoimmune Diseases</td>
</tr>
<tr>
<td>Target</td>
<td>Human FcRn</td>
</tr>
<tr>
<td>Concept</td>
<td>hFcRn blocking → Inhibition of hIgG binding to hFcRn → Reducing pathogenic IgG level → Disease recovery</td>
</tr>
<tr>
<td>Development status</td>
<td>IND-ready</td>
</tr>
<tr>
<td>Route of Administration</td>
<td>SC Injection</td>
</tr>
<tr>
<td>Competition</td>
<td>Other anti-FcRn antibody drug</td>
</tr>
<tr>
<td>Differentiation</td>
<td>High potency &amp; Patient compliance based on SC injectable formulation (First-in-Class Potential)</td>
</tr>
<tr>
<td>Intellectual Property</td>
<td>PCT/KR15/04424</td>
</tr>
</tbody>
</table>

**Data**

**Project Milestone**

Milestone 1: Candidate Development & non-clinical study (2017.06.30.)

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### References

- Inhibition of hIgG binding to hFcRn
  - FACS competitive binding assay with hFcRn-expressing HEK293 cells at pH6.0
- PK/PD Study in cynomolgus monkey
  - IgG levels were reduced to about 80% of baseline at both doses of 5 mg/kg and 10 mg/kg

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**Contact Information**

- Ewha Womans University: klyoon@ewha.ac.kr, +82-2-3277-3024
- HanAll BioPharma: Emptymj@hanall.co.kr, +1-301-655-8569
KDDF-201606-04
Y-Biologics

Asset Overview
Product Type: Protein (bi-specific antibody)
Therapeutic Area: Auto-inflammatory & auto-immune disease
Target: TNF-alpha & IL-17
Concept: Neutralizing TNF-alpha & IL-17 in same time
Development status: Cell line development
Route of Administration: SC / IV
Competition: TNF-alpha blockade & anti-TNF-alpha & anti-IL-17 bispecific antibody
Differentiation: Biobetter of TNF-alpha blockade (better response rate & Disease modifying), targeting IL-17 driven disease segment
Intellectual Property: Undisclosed (preparation)

Data
![Graph showing TNFα/IL17A-CXCL1 inhibition]

Project Milestone
Milestone 1: primary CMC & pretoxicity study (2018.03.08.)

www.ybiologics.com
Young-Gyu Cho
Yonggyuchoi@ybiologics.com
+82-42-716-4979

KDDF-201612-09
Sookmyung Women’s University

Asset Overview
Product Type: Peptides
Therapeutic Area: Rheumatoid Arthritis (RA)
Target: Regulatory T cells (Treg)
Concept: Increased Treg cell number and activity → Inhibition of Th17 cells and Osteoclast differentiation → Suppression of RA pathogenesis
Development status: Lead Optimization
Route of Administration: IV or SC
Competition: TNF inhibitors
Differentiation: Novel small peptide from Erdr1 protein (first-in-class)
Specific target identification for each peptides
Intellectual Property: PCT applications

Data

Project Milestone
Milestone 1: Lead optimization → Candidate selection

http://snowe.sookmyung.ac.kr/club/cdhkor
Prof. Daeho Cho
cdhkor@sookmyung.ac.kr
+82-2-710-9416
KDDF-201509-05
Oscotec Inc.

Asset Overview
Product Type: Chemical
Therapeutic Area: Rheumatoid arthritis
Target: Spleen tyrosine kinase
Concept: Spleen tyrosine kinase (SYK) is involved in regulating leukocyte immune function. Aberrant SYK activation is associated with diverse allergic disorders and antibody-mediated autoimmune diseases such as RA, asthma, and allergic rhinitis. SKI-O-703 inhibits SYK.
Development status: Phase I
Route of Administration: Oral
Competition: Fostamatinib (R788) developed by Rigel Pharmaceuticals, Inc. jointly with AstraZeneca was discontinued after Phase III clinical trials due to low efficacy and severe adverse events which were caused from low selectivity. P505-15, from Portola Pharmaceuticals Inc. exhibited high selectivity, but revealed a high level of toxicity and low bioavailability.
Differentiation: Our clinical candidate SKI-O-703 demonstrated a superior selectivity to SYK, an improved bioavailability and a low level of toxicity. It has been established from in vivo models that SKI-O-703 has better efficacy and safety characteristics when compared to existing SYK inhibitors. (First/Best in class)
Intellectual Property: PCT/US patents filed and national phases applied
Data:
- Single ascending dose (SAD) study: completed
  - Clinical safety (50 to 800 mg oral qd dosing): no outstanding issue found at any test dose and no other significant findings, including vital signs, ECG and laboratory tests (hematology, serum chemistry, urinalysis)
  - Strong PD effect in activated basophil followed by anti-IgE stimulation
  - Estimated EC50 of SKI-O-703, ~350 nM in the % activated basophil
- Multiple ascending dose (MAD) study: completed (preparing the CSR)
  - 200 mg (qd & bid) and 400 mg (qd): completed at Q2, 2017
  - Clinical safety: no outstanding issue found at any test dose
  - Reproducible PD effect in activated basophil followed by anti-IgE stimulation
Project Milestone:
Milestone 1: Completion of SAD study (2016.10.07.)
Milestone 2: Completion of MAD study (2017.11.07.)

