

KOREA DRUG DEVELOPMENT FUND



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## BUSINESS -----**MODEL DIAGRAM**







# **KOREA DRUG** DEVELOPMENT **FUND**

KDDF has supported all stage of drug development with brilliant achievements. As of 2017, 20 assets 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.



### **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 network in business development field
- More than 112 pipeline in various therapeutic areas from lead stage to clinical trial stage





# **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.





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



Investment decision Investment Committee selects select projects with a business point of View

INVESTMENT

DECISION



Milestone

and Budget

Consulting or

research plan

including milestone

and budget

adjustment

> Project Manage Ensure Project SUCCESS Trouble shooting Milestone check, Monthly review and Consulting



Patents Global: 340. Domestic: 87. SCI Journal: 41











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42 Taejoon Pharmaceutical Co., Ltd.

## 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 $ ightarrow$ 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)

### Intellectual Property Data



In vitro data

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In vivo data

### **Project Milestone**

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

### CHODANG PHARM.

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

### **Asset Overview**

Data

07

Product Type	Genetics (virus
Therapeutic Area	Cancer
Target	TGF-β/HSP27
Concept	<ul> <li>Boosting ant</li> <li>Breakage of anti-invasion</li> <li>Enhanced tu</li> <li>Decrease of</li> </ul>
Development status	Lead Generation
Route of Administration	Intratumoral
Competition	T-vec, JX-594
Differentiation	Best-in-class selectivity by co
Intellectual Property	Priority applica



**Project Milestone** 



### rus)

- anti-tumor immune responses by GM-CSF, Flt3L transgenes
- of immune tolerance in tumor microenvironment and anti- angiogenesis, sion/metastasis by shTGF- $\beta$
- I tumor-selective apoptosis by TRAIL
- of survival potential acting as a sensitizer by shHSP27

ation

- ss of on oncolytic viral therapeutics with both of tumor versatility and combining of genes acting co-operatively
- Priority application for Korea (10-2016-0166171) and PCT (PCT/KR2016/014325)

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

## KDDF-201612-12 Wellmarkerbio Co., Ltd.



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	4,000



**Project Milestone** 

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



**Project Milestone** 

Milestone 1: Proof of Concept (2018. 3Q) Milestone 2: Preclinical study (2019. 3Q)

<b>CDDF-201408-11</b>	
Eutilex Co., Ltd.	

Asset Overview	
Product Type	Protein (Antib
Therapeutic Area	Solid tumors
Target	AITR
Concept	AITR agonist - $ ightarrow$ Suppress c
Development status	Lead Optimiza
Route of Administration	IV
Competition	Anti-AITR ant
Differentiation	Our AITR hur gamma and c
Intellectual Property	Undisclosed (
Data	CD4+T cells Anti-CD3 /Anti-AITR





09

08

**WMBIO** 



ody)

 $\rightarrow$  Th1 polarization and convert Treg into Th1 cancers

ation

tibody (TOLERx, Merck, BMS)

man antibody has the ability to convert Treg into Teff and induce IFNcan effectively suppress cancers (Best In Class)

(preparation)



## KDDF-201603-08 Abion. Inc

### **Asset Overview**

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





Fig.1 SNU5 Cell-line Derived Xenograft data

**Project Milestone** 

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



Monitoring 1. Tumor volume 2. Body weight Endpoint Tumor volume = 2000 mm

PDX##: CNV14 - Vahirla 

Treatmen

weight change

Fig.2 Patient Derived Xenograft data

## KDDF-201312-06 UNIST

### **Asset Overview**

Product Type
Therapeutic Area
Target
Concept
Development status
Route of Administration

Competition Differentiation

Intellectual Property

Data







**Project Milestone** 

Milestone 1: ADME optimization (2018.03.31.)







