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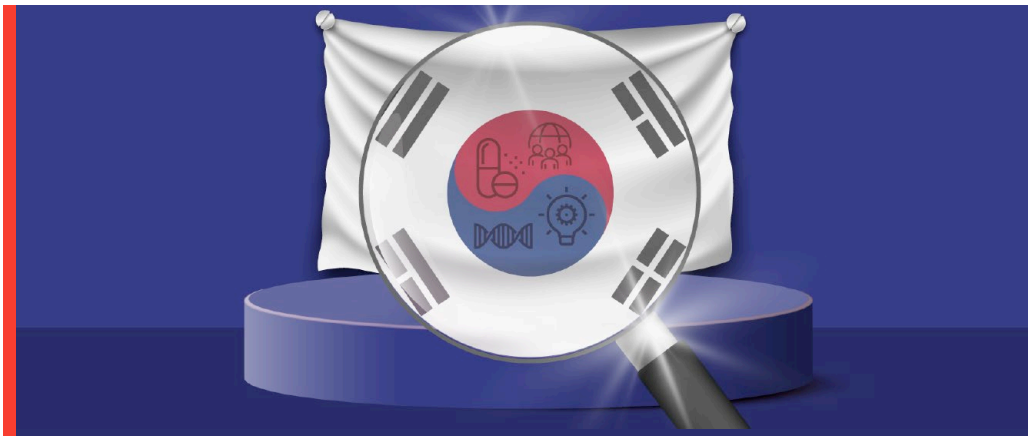


Shaking off BI setback, Bridge expands scope of BD, advances in-house therapies

James Lee-led biotech has honed its focus and begun seeking deals as far off as Europe

Dealmaking and bispecifics cut trail to IPO for Y-Biologics

Y-Biologics' in-house antibody technology key to series of global partnerships

How OliX is spreading its siRNA beyond Korea's borders

New mRNA unit is the biotech's latest bid to realize its global ambitions

Eutilex readying first U.S. trial as cancer company aims for global stage

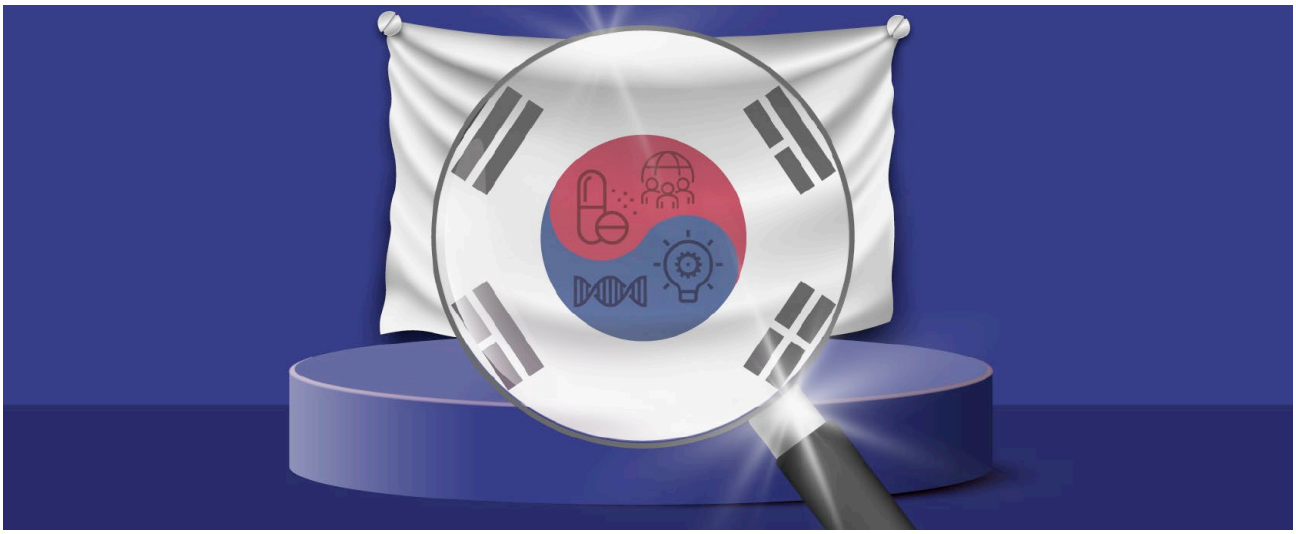
Asian biotech developing platforms for antibodies, T cell therapies and CAR T cells

