



Global Leader of Cancer Treatments

AUTOTELIC BIO

오토텔릭바이오

**Oligonucleotide Anticancer
New Drug Development Company**

August 2021



Disclaimer

The purpose of this file is for the investment community to gain an understanding of our company, through information provided by Autotelic Bio Inc.

- This file contains forward looking statements based on the information available to our company at the present time. Since such projections do represent some risk and uncertainty, please be aware that a variety of factors may operate to produce final results that vary greatly from these projections. These projections are expressed with “forecast”, “forward looking”, “plan” and “tendency”.
- The content on this file other than past or present facts consists of plans, future projections, or strategies based on currently available information and includes risks and uncertainties. Actual results may vary materially from these projections due to factors including risks or uncertainties pertaining to the economic situation, market trends, or changes in the tax system or other regulatory regimes. The Company may alter or omit the content of this website without prior notice..
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Company Profile



Global Leader of Cancer Treatments

- Establishment** In November 2015
- Company Type** Foreign investment company, Autotelic Bio & Korean investors/ USA investors (under 10%)
- Location** R&D Center) 303, Inno-valley A dong, 253 Pangyo-ro, Bundang-gu, Seongnam-si, Gyeonggi-do, Korea
HQ) 194-41, Osongsaengmyeong 1-ro, Yeonje-ri, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, Korea
- Major Business**

New Drug development focusing
on cancer treatment

Global licensing, Market entry strategy
and RA consulting

Innovative
**Anti-Cancer
New Drug**
for unmet medical needs

IP Status

	Korea	Global
Grant	4	1
Apply	7	11

Major R&D Government Grant

Developing innovative new
drug based on antisense
oligonucleotide

ATB-301
ATB-320

Developing innovative
new drug based on
small molecule

ATB-330

Key History



Establishment 2015~2017

- 2015.11. Autotelic Korea Establishment
(Foreign investment)
- 2017.9. ATB-101 Government R&D grant
(Ministry of SMEs and Startups)
- 2017.9. **Corporate R&D center accreditation**

Growth Phase 2018~2020

- 2018.7. Investment agreement with TIPS
- 2018.7. ATB-301, Immuno-Oncology Government R&D grant
(Ministry of SMEs and Startups)
- 2018.8. Angel investment
- 2018.9. **Pankyo R&D center Establishment**
- 2019. 1. ATB-101 Tech Transfer and Investment agreement with Jeil Pharm.
- 2019. 4. ATB-301 selected in "Pharm Navi" project by MFDS
- 2019. 5. TASO CMO agreement with ST Pharm
- 2019.10. Investment agreement with Aju Pharm & KODIT
- 2019.12. **Series A round** with Mega Investment & UTC Investment
- 2020. 1. Technology Innovation-Oriented Small and Medium Enterprise
(Inno-Biz), (Ministry of SMEs and Startups)
- 2020. 2. **Series A round** with Stonebridge Ventures
- 2020. 4. ATB-301, R&D grant (Ministry of Trade, Industry and Energy)
- 2020.12. Strategic Investment with ST Pharm and other 2 Pharmaceutical companies

Active Phase 2021~

- 2021. 1. Clinigen(UK) ATB-301 Agreement
- 2021.2. ATB-301 Phase 1b IND Approval
- 2021.2. ATB-101 Phase 1 IND Approval

R&D Center Accreditation

Pipelines: Non-clinical stage
Series A and Strategic Investment Attract

Pipelines: Clinical Stage
Platform Technology: ASODE™

Autotelic Bio's Leadership



Tai KIM

<CEO; Business globalization/ Management>

- Boryung Pharm New drug (Kanarb) Global Business Team head
- Huya bioscience San Diego, Licensing part
- *Major success track record*
Boryung Pharm, KT&G Life Science and DaeWoong Pharm's New drug license out



Juneui PARK

<Executive Director; R&D / Head>

- JW CreaGene Research Institute, Genexine Clinical development team head
- Memorial Sloan-Kettering Cancer Center (NY), Research Associate (Dendritic cell, NKT cell)
- Roswell Park Cancer Institute (NY) Doctor, Biochemistry & Biophysics



Charlie ROH

<VP; Business globalization/Management>

- GE healthcare Marketing
- Boryung Pharm Overseas Biz team
- *Major success track record*
Crystal genomics, Ilyang Pharm and Boryung Pharm's new drug license out



Kyungwan NAM

<Director; R&D Strategy>

- SamJin Pharm. R&D Center, Pharmaceutical research head
- Boryung Pharm. R&D Center, Formulation research team leader CMC research & tech transfer of New drug (Kanarb)
- DaeWoong Pharm. R&D Center, Senior researcher



James JUN M.D.

<VP; R&D advisor>

- Boryung Biopharma Development Team Head
- KT&G Life science President
- Boryung Pharm R&D Center team Head/Kanab BD Head
- *Major success track record*
Boryung Pharm's New drug license out