### New Chemical Entity

Cancer

TRAP1

Preclinical

Oral or IV

TRAP1 inhibition  $\rightarrow$  Mitochondrial death program/metabolic dysfunction/ROS overproduction  $\rightarrow$  Cell death

No drug with similar MOA

Novel Target, Novel MOA (First In Class)

Partially disclosed (preparation)

Cytotoxic activity of Pan-401 in cancer cells

in vivo xenograft with PC3



## KDDF-201606-15 **Scripps Korea Antibody Institute**

### **Asset Overview**

Product Type	Protein (Therapeutic Antibody)	Product Type	New C
Therapeutic Area	Metastatic Non-Small Cell Lung Cancer	Therapeutic Area	Cancer
Target	PD-L1	Target	Wnt pa
Concept	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	Concept	Wnt pa endopl
	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	Development status	Phase
	PD-L1 interaction through anti-PD-L1 antibody, such as 'KL001', body's anti-cancer	Route of Administration	IV
	immune activity can be efficaciously re-activated and eradicate cancers even at very	Competition	Other A
	diverse cancers, such as NSCLC, melanoma, H&N cancer, stomach cancer, etc.	Differentiation	Novel
Development status	Lead optimization and Cell-line development	Intellectual Property	Worldv
Route of Administration	IV	Data	AML
Competition	Atezolizumab (Roche), Durvalumab (AstraZeneca), Avelumab (Merck Serono)		2000
Differentiation	'KL001' has an unique binding epitope on PD-L1 and PD-L2		teretere
Intellectual Property	Undisclosed (in preparation) Unable to open experimental DATA because the patent for KL001 has not been filed yet		
Data	<ul> <li>Brief Description of KL001</li> <li>1. 'KL001', anti-PD-L1 I/O therapeutic antibody was isolated through proprietary phage display screening from fully human antibody libraries</li> <li>2. 'KL001' showed good PD-1/PD-L1 interaction blockade in SPR assay and in vitro cell-based assay</li> <li>3. In vivo study using murine colon cancer MC38 &amp; C57BL/6 syngeneic mouse model showed strong anti-cancer efficacy of 'KL001'</li> <li>4. Physico-chemical druggable properties. Biodistribution, epitope mapping analysis and rodent tox study (multiple injection) also showed unique characteristics of 'KL001'</li> <li>5. Affinity maturation study is at its final stage</li> </ul>	Project Milestone	AML P MM P1
Project Milestone	<ol> <li>Finalization of preclinical candidate (2017.06.30.)</li> <li>Production cell-line development</li> </ol>		



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

### **Asset Overview**

r (AML, MM) athway AML, MM drug









Chemical Entity

pathway inhibition by disrupting the unfolded protein response and inducing lasmic reticulum stress

- target (First-in-class)
- wide IP 2028~2032

P1 combo (+cytarabine) trial 2018. 2Q 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)
Intellectual Property	WO2011/040668, WO2013/147509

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
Therapeutic Area
Target
Concept

Development status Route of Administration

Competition

Differentiation

Intellectual Property

Data

## Protein (Antibody) VEGFR-2 (KDR) $\rightarrow$ Apoptosis of Tumor cells Phase IIa in Australia IV

- BIC mAb

Registered in 23 countries, including KR, US, JP, CN, EP, CA, AU etc.

HNSCC	
Rectal ca.	A
Rectal ca.	L
Rectal ca	
Rectal ca.	
Colon ca.	
Rectal ca.	_
MFH	
Gastric ca.	X
Esophageal ca.	
Colon ca.	
Colon ca.	
Rectal ca.	
Rectal ca.	
Rectal ca.	L .
Rectal ca.	L .
Colon ca.	x
ACC	
Colon ca.	
Rectal ca.	L
Colon ca.	
Rectal ca.	_
Colon ca.	
NSCLC	
Colon ca.	
HNSCC	x
	-
	0
<ul> <li>Previous bevacizun</li> </ul>	
<ul> <li>Stable disease</li> </ul>	
<ul> <li>Progressive disease</li> </ul>	
Hemangioma	

**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.)







• 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



SCIENCE

## 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	
Therapeutic Area	
Target	
Concept	

Development status Route of Administration

Competition Differentiation

Intellectual Property

Data



rat pup model

**Project Milestone** 

Milestone 1: Update nonclinical data, (2016.04-2017.06.) Milestone 2: Preparing for IND submission, (2017.07-2018.09.)