BIOCENTURY

PRODUCT DEVELOPMENT | REPRINT FROM MAY 25, 2021

Korea Spotlight: Shaking off BI setback, Bridge expands scope of BD, advances in-house therapies

BY JEFF CRANMER, EXECUTIVE EDITOR



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Led by Korean biotech entrepreneur James Lee, Bridge notched another milestone last month when it became the first company worldwide to start a trial for a subgroup of EGFR-mutant NSCLC, edging out a program developed by Blueprint.

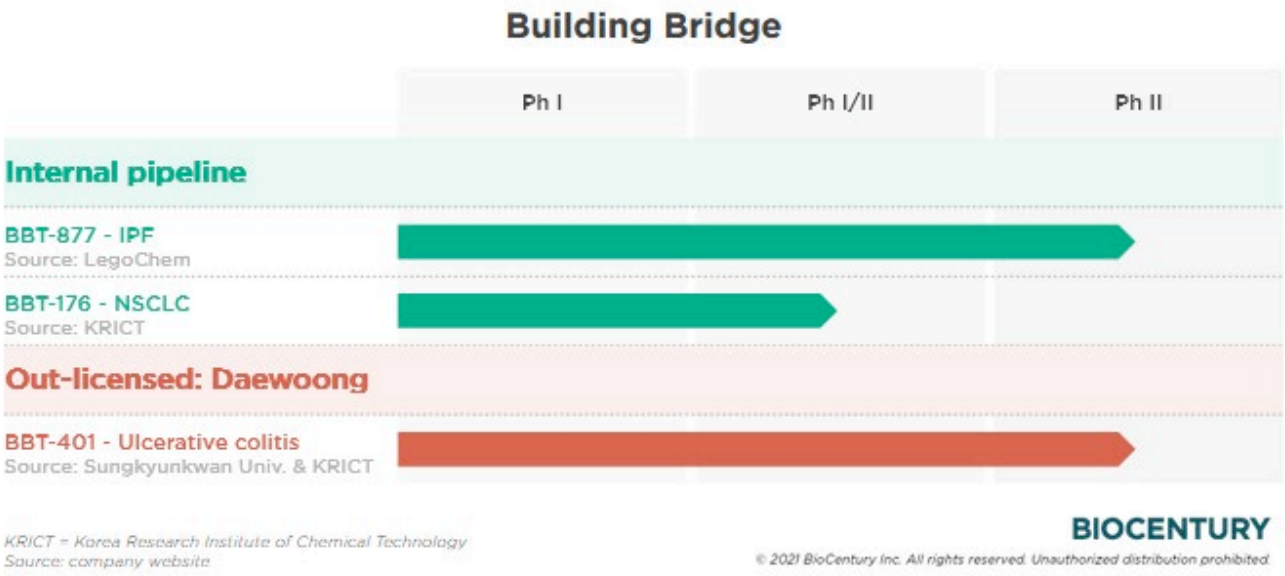
Bridge Biotherapeutics Inc. (KOSDAQ:288330), now six years on from its founding as a company focused on translation of technology from Korean institutions for a broad swath of diseases, has honed its focus to autoimmune, cancer and respiratory indications and begun to discover its own therapeutics as it continues to translate early stage science with an eye toward the global stage.

The company hails from a Korean biotech lineage that originated in LG Life Sciences Ltd., the pioneering LG Corp. unit that produced the first globally approved drugs developed by a company from the country. A shift in priorities around the turn of the century all but stopped the flow of innovative drugs from LG to the world market, yet the pharma's legacy lives on in a stable of biotech companies developing first-in-class and best-in-class molecules.

Lee, who was a structure-based drug discovery scientist and a member of the BD team at LG, and Bridge are examples of that influence.

LG's role in sparking the development of a Korean biotech industry has less to do with the specific research programs it developed, and everything to do with the environment it created for its scientists. A former LG researcher, Lee estimated that 25-30% of the innovative biotechs in Korea founded in 1997-2015 are led by ex-LG scientists.