KDDF-201609-04
Chong Kun Dang

Asset Overview
Product Type: New Chemical entity
Therapeutic Area: Autoimmune Disease (RA, IBD)
Target: Histone Deacetylation 6 (HDAC6)
Concept: Inhibits TNF alpha and regulates T cell function
Development status: Phase I
Route of Administration: Oral
Competition: Chemical and biological DMARDs
Differentiation: Novel Target (First-in-Class)
Intellectual Property:
The patent of CKD-506 was granted in Korea on July 2016, and filed in 53(fifty-three) countries on April 2014
Data:
- CKD-506 in autoimmune diseases. (A) CKD-506 represses arthritis in rat AIA model. (B) CKD-506 prevents bone deformation in rat AIA. (C) HDAC is overexpression in colon tissues of ulcerative colitis and Crohn’s diseases patients. (D) CKD-506 represses diseases activity in CD4+CD45RBhi T cell adaptive transfer model and preserves IBD epithelium.
Project Milestone:
Phase I: SAD, FE, MAD (2017. 3Q)
### Asset Overview

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Protein (Immunoglobulin)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapeutic Area</td>
<td>Infectious disease (HBV, Influenza, etc)</td>
</tr>
<tr>
<td>Target</td>
<td>Virus Suppressing Factor (VSF) receptor</td>
</tr>
<tr>
<td>Concept</td>
<td>Virus infection $\rightarrow$ Anti VSF receptor expression only on virus infected cells $\rightarrow$ VSF treatment $\rightarrow$ anti-viral and anti-inflammatory effects to cell</td>
</tr>
<tr>
<td>Development status</td>
<td>Preclinical to Phase I (expected to 2017)</td>
</tr>
<tr>
<td>Route of Administration</td>
<td>IV/ IM</td>
</tr>
<tr>
<td>Competition</td>
<td>It works a different mechanism of action compared to conventional anti-viral treatments. No competition</td>
</tr>
<tr>
<td>Differentiation</td>
<td>Novel target (FIC)</td>
</tr>
<tr>
<td>Intellectual Property</td>
<td>Undisclosed (preparation)</td>
</tr>
</tbody>
</table>

### Data

**Project Milestone**

Milestone 1: Lead optimization (2016.02.28.)
Milestone 2: Preclinical toxicology and efficacy test (2017.02.28.)

---

### Asset Overview

<table>
<thead>
<tr>
<th>Product Type</th>
<th>New Chemical Entity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapeutic Area</td>
<td>Tuberculosis</td>
</tr>
<tr>
<td>Target</td>
<td>Inhibition of cytochrome bc1 complex QcrB subunit in TB</td>
</tr>
<tr>
<td>Concept</td>
<td>Cytochrome bc1 complex inhibition $\rightarrow$ Inhibition of energy metabolism in TB $\rightarrow$ Bactericidal effect</td>
</tr>
<tr>
<td>Development status</td>
<td>Phase I</td>
</tr>
<tr>
<td>Route of Administration</td>
<td>Oral</td>
</tr>
<tr>
<td>Competition</td>
<td>TB drugs are used in combination to take advantage of synergistic effect, yet preventing resistance. There is no competition in this class of compound</td>
</tr>
<tr>
<td>Differentiation</td>
<td>First in class compound</td>
</tr>
<tr>
<td>Intellectual Property</td>
<td>Undisclosed (preparation)</td>
</tr>
</tbody>
</table>

### Data

- Strong efficacy in an established mouse TB model. CFUs were enumerated in the lung of infected animals after 14 days (blue bars) and 28 days (red bars) of treatment (Q203: 10, 2, 0.4 mg/kg, TMC207: 6.5 mg/kg, Isoniazid: 15 mg/kg)
- Strong efficacy against 13 MDR & 15 XDR clinical isolates

**Project Milestone**

End of Phase 1 study: 2017
End of phase 2A study: 2018
**KDDF-201512-03**
**Dong-wha pharm. Co.**