- New Chemical Entity
- Infantile Spasms (pediatric epilepsy)
- Metabotropic glutamate receptor family I & III
- Inhibit glutamate release and de-inhibit GABA signaling
- $\rightarrow$  decrease risk of excitotoxicity
- Preparing for Phase I/II

### Vigabatrin/ACTH

Oral

- Novel MoA with anticonvulsant, anti-epileptogenesis and Neuroprotection (Best in Class potential)
- Registered: JP6062077, KR10-1717872 PCT: KR2014-001903

**A)** Efficacy in Symptomatic infantile spasms

B) Protect hippocampal neurons against benzodiazepine-resistant status epilepticus in adult rats

**DONG-A ST** 

## KDDF-20160603-03 **Dong-A ST**

### **Asset Overview**

Product Type	Botanical drug
Therapeutic Area	Alzheimer's Disease
Target	Multi-Target (Aβ, Tau, AChE)
Concept	<ol> <li>Disease-treating via removal of disease-causing source Aβ (Neprilysin) ptau(GSK-3β)</li> <li>Improving cognitive ability via AChE inhibition</li> <li>Neuroprotection via NGF</li> </ol>
Development status	Pre-Clinical
Route of Administration	Oral
Competition	A $eta$ antibody and/or AChE inhibitor
Differentiation	Multi-function (Disease modifying and symptomatic effects)
Intellectual Property	PCT/KR-2015-013134, PCT/KR2015/013136
Data	Amyloid beta research (Brain of APP/PS1 mouse)



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**Project Milestone** 

2. US clinical initiation and clinical completion (2018. 2Q ~ 2019. 4Q)



### **Asset Overview**

Product Type	Chemical (OliPa
Therapeutic Area	Neuropathic Pa
Target	SCN9A / Nav1.7
Concept	OLP-1002 selec pre-mRNA → In Reproduce Pha
Development status	Preclinical
Route of Administration	Subcutaneous
Competition	Small molecule human subjects
Differentiation	Novel Target (Fi - OLP-1002 pos and distribute - Therapeutic d in patients wit affordable and
Intellectual Property	PCT/KR2009/00 OLP-1002 is a which was dev permeability as
Data	₿ <sup>1.2</sup> ] —



**Project Milestone** 





we create breakthru medicines

ass Oligonucleotide)

ain

ctively binds to SCN9A pre-mRNA  $\rightarrow$  Induce Exon Skipping of SCN9A nhibition of Translation of Nav1.7 ightarrow Inhibition of Nav1.7 Expression ightarrowarmacological Phenotypes of SCN9A Channelopathy

e Nav1.7 selective inhibitors—Found to show poor analgesic activity in S

irst In Class Potential)

ssesses an extremely high selectivity for Nav1.7 over Nav1.5,

es well to CNS tissues.

lose of OLP-1002 is predicted to be as small as 10 to 20 mg per week th chronic neuropathic pains, which may be developed for an readily nual treatment cost.

01256

derivative of OliPass Oligonucleotide, a novel class of oligonucleotide veloped by rationally modifying PNA to possess good membrane well as ultra strong affinity for nucleic acid.

abio

**Asset Overview** 

KDDF-201512-08

## KDDF-201502-07 Abion. Inc

### **Asset Overview**

Product Type	Protein	Product Type	New Chemical I
Therapeutic Area	Multiple Sclerosis	Therapeutic Area	Acute Ischemic
Target	The next generation Biobetter version of the human Interferon-beta through glycoengineering	Target	PARP-1 Reperfusion of
Concept	Immune modulation	concept	Reducing dama
Development status	Process Development / Preclinical	Development status	Phase II
Route of Administration	SC	Route of Administration	IV bolus + Infusi
Competition	Merck Serono (Rebif), Biogen IDEC (Avonex).	Competition	MP-124 of Mits
Differentiation	Decrease of aggregation tendency with additional glycosylation	Differentiation	Novel Target (Fi
	<ul> <li>Improvement of solubility and stability</li> <li>Price rationalization through improved productivity</li> <li>Increase of in-vivo half-life and activity</li> <li>Possibility of use in the off-label market, such as to treat viral disease</li> </ul>	Intellectual Property	1. Patent applic 2009, and the the US, Europ - PCT: WO 20
Intellectual Property	<ul> <li>Human Interferon-beta Mutein (BR, CN, EP, IN, JP, KR, PCT, US)</li> <li>Modified Interferon-beta Conjugated with Polyethylene Glycol (KR, PCT)</li> <li>Stabilized Formulations of Interferon beta Mutant (KR, PCT)</li> <li>Immunocytokine Conjugated with Human Interferon Beta-mutein and Method for Preparing Thereof (KR, PCT)</li> </ul>		<ol> <li>Application for the registration</li> <li>In summary, registered, ar and 4 interna</li> </ol>
Data	$i_{p} = 0$	Data	<ol> <li>Ongoing Phase</li> <li>Phase 1 comp</li> <li>Clinical trials</li> <li>64 subjects</li> <li>No SAEs, MT</li> <li>Monkey tMCA</li> <li>IV infusion for</li> <li>The best resu</li> </ol>
	Aggregation propensity Anti-proliferation effect Cell line productivity	Project Milestone	Milestone 1: Pro
Project Milestone	European Medicines Agency (EMA) approved (2023)		