"There's a big contrast between ex-LG and non-ex-LG entrepreneurs in Korea," said Lee. Speaking of the culture fostered by LG's leadership, he said, "There's really free discussion among us regardless of rank and title, especially the head of R&D, Dr. Choi, who encouraged his team to share



their thoughts without any hesitation." He added that LG's organization was "non-bureaucratic, with few layers."

According to Lee, LG's work on recombination DNA technology with Chiron Corp. in the mid-1980s through 1992 also helped seed Korea's fledgling biotech ecosystem.

After cutting his teeth as a biotech co-founder and executive at chemoproteomics company CrystalGenomics Inc., Lee founded Bridge in 2015, which he called a "historic year" for Korean biotech after a series of deals by Hanmi Pharmaceutical Co. Ltd. (KSE:128940) bolstered confidence in the sector and triggered an inflow of investment.

Lee's goal for Bridge was to tap into the "steady rise of basic science in Korea" that he had observed emerging from research centers and small biotechs over the past two decades.

"Fortunately for me, their development capability was really, really limited," Lee told BioCentury. "I know how business development works. I know how to build a development team. So, I decided to build a company that is really specialized in early-stage development who can help other companies to develop compounds."

While the bulk of Bridge's deals hinge on in-licensing assets, it has completed a handful of out-licensing deals.

Pipeline

Bridge's most advanced program is ulcerative colitis therapy BBT-401; it out-licensed rights to the asset in 22 Asian countries, including China, Japan and Korea, to Daewoong Pharmaceutical Co. Ltd. in 2018, and is seeking a partner to license rights elsewhere. Bridge has rights to the compound from Sungkyunkwan University and the Korea Research Institute of Chemical Technology, which discovered the GI-tract restricted small molecule inhibitor of PELI1.

In 2019, Bridge parlayed an out-licensing deal with Boehringer Ingelheim GmbH for IPF therapy BBT-877 into support for its $27.3 million series C round and, later in the year, a W42 billion ($35.8 million) IPO on KOSDAQ.

Boehringer paid Bridge €45 million ($51 million) up front for rights to the ENPP2 inhibitor, and the Korean company was eligible for €1.1 billion in milestones, plus royalties. Before the IPO, Bridge had raised about $52.9 million in venture financing.

But the deal was short-lived after BI returned rights last December due to a toxicity issue. Lee said Bridge disagreed with its former partner's assessment, and has since run studies to support the compound's safety. It submitted a meeting request to FDA in March, and expects a response from the agency by the end of June.

If FDA green lights the program, Bridge will run the Phase II program on its own, according to Lee. Bridge's cash position at the end of 1Q21 was about $52 million; it expects that Phase II testing would cost roughly $30 million.

As for its newest clinical program, BBT-176 for non-small cell lung cancer, the company hopes to have an initial readout from the dose-escalation study next half. Bridge gained exclusive rights to the program in December 2018 via one of its characteristic in-licensing deals. It paid Korea Research Institute of Chemical Technology (KRICT), a government research institute, $900,000 up front for the compound, in a deal worth up to $27 million.

BBT-176 targets EGFR containing the C797S mutation, a leading cause of resistance to Tagrisso osimertinib and other EGFR-TKIs. Bridge's Phase I/II trial is enrolling NSCLC patients who have progressed on EGFR-TKI monotherapy.

Blueprint Medicines Corp. (NASDAQ:BPMC) is also developing an EGFR-TKI therapy that aims to inhibit C797S-mutant EGFR, BLU-945. The program is slated to enter the clinic by the end of June.

A broader Bridge

Since the company's IPO in late 2019, Bridge has honed its focus to lung diseases and targeted cancer therapies — excluding immunotherapies — with a plan to in-license more assets in IPF/lung diseases.

The company is also seeking to broaden its partnership base, which includes a push to hunt for assets in Europe. Toward that end, it is participating in BaseLaunch as one of six partner companies that include Roche (SIX:ROG; OTCQX:RHHBY) and Johnson & Johnson (NYSE:JNJ). The Basel-based initiative helps start-ups grow to the point of raising series A funding.