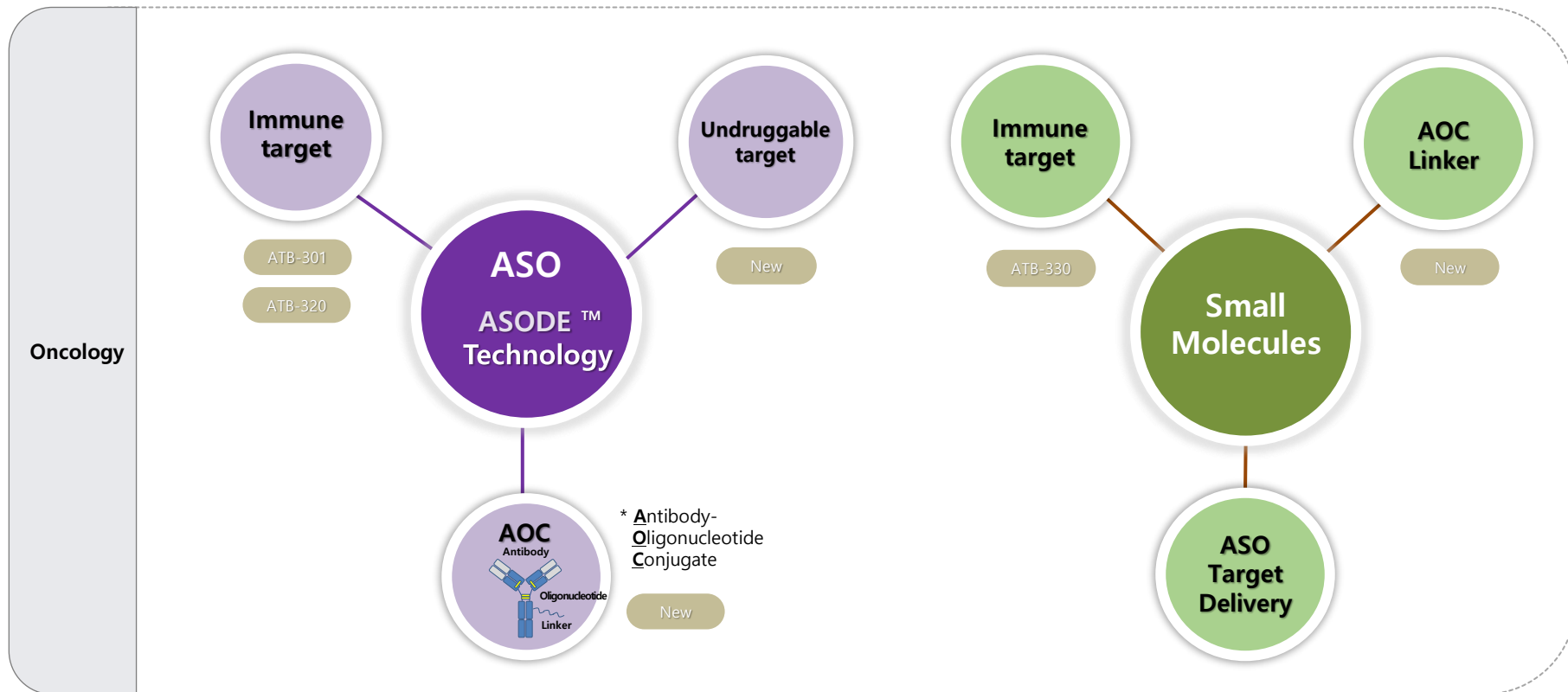
Changhee PARK

<Director; R&D / MediChem>

- Hanmi research center NCE/ICE discovery team Project Leader, Oncology pipeline discovery & development, Medicinal chemistry
- Chung-ang University, Ph.D., Pharmacy

4

R&D Key Word_ASODE™, Oncology, Immune target



ASODE™ (AntiSenseOligo Development) Technology



Target Search

Homo sapiens transforming growth factor beta 2 (TGFB2), transcript variant 1, mRNA

NCBI Reference Sequence: NM_001135599.4

FASTA Graphics

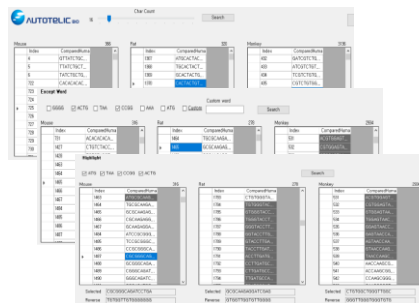
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ORIGIN

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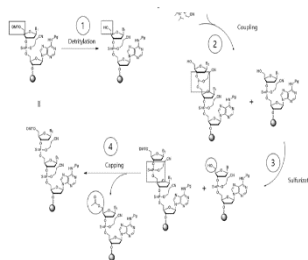
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Selection

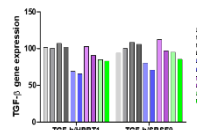


ASO Design/Manufacture

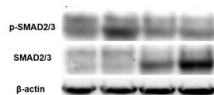
Seq No.1 5'-GGCCGATGATTGCAACTAG-3'
Seq No.2 5'-AGCGATGATTGCAACTAG-3'



In-vitro



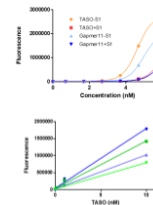
mRNA Level



Protein Expression

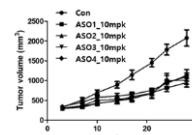


Plasma Stability



PK (H-ELISA)

In-vivo



Xenograft model

Evaluation

Effective New Molecule

ASO Developmental Case



[BioS Letter] Evolving ASO, Global approval & Development Status?

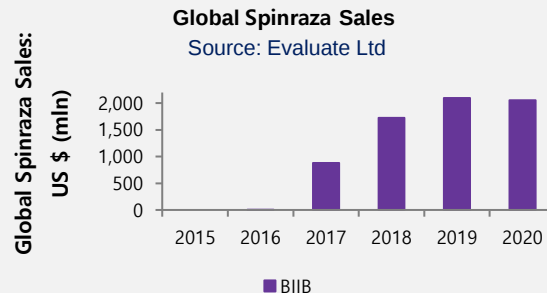
2021-01-12

By UiJeong Lee, BIOSPECTATOR

ASO has been continuously developing from the first generation to the current third generation from 1978 when it was first discovered. The pre-modification (old generation) ASO had a limitation in that it was difficult to diffuse into cells due to its large size and charge, and was susceptible to nucleic acid degradation. However, at present, through chemical modification of ASO, immune response and off-target toxicity decreases, and enzyme stability and drug efficiency are increased, making it one step closer to commercialization of ASO therapeutics by supplementing the shortcomings. ~omitted~

Drug	Target	Indication	Company	Approval
Formivirsen (Vitravene TM)	CMV mRNA	CMV infection	Ionis	FDA (1998)
Mipomersen (Kynamro TM)	apo-B-100 mRNA	HoFH	Genzyme	FDA (2013)
Nusinersen (Spinraza [®])	SMN2 pre-mRNA	SMA	Biogen	FDA (2016), EMA (2017)
Inotersen (Tegsedi [®])	TTR mRNA	hATTR	Ionis	FDA (2018), EMA (2018)
Eteplirsen (Exondys 51 [®])	exon 51	DMD	Sarepta	FDA (2016), EMA (2018)
Golodirsen (Vyondys 53 TM)	DMD pre-mRNA	DMD	Sarepta	FDA (2019)
Milasen	intron 6 splice acceptor cryptic site	CLN7	Boston Children's Hospital	FDA (2018) for a single patient

◆ Spinraza (Spinal Muscular Atrophy) : \$2 Bil in 2020



◆ Leqvio (Approved 2020, EU) : Exp \$2 Bil in 2026



Aggressive development of Combination Therapy



Immune check point inhibitor + TGF- β inhibitor



acquire Tilos Therapeutics, a total of \$733 million... "Potential to overcome PD-(L)1 drug resistance with LAP target antibody that inhibits Latent TGF- β "

Merck web-site

Merck, Inc. (MSD), a leader of immune check point inhibitor, has acquired antibodies; the second-generation **TGF- β drug**, targeting the latency-associated peptide (LAP).

In recent years, Merck has been aggressively acquiring a combined partner candidate to strengthen Keytruda's position as the first-line. Last month, Merck acquired Peloton Therapeutics, which develops HIF-2 α inhibitors as a drug to treat kidney cancer with Keytruda, for a total of \$ 2.2 billion. Which was announced a month later when the US Food and Drug Administration (FDA) approved combination of Keytruda and Pfizer's Inlyta[™] (axitinib) as first-line treatment. Evaluate Pharma estimates that in 2024, Keytruda will outstrip HUMIRA and raise \$ 17 billion to become the world's best-selling drug (in the report of 2019.06).

nature

TGF β attenuates tumour response to PD-L1 blockade by contributing to exclusion of T cells

Sanjeev Mariathansan, et al. 14 February 2018

therapeutic co-administration of **TGF β -blocking** and anti-PD-L1 antibodies reduced TGF β signalling in stromal cells, facilitated T-cell penetration into the centre of tumours, and provoked vigorous anti-tumour immunity and tumour regression.