## JEIL Pharmaceutical Co., Ltd.

Entity

: Stroke

stroke patient  $\rightarrow$  PARP-1 over-activation  $\rightarrow$  PARP-1 inhibition  $\rightarrow$ ages caused by necrosis and apoptosis  $\rightarrow$  Neuroprotective effect

sion

ubishi Tanabe

First in Class and Best in Class potential)

cations covering materials and preparation methods were submitted in registration was approved in 2010 in Korea (10-0968175), as well as in pe, China, Japan, Australia, Canada, Russia, Mexico, and Hong Kong. 010/056038

or the JPI-289 crystalline structure patent was submitted in 2012, and ion was approved in the US and Russia.

one application in Korea and 12 international applications have been nd review processes for registration of another application in Korea ational applications are currently underway.

se 2 (Clinical POC Study): pleted in 2015 s (Korea): NCT #02396069

TD = 900 mg/day

AO model study:

or 1 h

ults in the world compared to those of competitors

roof of Concept (2018.03.31.)

**LG** Chem

## 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	<ul><li>(1) A mitochondria-targeted ROS scavenger</li><li>(2) A novel necrosis inhibitor</li><li>(3) A mPTP modulator (indirect)</li></ul>
Development status	Phase II (STEMI patients with AMI)
Route of Administration	IV (orally available)
Competition	No competition (all clinical trials failed)
Differentiation	<ul><li>(1) A novel necrosis inhibitor (First In Class potential)</li><li>(2) Downregulation of RIP-1 &amp; -3 expression (necroptois inhibition)</li></ul>

🛞 www.lgchem.com 🛛 Soon-Ha Kim 🖾 shakim@lgchem.com

## Intellectual Property

Data



### Project Milestone

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

+82-10-7755-0235

# KDDF-201609-12 **Ulsan University**

Data	Normal o
	Unuisclosed (
Intellectual Property	
Differentiation	Novel Target (
Competition	None
Route of Administration	Oral
Development status	Lead Optimiza
Concept	DPP-4 inhibiti $\rightarrow$ Attenuatior
Target	Dipeptidyl pep
Therapeutic Area	Calcific aortic
Product Type	New Chemica
Asset Overview	

Project Milestone

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

🛞 www.ails.amc.seoul.kr 🛛 🖸 Jae-Kwan Song



### al Entity

- valve disease (CAVD)
- otidase-4 (DPP-4)
- tion  $\rightarrow$  Reduction of aortic valve calcification
- on of CAVD development
- ation

### (First In Class potential)

preparation)





+82-2-3010-3155

**Asset Overview** 

Product Type

Target

Concept

**Therapeutic Area** 

**Development status** 

Competition

Data

Differentiation

Intellectual Property

**Route of Administration** 

## KDDF-201601-03 **Gwangju Institute of Science and Technology**

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### **Asset Overview** Product Type New Chemical Entity **Therapeutic Area** NASH Target Concept metabolic syndromes Development status Lead Generation Route of Administration Oral Other T2DM medicines Competition Differentiation Intellectual Property Undisclosed (preparation) 150 (Md) ₩ 100·



**Project Milestone** 

Data



Undisclosed (preparation)

Novel Target (First In Class potential)