**Asset Overview**
- **Product Type**: Botanical, Herbal medicine
- **Therapeutic Area**: Allergic asthma
- **Target**: Multi-targets (4 targets identification)
- **Concept**: Multi-targeting relating to allergy \(\rightarrow\) Th2/Th17 selective blockade \(\rightarrow\) Reduction of allergic response
- **Development status**: Preclinical
- **Route of Administration**: Oral (QD)
- **Competition**: Singulair (Montelukast, Leukotriene receptor antagonist)
- **Differentiation**: Superior efficacy to montelukast, Novel targets (First In Class)
- **Intellectual Property**: Patent pending: Korea (2), PCT(2)

**Project Milestone**: Clinical IND approval. (2018.03.30.)

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**KDDF-201410-05**
**YUNGIN PHARM. CO., LTD.**

**Asset Overview**
- **Product Type**: Botanical Drug / NCE
- **Therapeutic Area**: COPD (Respiratory System)
- **Target**: HDAC2
- **Concept**: HDAC2 activator \(\rightarrow\) Inflammation controls and increasing of steroids sensitivity \(\rightarrow\) Prevention of COPD exacerbation
- **Development status**: Phase IIa Completion (CSR working)
- **Route of Administration**: Oral
- **Competition**: Oral COPD medicines
- **Differentiation**: Novel Target (First In Class potential)
- **Intellectual Property**: Patient 1: Registered, Covering world wide (15 countries)
  - Patient 2: Registered, Covering world wide (12 countries)
  - Patient 3: Registered, Covering world wide (12 countries)
  - Patient 4: Registered, Covering world wide (12 countries)
  - Patient 5: Registered, Covering world wide (12 countries)
  - Patient 6: Registered, Covering world wide (12 countries)

**Project Milestone**
- Milestone 1: FDA Phase IIa completion (2017.10.31.)
- Milestone 2: MFDS Phase IIb submission (2018.03.31.)

---

**Model**
- 6 ~ 8 weeks old male BALB/c mouse (n = 8/group)
- **Inducer**: LPS 100 μg/mL + CSE (Cigarette Smoke Extract) 4 mg/mL
- **Dosing**: YPL-001, Daxas, Ver (Active 1), and Pic (Active 2) [30 mg/kg]

**In Vivo (CSE mouse acute model)**

**In Vitro (human BEAS-2B cell)**
Asset Overview

<table>
<thead>
<tr>
<th>Feature</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Product Type</strong></td>
<td>Protein (Antibody)</td>
</tr>
<tr>
<td><strong>Therapeutic Area</strong></td>
<td>Wet AMD</td>
</tr>
<tr>
<td><strong>Target</strong></td>
<td>VEGFR2</td>
</tr>
<tr>
<td><strong>Concept</strong></td>
<td>VEGFR2-specific binding</td>
</tr>
<tr>
<td></td>
<td>→ Blocking not only VEGF-A, but as well as VEGF-C and VEGF-D</td>
</tr>
<tr>
<td><strong>Development status</strong></td>
<td>Preclinical</td>
</tr>
<tr>
<td><strong>Route of Administration</strong></td>
<td>Intravitreal injection</td>
</tr>
<tr>
<td><strong>Competition</strong></td>
<td>Lucentis, Eylea</td>
</tr>
<tr>
<td><strong>Differentiation</strong></td>
<td>- Potential to treat tachyphylaxis against Lucentis or Eylea</td>
</tr>
<tr>
<td></td>
<td>- by Inhibiting VEGFR2 signaling of VEGF-C and VEGF-D</td>
</tr>
<tr>
<td><strong>Intellectual Property</strong></td>
<td>Disclosed</td>
</tr>
</tbody>
</table>

**Project Milestone**

Approval of Ph1 IND (2018.09.)

**GOVERNMENT INITIATIVES**

The government selected the bio industry as a new growth engine and launched various initiatives to support pharmaceutical industries:

- **Government Initiative for Drug Development**: The government of the Republic of Korea launched the Korea Drug Development Fund (KDDF) in 2011 to transform Korea into the global leader for new drug development with a budget of US$1 billion.

- **State-of-the-art Infrastructures**: Korea National Enterprise for Clinical Trials (KoNECT), Korea Research Institute of Bioscience & Biotechnology (KIRIBB), Korea Institute of Technology (KIT), Korea Research Institute of Chemical Technology (KRICT), Two high-tech medical clusters (Osong, Daegu)

**EXCELLENCE IN PHARMACEUTICAL R&D**

Korea has strong human capital & research capability:

- **Large pool of R&D experts**: 22,817 workers in the bio industry (36.7% of them having master’s or doctor’s degrees)

- **Strong Competitiveness in Basic Research**
  - 28 Korean researchers’ papers related to biotechnology published in the top 3 global science magazines (Nature, Science, Cell)
  - Ranked 5th for number of patents (9,689 patents Statistics from the World Intellectual Property Organization in 2010)
  - Registered 520 patents in the bio sector of the United States between 2006 and 2010, and recorded 166 in technology strength, ranking 14th.