Last year, Bridge also partnered with AI drug discovery company Atomwise Inc. to develop up to 13 small molecule programs across various therapeutic areas. Atomwise is evaluating programs for PELI1 and other targets nominated by Bridge.

At the same time, Bridge's in-house discovery programs are beginning to move toward the clinic, with the company expecting its first homegrown compound to enter IND-enabling studies next half. Two projects are in discovery against hard-to-treat solid tumors.

In an age of mega-rounds, Lee believes that smaller companies in need of financing and academics will continue to create ample opportunities for Bridge to find assets.

Lee, like other leading Korean entrepreneurs, continues to look toward the global stage as a long-term goal. He hopes to establish a commercial organization in larger markets, starting with the U.S.

TARGETS

ENPP2 (ATX) - autotaxin

PELI1 (pellino-1) - Pellino E3 ubiquitin protein ligase 1

BIOCENTURY

PRODUCT DEVELOPMENT | REPRINT FROM AUG. 19, 2021

Dealmaking and bispecifics cut trail to IPO for Y-Biologics

BY JEFF CRANMER, EXECUTIVE EDITOR

The latest installment in a series of profiles of innovative South Korean companies.

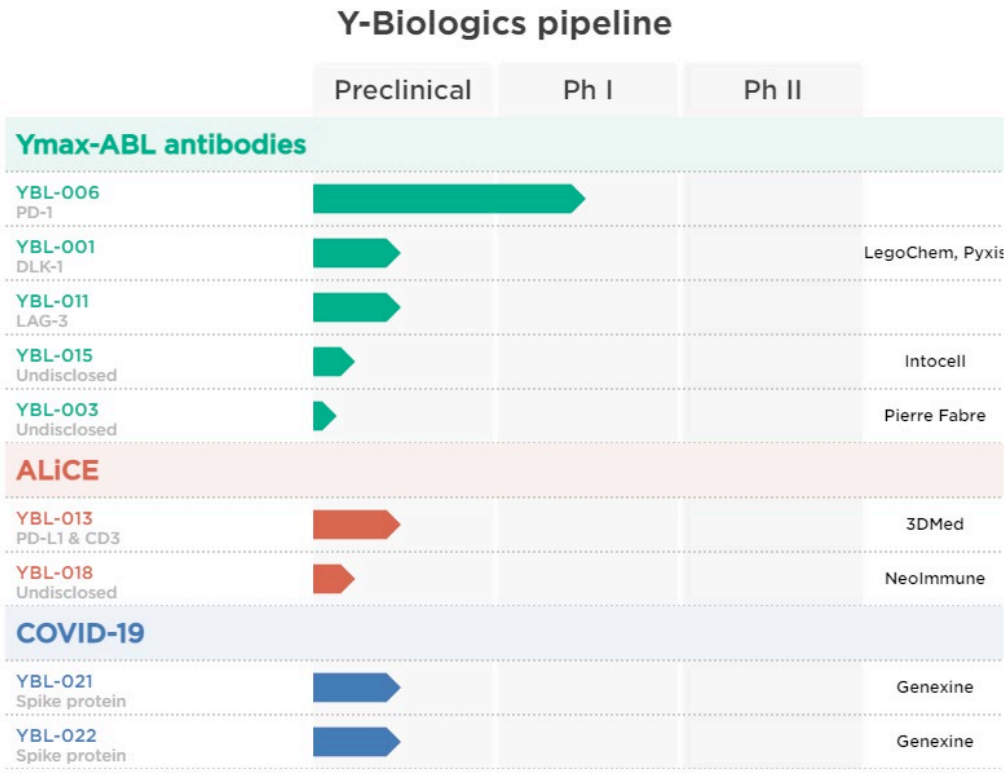
With seven disclosed oncology programs that include bispecifics and partners in the East and West, Y-Biologics is gearing up for a debut on KOSDAQ by year-end.

Founded in 2007, Y-Biologics Inc.'s roots lie in the work of CEO Young Woo Park during his tenure at the Korea Research Institute of Bioscience & Biotechnology (KRIBB) in 2005-15.

Since then, Y-Biologics has built a pipeline of antibody-based programs developed in-house, one of which is in the clinic. The company has used its naïve cDNA library, Ymax-ABL, to discover the majority of its therapies, which include programs against DLK1, PD-1 and LAG3 and feature two antibody-drug conjugates.