Other T2DM medicine

	PDK4 IC50	M.S. After 30 min	Solubility (u SOL)	Herg % inhibition at 10 uM	CYP450-F % inhibition at 10 uM	PK (iv and oral)	In vivo study (7 days)
67419	1759 nM	98% (rat) 99% (human)	>250 ug/ml	2.12%	1A2 : <1 2C9 : 13.70 2C19 : 6.15 2D6 : 3.43 3A4 : 5.12	BA 11%	
10076	587 nM	66% (rat) 74% (human)		2.93%	1A2 : <1 2C9 : 56.4 2C19 : 27.6 2D6 : 3.08 3A4 : 18.1	BA 19%	
10002	75 nM	99% (mouse) 99% (human)				pending	Glucose lowering efficacy
10136	93 nM	99% (mouse) 99% (human)				pending	Glucose lowering efficacy

Data

**Project Milestone** 

Milestone 1: Lead generation (2017.12.31.)

PDK4 inhibitor



# GLP-1 otal

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25

### **EWHA WOMANS UNIVERSITY**

Diabetes Mellitus, Type 2 (Metabolic Disease)

Gut-restricted Farnesoid X Receptor (FXR)

Gut-restricted FXR agonism  $\rightarrow$  Enhancing GLP-1 signaling & energy expenditure, reducing serum inflammatory cytokines, altering serum bile acid composition & gut microbiome  $\rightarrow$  Reducing blood glucose levels & diet-induced weight gain, improving

Gut-restricted FXR Modulator (First In Class potential)



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

## KDDF-201601-04 **Aptamer Sciences Inc.**

### aotsci Sciences Inc

26

## KDDF-201502-11 Genexine, Inc.

Asset Overview		Asset Overview	
Product Type	Chemical (Aptamer)	Product Type	GX-H9 (Hybrid Fc fu
Therapeutic Area	Diabetes Mellitus, Type 2 (Metabolic Disease)	Therapeutic Area	Growth hormone de
Target	Insulin Receptor	Target	Growth hormone de
Concept	Allosteric activation of Insulin Receptor $ ightarrow$ Biased Function (Blood glucose control without mitogenic activity)	Concept	Developing long-a safety
Development status	Lead Optimization	Development status	Global Phase II (In-
Route of Administration	SC	Route of Administration	SC injection (liquid)
Competition	Insulin Analogues (Basal insulin)	Competition	Opko (L/O to Pfizer)
Differentiation	Novel mechanism of action without side effect (First in class)	Differentiation	Twice-monthly and
Intellectual Property	Undisclosed (preparation)	Intellectual Property	US 8,586,038; US 8, KR 1 380729; KR 1 3
<b>B</b> utu	IR-A48 + + + Insulin - + - + piR (Y1150/Y1151) <u>10C3</u> piR (pY) 4G10 IR piR (Y608) pAKT (T308) pAKT (S473) PAKT (S473)	Data	(A) PK profile

### **Project Milestone**

Milestone 1: Chemical optimization (2018.06.08.)

ERK1/2 (T202/Y204)

20

40

60

Time (min

80

100

120

**Project Milestone** 



27





- usion human growth hormone)
- leficiency
- eficiency in Adult
- acting growth hormone to ensure compliance, convenience and
- -process of completion)
- ), Versartis, Novo Nordisk, Ascendis
- weekly doses and improved safety profile
- ,586,048; US 8,586,531; US 8,529,899; 380732



## KDDF-201509-12 Genexine, Inc.

### 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	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

Milestone 1: 6 month aHV result (2017.04.) Milestone 2: License out (2017.10.)



## KDDF-201404-10 CJ HealthCare

Asset Overview			
Product Type	New Chemica		
Therapeutic Area	Acid-related o		
Target	Gastric Protor		
Concept	P-CABs inhib Consequently anti-secretory to rapid rise healing.		
Development status	Phase 3 for G		
Route of Administration	Oral / Tablet /		
Competition	PPIhas ident days to achie prandially, an unmet needs		
Differentiation	Best-in class		
Intellectual Property	Undisclosed (		
Data	Assay St		
	н		
	C		
	Na <sup>+</sup> /K <sup>+</sup> - ATPase		
	In vitro P		
Project Milestone	NDA submiss		





### al Entity

diseases (GERD, Peptic ulcer, and H.pyloriinfection)

npump (H<sup>+</sup>/ K<sup>+</sup> ATPase)

bit gastric H⁺/K⁺-ATPase in a K⁺competitive but reversible mechanism. y, P-CABs do not require prior proton pump activation to achieve their ry effect. P-CABs exhibit an early onset of acid-secretion inhibition due in peak plasma concentration, resulting in guicker symptom relief and

GERD is completed

### QD

tifiable limitations related to mechanismof action. It requires several eve maximum suppression, is less efficacious when administered postnd has large individual differences inefficacy. Tegoprazancan satisfy these in gastric-acid related diseases, which are notaddressed by PPI.