Bristol Myers Squibb[™]

FORBIUS

Bristol Myers Squibb Completes Acquisition of Forbius

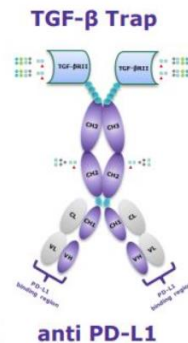
BMS News

Bristol Myers Squibb (NYSE: BMY) today announced that it has successfully completed its transaction to acquire Forbius for their **TGF-beta program**, including its lead investigational asset AVID200, currently in Phase 1 for oncology and fibrosis.



Merck, GSK to jointly develop novel immunotherapy 'bintrafusp alfa' for multiple difficult-to-treat cancers

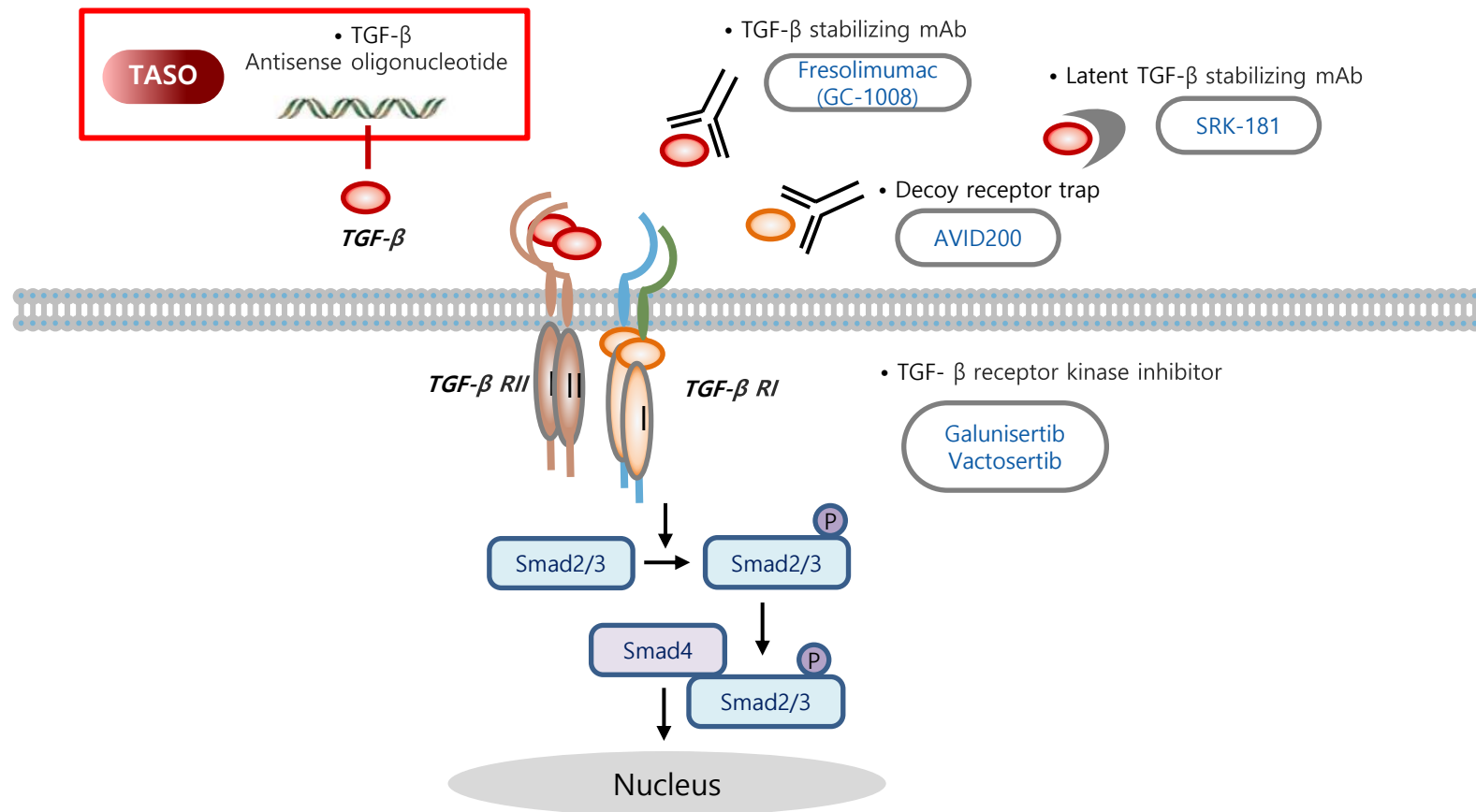
06 February 2019



European drug multinationals Merck KgaA and GSK Plc have jointly announced that they have entered into a global strategic alliance to jointly develop and commercialize M7824 (bintrafusp alfa), a novel immuno therapy drug with potential to treat multiple difficult-to-treat cancers.

M7824 is designed to simultaneously target two immuno-suppressive pathways, transforming growth factor- β (TGF- β) trap and an anti-programmed cell death ligand-1 (PD-L1), that are commonly used by cancer cells to evade the immune system.

Competition status - Target of TGF- β



ATB-301; Combination Therapy of TASO + IL-2



◆ TGF-β2 Targeting ASO ◆

18-mer Anti-sense Oligonucleotide new drug targeting human **TGF-β2**

- Designed based on the correlation between **TGF-β** overexpression and tumor progression
- Pre-&clinical efficacy data on single therapies for pancreatic cancer, melanoma, glioblastoma

In-vitro synergistic test
2019 ~ 2020

Autotelic Bio

Breast cancer cell line (MDA-MB-231, Hs578T, BT549), pancreatic cancer cell line (AsPC-1), lung cancer cell line (A549), melanoma cell line (Hs294T, A2058), colorectal cancer cell line (LS174T, HT29).

In-vivo synergistic test
2019 ~ 2020

Charles River, Chungbuk National Univ.