The company is generating another set of programs from its ALiCE (Antibody Like Cell Engager) platform. Therapies representing both technologies are among its five out-licensed programs, with partners on its home turf and in China, Europe and the U.S.

Y-Biologics is now evolving from a discovery company to a clinical one, Chief Technology Officer and Head of Discovery and Antibody Discovery Bum Chan Park told BioCentury. Park and Y-Biologics' CEO met at NIH early in their careers and later reunited at KRIBB.



CEO Park has a similarly long-standing relationship with the biotech's head of development, Han Seung Lee, with both executives hailing from a Korean biotech lineage that originated in LG Life Sciences Ltd. The pioneering LG Corp. unit produced the first globally approved drugs developed by a company from the country, and the pharma's legacy lives on in a stable of biotech companies launched by LG veterans who are seeking to develop first- and best-in-class molecules.

Park's tenure at LG spanned two decades, during the final six years of which he was antibody therapeutics team leader and led the target discovery group. He gained his Ph.D. in microbiology from the University of Washington. Lee, who earned his Ph.D. in chemical and biochemical engineering from University of California Irvine, was an LG senior research scientist in 1999-2004.

Y-Biologics' first partnerships were straight-up licensing deals.

But the company's most recent deal, with Laboratoires Pierre Fabre S.A., represented a different type of partnership for Y-Biologics, BD Manager Dong-Ock Chang told BioCentury. Under the licensing option deal, the Korean company has used its human antibody display platforms to generate mAbs against targets picked by Pierre Fabre.

While the targets are undisclosed, Executive Manager of BD Jin Sung Kim said the partners are pursuing targets that regulate the solid tumor microenvironment.

The deal bore fruit last month when Pierre Fabre licensed worldwide rights to develop and commercialize a family of Y-Biologics' human antibodies generated by the Ymax-ABL library. The French company plans to select an immuno-oncology compound to develop; the companies are targeting relapsed or refractory cancers. Details are undisclosed.

The Y-Biologics pipeline is anchored by five antibodies, which include lead program YBL-006, an anti-PD-1.

It's a crowded space, but Bum Chan Park said, "Our PD-1 antibody shows better binding affinity compared to others."

He also notes the importance of having a PD-1 as a backbone therapy in combinations.

Y-Biologics has disclosed two programs from its ALiCE platform, which comprises T cell redirecting bispecific antibodies that the company believes will minimize off-target toxicity while maintaining high binding affinity.

The antibodies are structured with two arms that bind the tumor antigen, and just one — a monovalent Fv region that replaces the Fc — to bind to the immune cell. The result, the company believes, is higher avidity for the tumor antigen, and a more tumor-directed T cell response.

Bispecific antibodies are steadily becoming a must-have for cancer drug developers, with the modality surpassing both mAbs and cell therapies as the focus of pharma oncology deals.

Y-Biologics has already found one partner for an ALiCE compound, out-licensing Greater China and Taiwan rights to preclinical therapy YBL-013 in December to Shanghai biotech 3DMed Corp. Y-Biologics received $2 million up front and is eligible for $85 million in milestones, plus double-digit royalties. The therapy targets CD3 on T cells and PD-L1 on cancer cells.

Expect more dealmaking from Y-Biologics, said Park, as the company has more compounds than it can bring forward on its own.

Data Content Analyst Gunjan Ohri contributed to this report.

BIOCENTURY

EMERGING COMPANY PROFILE | REPRINT FROM MAR. 11, 2021

Korea Spotlight: How OliX is spreading its siRNA beyond Korea's borders

BY JEFF CRANMER, EXECUTIVE EDITOR

The launch of an mRNA subsidiary is the latest move by RNAi company OliX to build upon its trio of partnerships and bicoastal beachhead of U.S. offices to realize its global ambitions.

OliX Pharmaceuticals Inc., which develops nucleic acid-based therapeutics using RNA interference technology, decided to found its new unit, mCureX Therapeutics Inc., early this year to capitalize on the expertise of its director of oligonucleotide chemistry, Dong Won Shin. Shin specializes in modified nucleic acid technologies including co-transcriptional reagents for mRNA capping and mRNA with natural and chemically modified nucleosides.