### P-CAB

(preparation)





<sup>D</sup>harmacology

sion in 2017

**ALTEOGEN** Inc.

## KDDF-201606-02 Alteogen, Inc.

### **Asset Overview**

Data	1000 - E	20 ■ NovoSeven
Intellectual Property	US patent No. 9012606 (registered; application dat	e: 2011.10.21)
Differentiation	Prolonged half-life with equivalent effects (Best In	Class potential)
Competition	FVIIa-FP (albumin fusion), FVIIa-CTP (CTP fusion)	
Route of Administration	IV	
Development status	Lead Optimization	
Concept	$Recombinant\;FVIIa\;+\;NexP^{\mathsf{TM}}\;{\rightarrow}\;Long-acting\;FVIIa$	
Target	Coagulation Factor VIIa	
Therapeutic Area	Hemophilia	
Product Type	Protein	



### **Project Milestone**

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

## KDDF-201606-08 **ENZYCHEM LIFESICENCES**

### **Asset Overview**

Product Type	New Chemica	
Therapeutic Area	Neutropenia (I	
Target	STAT3	
Concept	Inhibition of pl CXCL8 → Dec extravasation	
Development status	Phase II	
Route of Administration	Oral	
Competition	IV-infusible/S0	
Differentiation	Novel MOA/Or	
Intellectual Property	Undisclosed (p	
Data	PLAG	
	PLAG GEM -	

**Project Milestone** 

Milestone 1: Clinical Proof of Concept (2018.10.)

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### **ENZYCHEM LIFESCIENCES**

- ical Entity
- ia (Febrile)
- phosphorylation of STAT3  $\rightarrow$  Decrease of production of Decrease of neutrophils mobility  $\rightarrow$  Decrease of neutrophils
- e/SC-injectable recombinant myeloid growth factors
- /Oral route (FIC)
- ed (preparation)







Figure 2. PLAG concentration-dependent increase of PLAG on number of neutrophils in Balb/c mice treated with or without gemcitabine (GEM)

## KDDF-201609-01 **Ewha Womans University**

### **Asset Overview**

Product Type	Peptide
Therapeutic Area	Atopic dermatitis
Target	Histamine Releasing Factor (HRF)
Concept	HRF inhibiting peptide (dTBP2) $\rightarrow$ HRF inhibition $\rightarrow$ Targeted therapy for atopic dermatitis
Development status	Lead Generation
Route of Administration	Subcutaneous
Competition	Dexamethasone (a corticosteroid)
Differentiation	Novel Target (First In Class potential)
Intellectual Property	Undisclosed (preparation)

dTBP2 or PBS Biostir • NC/Nga mice



**Project Milestone** 

Data

Milestone 1: Proof of Concept (2018.04.15.)

**EWHA WOMANS UNIVERSITY** 

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## KDDF-201410-02 HanAll BioPharma

### **Asset Overview**

Product Type	Protein (Fully I
Therapeutic Area	Pathogenic Ig(
Target	Human FcRn
Concept	hFcRn blockir level $ ightarrow$ Diseas
Development status	IND-ready
Route of Administration	SC Injection
Competition	Other anti-FcF
Differentiation	High potency & (First-in-Class
Intellectual Property	PCT/KR15/044
Data	100 80 80 40 20 -20 0,001 0.01
	/ 1 h th to the second

pH6.0

**Project Milestone** 

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

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33



Human Monoclonal Antibody)

G-Mediated Autoimmune Diseases

ng ightarrow Inhibition of hIgG binding to hFcRn ightarrow Reducing pathogenic IgG se recovery

Rn antibody drug

& Patient compliance based on SC injectable formulation Potential)