On humanized mouse (humanized mouse, NSG mouse model) using TNBC cell line (MDA-MB-231) and melanoma (A2058) xenograft model with TASO + IL-2

Patent granted
2020.10

Korean IP Office

Patent Approved:
Anticancer Composition
Comprising TASO and IL-2

Clinical P1b IND
2021. 01

MFDS

IND approved for phase 1 clinical trial in solid tumor

Clinical P2a
2022. First Q

MFDS

Expect phase 2 clinical trial in solid tumor

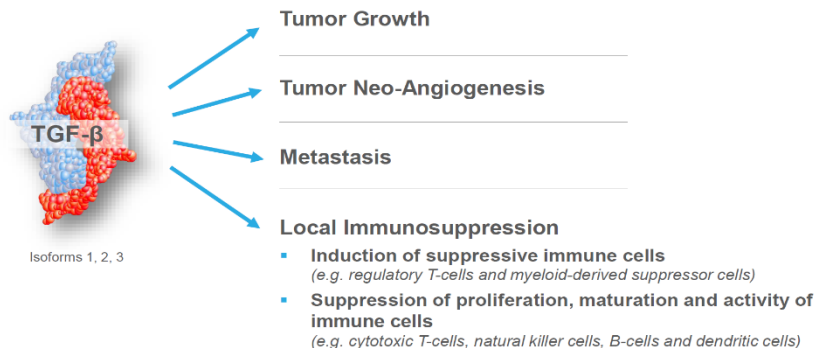


TASO (TGF- β 2 Targeting Anti-Sense Oligonucleotide)



TGF (Transforming Growth Factor)- β

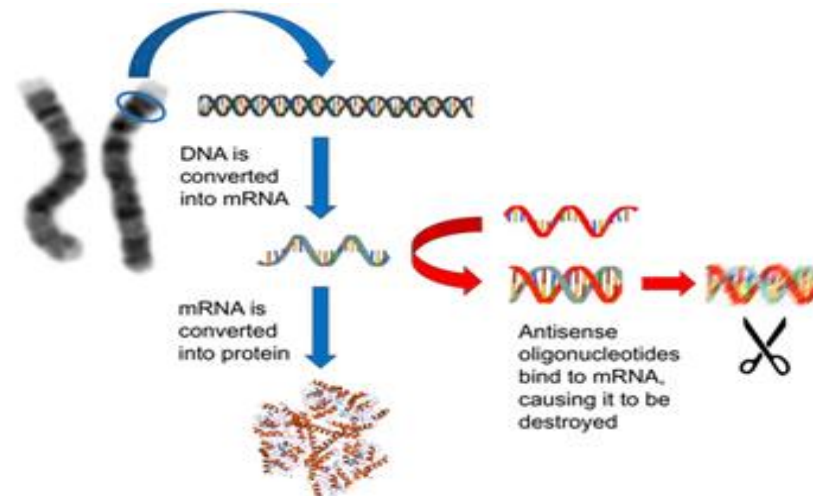
- A dimeric structure protein with a M/W of 25,000
- An important factor for cancer growth and metastasis, and acts as a protective factor for fibrosis and cancer.



Efficacy and safety of monotherapy are confirmed for pancreatic cancer, melanoma, and glioblastoma

Anti-Sense Oligonucleotide

- Synthesized single stranded nucleic acid polymer
- Regulate protein expression by specifically complementary binding to the target mRNA sequence

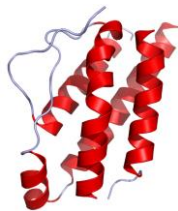


How antisense therapy works. Various public domain images. Author provided

Interleukin-2 (IL-2)



Interleukin-2 (IL-2)



IL-2

High Dose

Strong anti-tumor activity

- Stimulating effector T-cells and NK cells

Toxicity

- Vascular leak syndrome
- Severe hypotension

♦ The recent big deals around IL-2

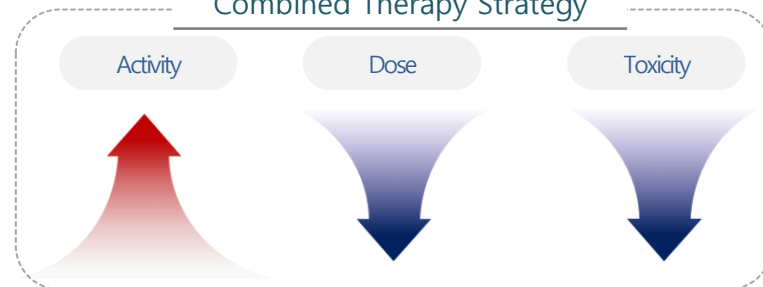
Development	Funder	Partner	Up-front funding	Technology	Date announced
	BMS	Nektar Therapeutics	\$ 1 billion	Pegylated IL-2	Feb. 2018
	Eli Lilly	Nektar Therapeutics	\$ 150 million	Pegylated IL-2	Jul. 2017

Acquisition	Acquirer	Target	Price	Technology	Date announced
	Merck & Co.	Pandion Therapeutics	\$ 1.85 billion	Antibody-coupled IL-2	Feb. 2021
	Sanofi	Synthorx	\$ 2.5 billion	Engineered IL-2	Dec. 2019

Recombinant IL-2 (rIL-2; aldesleukin)

- ♦ First FDA approved potent immunostimulatory cytokine anticancer drug
- Promotes CD8+ T cells and NK cells
- FDA approval: Metastatic renal cell carcinoma (1992), Metastatic melanoma (1998)
- However, **IL-2 should be given in a high dose**, which will inevitably **result in severe toxicities** including vascular leak syndrome (VLS), pulmonary edema, hypotension, and heart toxicities

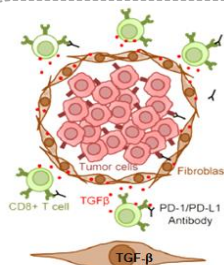
Combined Therapy Strategy



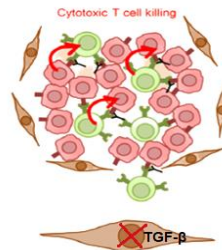
Mode of Action for Combination; Rationale

TASO

Weakening defensive power of cancer cell by suppressing TGF- β



TASO

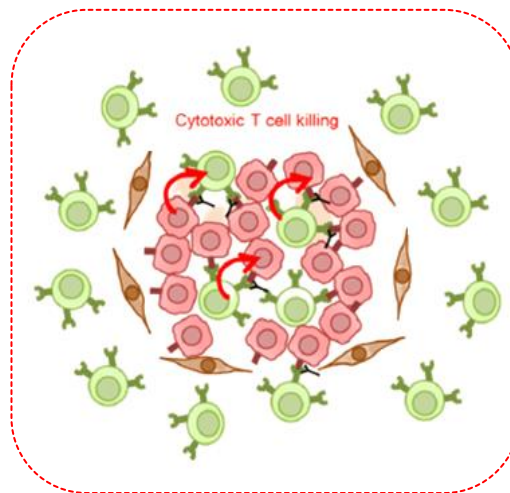


TGF- β pathway genes **ON**
T cell exclusion from Tumor

TGF- β pathway genes **OFF**
T cell infiltration into Tumor

Immunity. 2018 Apr 17; 48(4): 626–628. doi: 10.1016/j.immuni.2018.03.037

Increased number of T cells infiltrate into Tumors



Combination Therapy

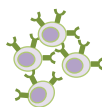


IL-2

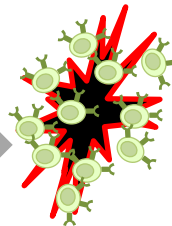
Strengthen T cell's attack to cancer cell