"We realized we actually had an expert in-house, and thought, why not?," CSO and CEO Dong Ki Lee told BioCentury.

Shin, who was previously a senior staff scientist at TriLink BioTechnologies Inc., developed the foundational technology of mRNA 5'-capping, which OliX said is used in COVID-19 mRNA vaccines developed by BioNTech SE (NASDAQ:BNTX) and Pfizer Inc. (NYSE:PFE).

Based in Korea, mCureX will focus on mRNA vaccines and therapeutics for human diseases, including COVID-19, as well as animal indications, with Shin overseeing R&D for the unit as chief technology officer.

The endeavor complements OliX's pair of European partnerships and U.S. outposts in its strategy to grown beyond Korea.

OliX launched with RNAi technology from Lee's lab in 2010, the heart of a decade-long dry spell in venture funding for Korea's biotech ecosystem. The company's core technology is its asymmetric siRNA structure platform, which the company says results in fewer off-target effects and less overloading of the cell's endogenous RNA processing machinery than conventional siRNA.

OliX's pipeline spans dermatological, ophthalmic, liver, pulmonary and CNS and cancer indications, with nearly all the company's 14 disclosed programs in preclinical development.

COMPANY PROFILE
OliX Pharmaceuticals Inc. (KOSDAQ:226950)

Suwon, South Korea

Disease focus: Dermatology, ophthalmic, pulmonary and liver diseases

Clinical status: Phase II

Founded: 2010

Corporate partners: Hugel Inc., Théa Open Innovation

Funds raised: $103.7 million

CEO: Dong Ki Lee

Its lone clinical program, OLX101A, is in Phase II testing in Korea for hypertrophic scarring. The company's partner, Hugel Inc. (KOSDAQ:145020), is running the trial, with OliX preparing to run a U.S.-based study of the therapy.

OliX out-licensed the compound to its South Korean partner in 2013; while Korean biotechs today typically seek to retain rights on their home turf, the deal helped sustain OliX at a time when few were investing in Korean biotech, Lee told BioCentury.

After a 2018 IPO on KOSDAQ, OliX reached beyond Korea's borders the next year to partner with French biopharma Théa Open Innovation to develop OLX301A, a treatment for dry and wet age-related macular degeneration, and OLX301D, for subretinal fibrosis. The deal, which grants Théa exclusive rights outside the Asia Pacific, has already been expanded once. In all, OliX received €10 million ($12 million) up front and is eligible for undisclosed milestones, plus royalties. Théa has an option for two additional ocular programs.

Under a third partnership, OliX is applying its GalNAc-siRNA technology to evaluate four different liver targets picked by its undisclosed partner, a European biotech. The deal, which began in June 2020 and came with a $1.5 million upfront payment, runs through this June. OliX licensed its GalNAc technology in March 2020 from San Diego-based chemistry

company AM Chemicals LLC, which was founded in 2003 by Ionis Pharmaceuticals Inc. veteran Andrei Guzaev.

OliX has two U.S. hubs. In San Diego, where Shin is based, OliX has siRNA synthesis and chemistry capabilities. The company's most recent fund-raise, in December, brought in ₩41.5 billion ($37.2 million) via the sale of equity and convertible bonds to fund construction of a RNA synthesis GMP facility in San Diego. It also will support OliX's goal of having 10 programs in the clinic by 2024.

The company's Boston location houses preclinical development and pharmacology along with CMC, clinical and regulatory capabilities. It has also proved useful in attracting SAB members, said Lee, pointing to the addition of Aaron Hakim, Gordon Jiang, Yury Popov and Demetrios Vavvas from Harvard Medical School.

Asked whether a secondary listing on a foreign exchange would be in the cards, Lee said OliX considers that a long-term goal, preferring to build its value on KOSDAQ — currently sitting north of $500 million — in the near term.

BIOCENTURY

PRODUCT DEVELOPMENT| REPRINT FROM FEB. 19, 2021

Korea Spotlight: Eutilex readying first U.S. trial as cancer company aims for global stage

BY JEFF CRANMER, EXECUTIVE EDITOR

Eutilex hopes data from an upcoming Phase I trial of its anti-4-1BB antibody will help land the South Korean biotech a global licensing partner for the compound, VP and Head of Open Innovation and Global Strategy So Heui Choe told BioCentury.