424







RIOLOGICS

## 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	TNFα/IL17A-CXCL1 inhibition
	3.0 $3.0$ $4$ $4$ $4$ $4$ $4$ $4$ $4$ $4$ $4$ $4$
	<ul> <li>YBL-004 : Full-IgG(Humira)-scFv (anti-IL17) form</li> </ul>

- IL-17 antibody
- Fully human antibody
- Highly IL-17A specific (no binding to IL-17F)
- Creactive to marmoset and cynomolgous II-17A
- 10<sup>-11</sup> KD value
- Highly stable

### Project Milestone

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



## KDDF-201612-09 **Sookmyung Women's University**

Peptides

IV or SC

TNF inhibitors

### **Asset Overview**

Product Type	
Therapeutic Area	
Target	
Concept	

Route of Administration

Competition

Development status

Differentiation

### Intellectual Property

### Data



	Norma
	Vehicle
-	P6
	P9
-	R6-2
	MTX

### Day 0

**Project Milestone** 

Milestone1: Lead optimization  $\rightarrow$  Candidate selection





- Rheumatoid Arthritis (RA)
- Regulatory T cells (Treg)
- Increased Treg cell number and activity  $\rightarrow$  Inhibition of Th17 cells and Osteoclast differentiation  $\rightarrow$  Suppression of RA pathogenesis
- Lead Optimization
- Novel small peptide from Erdr1 protein (first-in-class) Specific target identification for each peptides
- PCT applications

**Oct** | Oscotec Inc.

## KDDF-201509-05 **Oscotec Inc.**

### **Asset Overview**

Product Type	Chemical
Therapeutic Area	Rheumatoid arthritis
Target	Spleen tyrosine kinase
Concept	Spleen tyrosine kianse (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-0-703 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	<ul> <li>Single ascending dose (SAD) study : completed</li> <li>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)</li> <li>Strong PD effect in activated basophil followed by anti-IgE stimulation Estimated EC50 of SKI-0-703, ~350 nM in the % activated basophil</li> <li>Multiple ascending dose (MAD) study : completed (preparing the CSR)</li> <li>200 mg (qd &amp; bid) and 400 mg (qd): completed at Q2, 2017</li> <li>Clinical safety : no outstanding issue found at any test dose</li> <li>Reproducible PD effect in activated basophil followed by anti-IgE stimulation</li> </ul>
Project Milestone	Milestone 1: Completion of SAD study (2016.10.07.) Milestone 2 : Completion of MAD study (2017.11.07.)
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## KDDF-201609-04 **Chong Kun Dang**

### **Asset Overview**

Data

_	F # 1
	countries or
Intellectual Property	The patent of
Differentiation	Novel Targe
Competition	Chemical ar
Route of Administration	Oral
Development status	Phase I
Concept	Inhibits TNF
Target	Histone Dea
Therapeutic Area	Autoimmune
Product Type	New Chemi





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<sup>+</sup>CD45RB<sup>hi</sup> T cell adaptive transfer model and preserves IBD epithelium.

**Project Milestone** 





cal entity

ne Disease (RA, IBD)

acetylation 6 (HDAC6)

alpha and regulates T cell function

nd biological DMARDs

et (First-in-Class)

of CKD-506 was granted in Korea on July 2016, and filed in 53(fifty-three) n April 2014

Phase I: SAD, FE, MAD (2017. 3Q)

🖸 Business Development Team

## KDDF-201406-08 ImmuneMed, Inc.



## KDDF-201509-02 Ourient

Asset Overview			Asset Overview	
Product Type	Protein (Immunoglobulin)		Product Type	New Chemical Ent
Therapeutic Area	Infectious disease (HBV, Influenza, etc)		Therapeutic Area	Tuberculosis
Target	Virus Suppressing Factor (VSF) receptor		Target	Inhibition of cytoch
Concept	Virus infection $ ightarrow$ Anti VSF receptor expression only on virus infected cells $ ightarrow$ VSF treatment $ ightarrow$ anti-viral and anti-inflammatory effects to cell		Concept	Cytochrome bc1 co $ ightarrow$ Bactericidal ef
Development status	Preclinical to Phase I (expected to 2017)		Development status	Phase I
Route of Administration	IV/ IM		Route of Administration	Oral
Competition	It works a different mechanism of action compared to conventional anti-viral treatments. No competition		Competition	TB drugs are used yet preventing resi
Differentiation	Novel target (FIC)		Differentiation	First in class comp
Intellectual Property	Undisclosed (preparation)		Intellectual Property	Undisclosed (prepa
Data	[A] HBV infected liver Normal liver	[B]	Data	