PROLEKIN IL-2
increases the number
of T cells

PROLEKIN IL-2
increases activates and
boosts cell production



Attacks



T cells

Specific T cells

Cancer cells

Programming Immunity: Defense to Offense AUG 19, 2011 By Miriam Lueck Avery

Target Market



Pancreatic Cancer

Types of Pancreatic Cancer

Exocrine
Most Common

Endocrine
7-8%

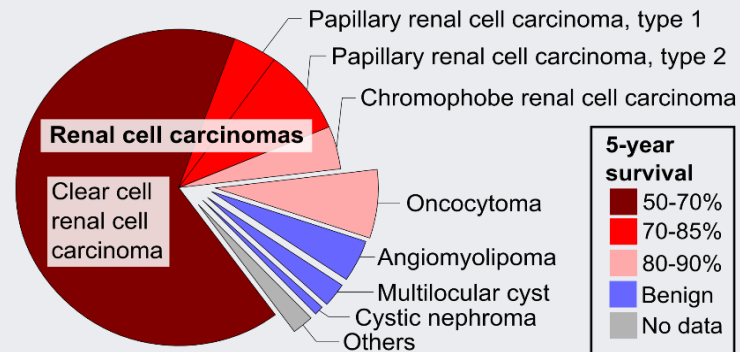


- One of cancer with lowest survival rate: 2% to 9% (5-years)
- Expected market size: Market was valued at 1.7B USD in 2015. With CAGR of 8%, market is expected to be ~ **4.2B USD in 2025**



- **1.5B USD** (More than 25% of global PC market)

Renal Cell Carcinoma and etc.



- Expandable indication market: **42B USD**
- RRC 6B USD (expect in 2025), Breast cancer 22B USD (expect in 2023), NSCLC 8B USD, Pancreatic cancer 2.5B USD, Melanoma 3.5B USD and etc.



- **4B USD** (More than 10% MS of global RCC, Breast cancer, Lung cancer market)

Expected Sales

- Targeted to achieve over 150M USD in annual revenue through the successful clinical trial & the product release of ATB-301
- Expected to receive more than 300M USD as upfront and milestone when licensing out after successful efficacy and safety P1 study just for pancreatic cancer and renal cell carcinoma only
- Larger market is expected when indication expands to RCC, Breast Cancer (TNBC) and Melanoma

TGF- β Target Developmental Trend



The possibility of overcoming the patients without immune anticancer drug responses

Dec. 2017

Confirmation of overexpression of TGF- β gene related to PD-L1 resistance

Roche's Genentech found main biomarkers during their Tecentrig trial in Bladder cancer and announced the finding at the European Society for Medical Oncology (ESMO)

June. 2018

M7824, a novel bifunctional anti-PD-L1/TGF- β trap fusion protein

Merck KGaA announced M7824's clinical trial results on NSCLC at American Society of Clinical Oncology (ASCO) that ORR = 40.7% was observed in the patients with $\geq 1\%$ and ORR = 71.4% was observed in the patients with high PD-L1+ expressing tumors

Feb. 2019

Merck KGaA and GSK Plc entered into a global strategic alliance to jointly develop and commercialize M7824

With Upfront payment of €300 Mil, Development milestone up to €500 Mil, and Approval & Commercial milestone up to €2.9 Bil, the total deal value is €3.7 Bil (~ \$4.2 Bil)

June. 2019

Merck acquires Tilos Therapeutics' 'TGF- β inhibitor'

A total of \$733 mil spent to overcome PD-(L)1 drug resistance with LAP target antibody that inhibits Latent TGF- β . It is differentiated in that the existing TGF β only inhibits that are already in activated state.

Aug. 2020

BMS acquires a Canadian biopharmaceutical company Forbius

Forbius has been focusing on developing a portfolio of potent highly selective TGF- β 1 and 3 inhibitors. It is believed that selective inhibition of TGF- β 1 and 3 can improve anticancer effects while exerting synergistic effects with immunotherapy drugs.

Competition status - Differentiation point



Combination therapy of TGF- β ligand / receptor inhibitor and Immunotherapy are under active clinical trial phases

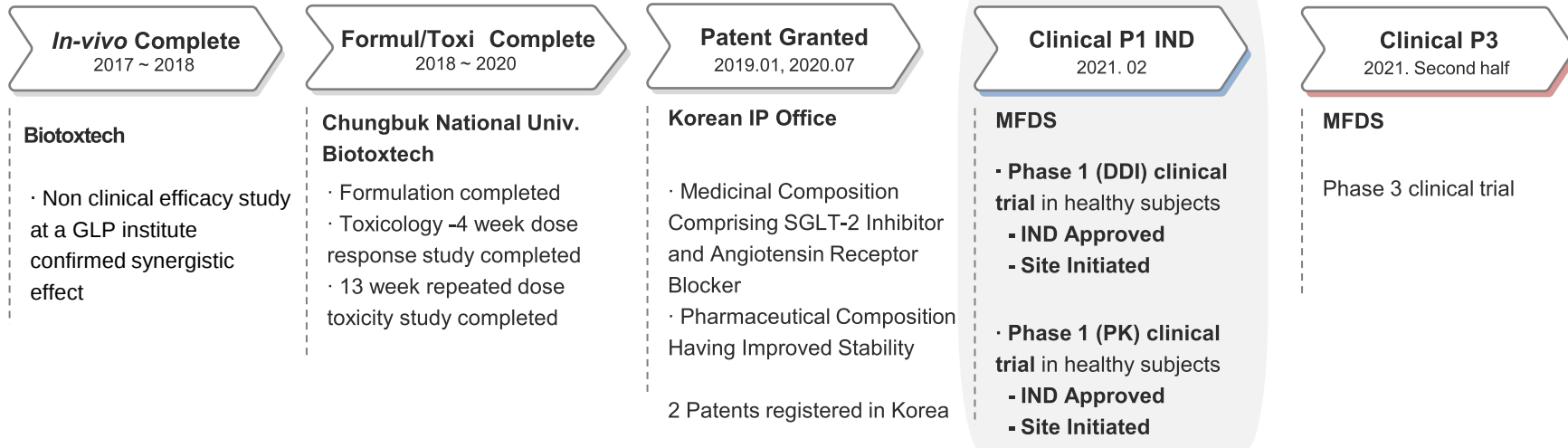
Type	Molecules	Developer	Target	Status	Study Start	Remarks
TGF- β Ligand Inhibitor	ATB-301 (TASO+IL-2)	Autotelic Bio	TGF- β 2	Phase 1	2021.02	• <i>in-vivo</i> synergistic effect confirmed
	M7824 (Bintrafusp alfa)	EMD serono/GSK	TGF- β X PD-L1 mAb	Phase 3	2018~	• Failed Gallbladder Cancer, NSCLC clinical trials, but other 47 clinical trials are active
	SAR439459	Sanofi	Anti-TGF β mAb	Phase 1	2021. 02	• Combi with Libtayo (Cemiplimab, anti PD-1)
	SRK-181	Scholar Rock	Anti-TGF β mAb	Phase 1	2020.04	• Combi with anti-PD-(L)1
	AVID200	BMS	TGF β 1,3	Phase 1	2019.01	• Combi with Opdivo (nivolumab, PD-1, BMS) • 2020, Acquired Forbuis
	TLS-010	MSD	Anti-Latent TFG β	Preclinical	-	• 2019, Acquired Tilos Therapeutics • Expected to combi with Keytruda (pembrolizumab)
TGF- β Receptor Inhibitor	Vactosertib (TEW-7197)	MedPacto	TGF- β RI	Phase 2	2020. 12	• Combi with Keytruda (pembrolizumab) on PD-L1 positive NSCLC
	LY3200882	Eli Lilly	TGF- β RI	Phase 1		• Combi with Capecitabine on TGF- β positive colon cancer