The trial, which will be the first run in the U.S. by Eutilex Co. Ltd. (KOSDAQ:263050), will assess EU101 and begin in May in up to 80 patients with colon cancer and other solid tumors. FDA accepted an IND for the study on Jan. 14.

Choe said that Eutilex expects the compound to have a better toxicity profile than prior programs from large pharmas, citing in particular urelumab from Bristol Myers Squibb Co. (NYSE:BMY). Clinical studies of the mAb as monotherapy administered at ≤1 mg/kg led to several cases of liver toxicity; higher doses of urelumab resulted in more frequent and more severe toxicity. BMS put the program on hold in 2009 due to severe liver toxicity in a Phase II melanoma trial before returning to the clinic with a lower dose.

Choe said Eutilex created EU101 with the toxicity of the BMS compound in mind, designing a compound with different binding epitopes and mechanism of action. No toxicity was seen in a monkey maximum tolerated dose study. The dose, 400 mg/kg, is equivalent to 132 mg/kg in humans, according to the company.

If the Phase I data are attractive, Choe said the company would be interested in out-licensing rights outside of Greater China, Korea and Taiwan.

The Seoul-based company already has a deal in China for the antibody. Zhejiang Huahai Pharmaceutical Co. Ltd. (Shanghai:600521) licensed rights in mainland China, Hong Kong and Macao as well as Taiwan in 2017 in exchange for up to $35.5 million, including a $1 million upfront payment, plus royalties. Huahai has the compound in Phase I testing.

Founded in February 2015 by Chairman Byoung Kwon, the company raised $56.5 million in venture money before going public in a $32.3 million IPO on KOSDAQ in December 2018. The venture money included $30 million from Huahai, which was the sole investor in its series B. The Chinese company is Eutilex's second-largest shareholder after Kwon.

In addition to its antibody platform, Eutilex has two other platforms: one for T cell therapies and another for CAR T cells. All three platforms have multiple programs in development, the most advanced of which is EBViNT (Epstein-Barr virus induced natural T cell). It is in Phase I/II testing for extra-nodal NK/T cell lymphoma in Korea.

The lead CAR T program is GPC3 IL-18 CAR-T. The company plans to submit an IND to China's NMPA in December for the fourth- generation CAR T against GPC3 armored with IL-18 to treat hepatocellular carcinoma.

TARGETS

4-1BB (TNFRSF9; CD137)Tumor necrosis factor (TNF) receptor superfamily member 9GPC3 - Glypican 3

IL-18 - Interleukin-18

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KoreaBIO promotes communication among all bio-industry related organizations and is striving to create a sustainable biotechnology industry ecosystem.
KoreaBIO is a central organization with around 500 members from major pharma & biotechnology enterprises to special members, representing the biotechnology industry of Korea. KoreaBIO also develops various training and policy-making programs to serve the member companies more efficiently and promotes co-operation, investment relations, and technological collaborations around the world.

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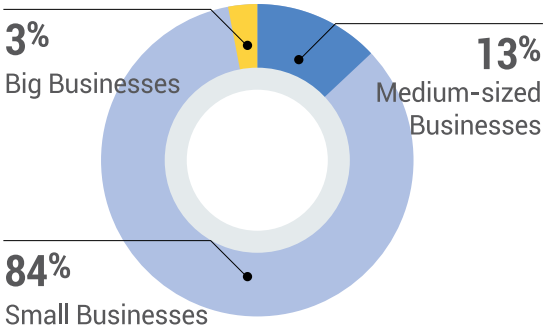

(Executive and general members only)

Members by Subsector

(February 2021)

Red Bio(Bio-pharmaceutical) : Pharmaceutical, vaccines, antibiotics, artifical organs, diagnostics tests

White Bio(Industrial Biotechnology) : Chemical ingredients, biofuels, bioenergy, cosmetics

Green Bio(Agriculture) : Genetic engineering, molecular markers/diagnostics, tissue culture, micro organisms

Others

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