Figure 1. Examination of VSF receptor (VR) in HBV and HCV infected human liver tissue (A)

Project Milestone

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

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**Project Milestone** 



### tity

- nrome bc1 complex QcrB subunit in TB
- omplex inhibition  $\rightarrow$  Inhibition of energy metabolism in TB ffect

I in combination to take advantage of synergistic effect, istance. There is no competition in this class of compound

- pound
- paration)



End of Phase 1 study: 2017 End of phase 2A study: 2018

treatment

• 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

## 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	Mutli-targeting relating to allergy $ ightarrow$ Th2/Th17 selective blockade $ ightarrow$ 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)

### Data

**Project Milestone** 



Neutrophilic asthma model (AHR)



Clinical IND approval. (2018.03.30.)



**DONGWHA PHARM** 

Data

**Project Milestone** 

## KDDF-201410-05 YUNGJIN PHARM. CO., LTD.

### **Asset Overview**

Botanic
COPD (F
HDAC2
HDAC2 Prevent
Phase I
Oral
Oral CO
Novel Ta
Patient Patient Patient Patient

25.0

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



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otanical Drug / NCE OPD (Respiratory System)

DAC2 activator  $\rightarrow$  Inflammation controls and increasing of steroids sensitivity  $\rightarrow$ revention of COPD exacerbation

nase IIa Completion (CSR working)

al COPD medicines

ovel Target (First In Class potential)

atient 1: Registered, Covering world wide (15 countries)

atient 2: Registered, Covering world wide (12 countries)

atient 3: Registered, Covering world wide (12 countries)

atient 4: Registered, Covering world wide (12 countries)

Patient 5: Registered, Covering world wide (12 countries)

Patient 6: Registered, Covering world wide (12 countries)



[A] In Vitro (human BEAS-2B cell)



[B] In Vivo (CSE mouse acute model)

• Model: 6 ~ 8 weeks old male BALF/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]

OPHTHALMOLOGY

## KDDF-201509-15 **Taejoon Pharmaceutical Co., Ltd.**

### **Asset Overview**

Product Type	Protein (Antibody)
Therapeutic Area	Wet AMD
Target	VEGFR2
Concept	VEGFR2-specific binding $ ightarrow$ Blocking not only VEGF-A, but as well as VEGF-C and VEGF-D
Development status	Preclinical
Route of Administration	Intravitreal injection
Competition	Lucentis, Eylea
Differentiation	Potential to treat tachyphylaxis against Lucentis or Eylea by Inhibiting VEGFR2 signaling of VEGF-C and VEGF-D
Intellectual Property	Disclosed

Data

### CNV Model



**Project Milestone** 

Approval of Ph1 IND (2018.09.)



Xenograft model

...............

Avastin (1mg/kg) TJO-054 (1mg/kg) TJO-054 (10mg/kg)

PBS

## **WHY "KOREA" IS THE PERFECT PLACE FOR NEW DRUG** DEVELOPMENT

- guideline.

• Efforts for Regulatory Harmonization across Korea, China, Japan – Established AHC(www. apec-ahc.org) and holds tripartite forum to elicit the right policy environment for life sciences innovation

## **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)



### **GEOGRAPHICAL ADVANTAGE**

Korea is strategically located at the center for transportation in Northeast Asia

• 61 cities with a population of more than 1 million within a 3-hour flight from Seoul • Korea, Japan and China boast a combined GDP of about \$14 trillion

• Total population of Korea, Japan and China exceeds 1.52 billion, or 22% of the global population, and total trade volume is \$5.32 trillion, or 17.6% of total world trade.

• Established the APEC Harmonization Center (AHC) for regulatory harmonization within ICH

### **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 (KRIBB), Korea Institute of Technology (KIT), Korea Research Institute of Chemical Technology (KRICT), Two high-tech medical clusters (Osong, Daegu)

- Registered 520 patents in the bio sector of the United States between 2006 and 2010, and recorded 166 in technology strength, ranking 14th.