ATB-101: Hybrid New Drug Candidate



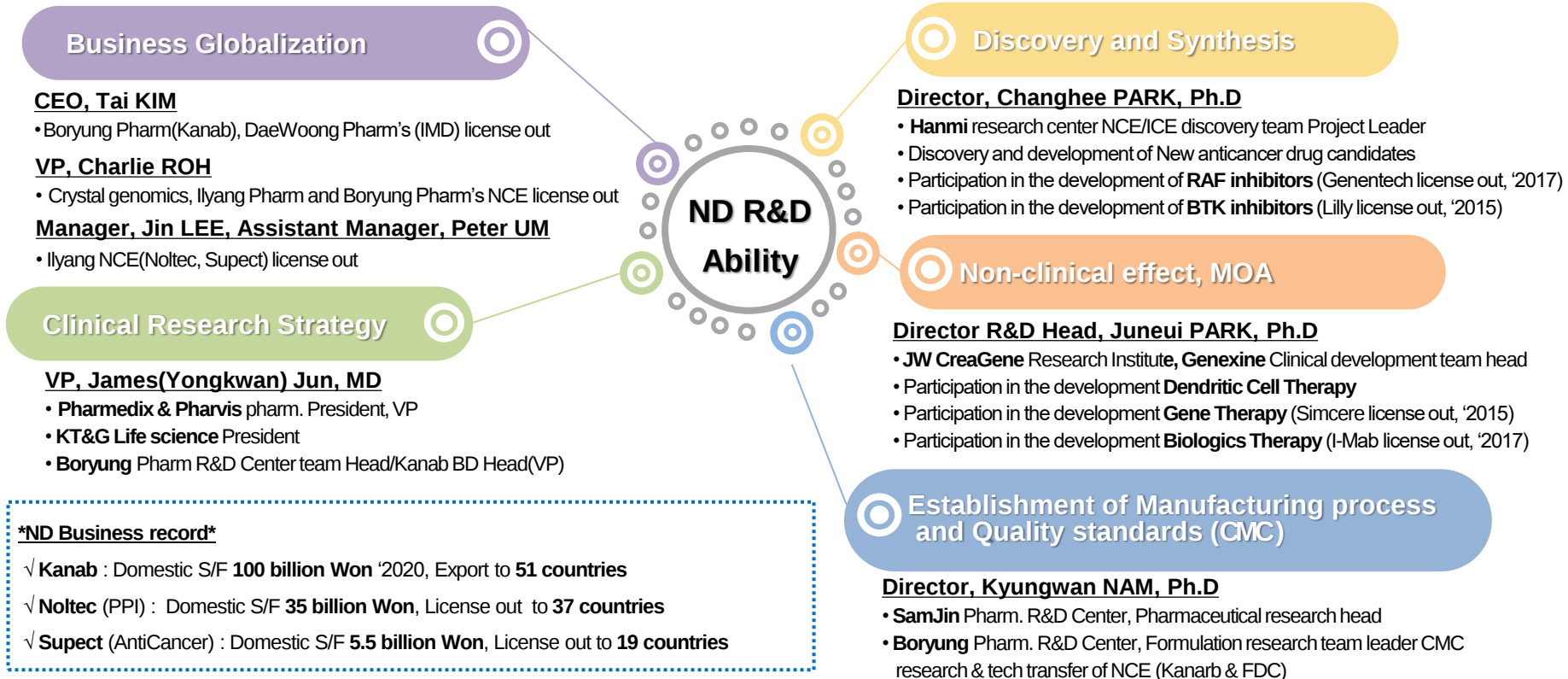
◆ Hypertension + Diabetes Hybrid New Drug ◆

- Provides dose convenience to patients by developing Hybrid New Drug which treats hypertension and diabetes concurrently having the biggest market shares in global pharmaceutical market
- Key features
 - Statistically improved anti-hypertensive effects were seen at a GLP site. (4 week study)
 - Proven improved efficacy of hypotensive effect in clinical trials will allow higher price
 - Hybrid New Drug suitable to go global



New Drug R&D & Global BD Ability

※ Borad Directors of Autotelic Bio **supervise successful R&D and commercialization of ND** in the domestic and global markets.



Press Release



Autotelic Bio deals with Clinigen for supply of IL-2 'Proleukin' (Jan. 2021)

2021-01-14

By Sungmin Kim, BIOSPECTATOR



Deal for supplying IL-2 'Proleukin' with English Biopharmaceutical Company, Clinigen...Plan to initiate phase1b clinical trials of IL-2 combo with Oligonucleotide TGF-β2

Autotelic Bio announced that they have entered into an agreement with Clinigen Group, the British global pharmaceutical product and services company, January 14th, for the supply of IL-2 for investigational purposes.

Autotelic Bio is planning to proceed the local (Korea, Republic of) clinical phase 1b of ATB-301 (TGF-β2 inhibition & T-Cell activation; Immuno-Target Dual Action Onco-therapeutic) which is an investigational anticancer drug candidate with the potential for dual function of immune targets. Where TGF-β2 inhibitors weaken the immune avoidance mechanism of cancer cells and IL-2 enhances the attack power of T cells.

Autotelic Bio-Jeil Pharm Co-development Agreement (Jan. 2019)

2019-01-30

By Byeongchul Noh, DAILYPHARM



▲ 성석재 제일약품 사장(왼쪽에서 네 번째)과 김태훈 오토텔릭바이오 대표(왼쪽에서 다섯 번째)를 비롯한 관계자들이 계약 체결 후 기념 촬영을 하고 있는 모습.



On the 30th, Jeil Pharm announced that it plans to enter co-development and technology transfer contract for Autotelic Bio's new drug for hypertension/diabetes (ATB-101), and to conduct global clinical trials from the second half of this year. Jeil Pharm has exclusive sales rights in Korea, China, and Japan, and Autotelic Bio has global exclusive sales rights, including the United States.

ATB-101 is an improved drug candidate that can replace the hydrochlorothiazide hypertension combination drug market and is evaluated as having high potential for growth. Autotelic Bio will receive a down payment of 2.2 billion won and milestones from Jeil Pharm through this joint development and technology transfer contract. The total contract size is about 20 billion won.

Press Release



Autotelic Bio, Immuno-targeted anticancer drug “Approved by the MFDS for Phase 1b” (Feb, 2021)

2021-02-17

By Sungmin Kim, BIOSPECTATOR



식품의약품안전처

수신자 오토텔릭바이오 주식회사, 대표:김태훈 귀하 (우 13486 경기도 성남시 분당구 판교로 253 판교이노벨리아동 303호)

(경유)

제목 의약품 임상시험계획 승인[오토텔릭바이오 주식회사 -ATB-301]

1. 귀하께서 2020.11.06.[접수번호:20200231459] 우리 처에 제출하신 “ATB-301”의 1b상 임상시험계획 승인신청에 대해 검토한 바, 「약사법」 제34조 및 「의약품 등의 안전에 관한 규칙」 제24조에 적합하므로 동 규칙 제24조제7항에 따라 불응과 같이 승인합니다.

2. 「약사법」 제34조, 「의약품 등의 안전에 관한 규칙」 제30조, 제38조의2 및 [별표4] 의약품 임상시험 관리기준 등 관련 법규를 준수하여 임상시험을 실시하시기 바랍니다. 아울러 해당 임상시험의 의뢰법 등 타 법령 부합 여부 등을 확인하시고 임상시험을 실시하시기 바랍니다.

3. 우리 처에서는 「의약품 등의 안전에 관한 규칙」 제24조제1항제8호에 따른 임상시험 피해자 보상제에 대한 규약 및 동 규칙 [별표4]의 의약품 임상시험 관리기준 제6호(의약품)에 따른 보상 절차 마련 시 고려사항 등을 제공하고자 2019년 11월 「임상시험 피해자 보상제에 대한 규약 및 절차 마련을 위한 가이드라인」을 마련한 바 있으나, 임상시험 피해자 보상과 관련하여 필요한 기준이나 절차 마련 시 우리 처 홈페이지(www.mfds.go.kr) > 정보자료 > 법령자료 > 지침, 가이드라인, 해설서 에 게시된 동 가이드라인을 적극 참고하시기 바랍니다. 시험대상자의 권리안전책지가 적절히 이루어질 수 있도록 노력하여 주시기 바랍니다.

4. 또한, 「의약품 등의 안전에 관한 규칙」 제30조제1항제10호에 따른 「임상시험 정보 등록·공개 제도」 시행(2019년 10월 26일)에 따라 임상시험 승인 현황 정보에 「의약품안전관리과」(https://medrug.mfds.go.kr) > 의약품 등 정보 > 임상시험 정보 > 임상시험정보공개에 공개됨을 알려드립니다.

Evaluation of safety and efficacy of “ATB-301 (TGF-β2 inhibitor + IL-2)” immuno-targeted anticancer on solid cancer....” Based on the results, specific indication for Phase 2 will be studied”

Autotelic Bio announced on the 17th that it has received IND approval from the Ministry of Food and Drug Safety for the clinical trial phase 1b of “ATB-301,” a candidate for immuno-targeted anticancer drug. In addition, it was announced that ATB-301 had obtained a patent for anticancer use and composition.

Autotelic Bio, a new drug for “Hypertension + Diabetes combination” “IND approval” (Feb. 2021)

2021-03-02

By Sungmin Kim, BIOSPECTATOR



식품의약품안전처

수신자 오토텔릭바이오 주식회사, 대표:김태훈 귀하 (우 13486 경기도 성남시 분당구 판교로 253 판교이노벨리아동 303호)

(경유)

제목 의약품 임상시험계획 승인[오토텔릭바이오 주식회사 -ATB-101]

1. 귀하께서 2020.11.10.[접수번호:20200241113] 우리 처에 제출하신 “ATB-101”의 2상 임상시험계획 승인신청에 대해 검토한 바, 「약사법」 제34조 및 「의약품 등의 안전에 관한 규칙」 제24조에 적합하므로 동 규칙 제24조제7항에 따라 불응과 같이 승인합니다.

2. 「약사법」 제34조, 「의약품 등의 안전에 관한 규칙」 제30조, 제38조의2 및 [별표4] 의약품 임상시험 관리기준 등 관련 법규를 준수하여 임상시험을 실시하시기 바랍니다. 아울러 해당 임상시험의 의뢰법 등 타 법령 부합 여부 등을 확인하시고 임상시험을 실시하시기 바랍니다.

3. 우리 처에서는 「의약품 등의 안전에 관한 규칙」 제24조제1항제8호에 따른 임상시험 피해자 보상제에 대한 규약 및 동 규칙 [별표4]의 의약품 임상시험 관리기준 제6호(의약품)에 따른 보상 절차 마련 시 고려사항 등을 제공하고자 2019년 11월 「임상시험 피해자 보상제에 대한 규약 및 절차 마련을 위한 가이드라인」을 마련한 바 있으나, 임상시험 피해자 보상과 관련하여 필요한 기준이나 절차 마련 시 우리 처 홈페이지(www.mfds.go.kr) > 정보자료 > 법령자료 > 지침, 가이드라인, 해설서 에 게시된 동 가이드라인을 적극 참고하시기 바랍니다. 시험대상자의 권리안전책지가 적절히 이루어질 수 있도록 노력하여 주시기 바랍니다.

4. 또한, 「의약품 등의 안전에 관한 규칙」 제30조제1항제10호에 따른 「임상시험 정보 등록·공개 제도」 시행(2019년 10월 26일)에 따라 임상시험 승인 현황 정보에 「의약품안전관리과」(https://medrug.mfds.go.kr) > 의약품 등 정보 > 임상시험 정보 > 임상시험정보공개에 공개됨을 알려드립니다.

A contract for co-development of 'ATB-101' with Firson was also announced....Firson secured domestic sales right

Autotelic Bio announced on the 2nd that the new chronic disease drug 'ATB-101', has been approved by the Ministry of Food and Drug Safety for the Phase 1 Clinical Trial (IND). In addition, on the same day, it announced the signing of a co-development contract with Firson. Autotelic Bio's new drug ATB-101 is the world's first candidate to simultaneously treat diabetes and hypertension and has proven synergistic effects in animal model, and based on the results, a composition patent was also obtained in January 2019.

Key Members of Mgmt/BD & Finance



Dept	Name	Position	Education(Major)		Career	Job Description	Joined
			Major	Degree			
Mgmt / Global Business	Tai Kim	CEO	Pharmacology	Completed doctoral course (pharmacist)	2015 ~ Present Autotelic Bio CEO 2014 ~ 2015 HCC KOREA President 2008 ~ 2014 Boryung Pharm New Drug Kanarb Global Business Team Leader 2008 ~ 2008 Huya Bioscience SanDiego, USA	Top Management	2015.11
	Charlie Roh	VP	Biology	Bachelor	2017 ~ Present Autotelic Bio VP(Global Business) 2008 ~ 2017 Pharmaphenix _President (Il-yang, Crystal Genomics, Ahngook New Drug L/O) 2006 ~ 2008 GE healthcare Marketing 2003 ~ 2006 Boryung Pharm Global Business	Global Business Local Business	2017.09
	Jin Sung Lee	Manager	Anatomy and Cell Biology	Bachelor	2019 ~ Present Autotelic Bio Business Development Manager 2014 ~ 2019 Il-yang Pharm. Oversea Department, BD team New Drug L/O; Radotinib & Ilaprazole	Global Business Local Business	2019.02

Key Members of R&D Center



Dept	Name	Position	Education(Major)		Career	Job Description	Joined
			Major	Degree			
R&D Head	Juneui Park	Director, R&D Head	BioChemistry/ Biophysical Pharmacy	Doctor (Pharmacist)	2018 ~ Present Autotelic Bio Head of Research Center 2016 ~ 2018 Genexine Clinical Development Team Head, Protein Therapeutic, Gene Therapy Development 2012 ~ 2016 JW CreaGene Research Institute Team Leader, Dendritic Cell Therapy Development 2004 ~ 2010 Memorial Sloan-Kettering Cancer Center (NY), Doctor and Post-doctor researcher Dendritic cell, NKT cell 1998 ~ 2003 Roswell Park Cancer Institute (NY), Doctoral course, heat shock protein, Immunovaccine 1997 ~ 1998 SNU Medical school Biochemistry lab researcher	Research Management	2018.09
R&D MediChem	Changhee Park	Director	Pharmacy/ Chemistry	Doctor/ Master	2020 ~ Present Autotelic Bio Director of Research Center 2005 ~ 2020 Hanmi research center NCE/ICE discovery team Project Leader	New drug Technology	2020.07
Oncology Research	JiHye Kim	Senior Manager	Medical Lifescience	Master	2019 ~ Present Autotelic Bio Research Center 2010 ~ 2018 AbClon, Antibody New Drug candidate and lead antibody screening 2007 ~ 2010 AdipoGen Inc, Antibody for research development, QC	Technology A-SAM Research	2019.01
RA	Rhoda Chung	General Manager	Pharmaceutica I Science	Bachelor (US/ Korean pharmacist)	2016 ~ Present Autotelic Bio R&D Strategy, RA 2010 ~ 2012 Nycomed/Takeda Korea RA, GMP inspection 2009 ~ 2010 IMS Health Korea, IMS Global Database, Manager 2006 ~ 2008 Hyundai Pharm Business Development/RA, Manager 2003 ~ 2005 CVS/Pharmacy Corporation (Virginia, USA)	RA Document Management	2016.04

Key Members of R&D Strategy



Dept	Name	Position	Education(Major)		Career	Job Description	Joined
			Major	Degree			
R&D Strategy Head	Kyungwan Nam	Director, R&D Strategy	Pharmaceutical / Pharmacology	Doctor (Pharmacist)	2019 ~ Present Autotelic Bio Head of R&D Strategy 2016 ~ 2019 SamJin Pharm. R&D Center, Pharmaceutical Research Head CMC and Analysis research of new product, New drug CMC research management 2014 ~ 2016 Janssen Korea, Technical operation Manufacturing process development, process analysis and improvement 2006 ~ 2014 Boryung Pharm. R&D Center, Formulation team leader New drug (Kanarb) and combination therapy formulation research, CMC reserach / tech transfer 2001 ~ 2006 DaeWoong Pharm. R&D Center, Formulation senior researcher	R&D Strategy CMC management	2019.09
R&D Strategy	Pearl Jin	Director	Microbiology	Bachelor	2017 ~ Present Autotelic Bio R&D Strategy Director 2015 ~ 2016 LM Co., LTD Global Business Team Leader, Manager 2012 ~ 2014 Pharmaphenix Global Business Team Leader 2009 ~ 2012 BoryungMediance Product Planning Team Leader 2001 ~ 2006 Boryung Pharm Export(EU, Japan) Team, Manager	R&D Strategy, Government Funded Projects	2017.06
	Yujeong Jeong	Senior Manager	IT Software	Bachelor	2020 ~ Present Autotelic Bio R&D Strategy 2016 ~ 2019 Hyerang Co., Ltd. Business Planning Team, National insurance 2010 ~ 2014 Pharmaphenix Business Planning Team 1999 ~ 2009 Boryung Pharm Business Development	R&D Strategy, Government Funded Projects	2020.02
Analytical Research	Dongkyu Oh	Senior Manager	Applied Chemistry	Bachelor	2020 ~ Present Autotelic Bio R&D Strategy, Analytical Research 2015 ~ 2020 Inist Bio Pharm. R&D Center, Formulation Analysis and Analytical Research 2007 ~ 2015 Myungin Pharm. QC	HYBRID New Drug Analytical	2020.03

Key Members of Clinical Research



Dept	Name	Position	Education(Major)		Career	Job Description	Joined
			Major	Degree			
Clinical Research Head	James (Yongkwan) Jun	Vice president	Management/ Medicine	Master (Doctor)	2020 ~ Present Autotelic Bio Head of Clinical Research 2019 ~ 2020 Boryung Biopharma Development Team Head 2016 ~ 2018 Pharmedix & Pharvis Pharm. President & Vice President 2014 ~ 2016 KT&G Life science President 2006 ~ 2014 Boryung Pharm R&D Center team Head/Kanab BD Head New drug "Kanab" Clinical Phase III/RA/Launching, License out 2005 ~ 2006 LSK Global Medical Director 2004 ~ 2005 BioHeart Korea Inc. President 2000 ~ 2003 Parexel Korea Vice President	Clinical Research Strategy	2020.07
Oncology Clinical	Hyojung Seo	Senior Manager	Nursing	Bachelor	2020 ~ Present Autotelic Bio Research Center Oncology New Drug Clinical Research 2016 ~ 2019 Genexine Clinical Development Team, Oncology & Gene Therapy development 2013 ~ 2015 JW Pharm., Clinical Development Team 2006 ~ 2012 ADM Korea, Clinical Team Leader	Oncology New Drug Clinical Research	2020.03
New Drug Clinical	Boyoung Lee	Senior Manager	Pharmaceutical	Bachelor (Pharmacist)	2020 ~ Present Autotelic Bio R&D Strategy, Hybrid New Drug Clinical Research 2015 ~ 2018 Boryung Pharm Clinical Development Team 2010 ~ 2014 DongA ST (DongA Pharm) Clinical Development Team 2009 ~ 2010 Quintiles Korea Clinical Team 2007 ~ 2009 CJ CheilJedang Clinical Development Team	HYBRID New Drug Clinical Research	2020.03



Global Leader of Cancer Treatments

AUTOTELIC BIO

오토텔릭바이오

Thank you.

<http://www.autotelicbio.com>



<https://www.youtube.com/watch?v=Myg8cBpi1iY>

