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Building on principles

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[Biotech/Healthcare]

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AbClon

(174900 KQ/Not Rated)

Encompassing bispecific antibodies and CAR-T

- An antibody drug developer with three platform technologies
- Key technologies and candidates: NEST, AffiMab (bispecific antibody), and CAR-T
- Technology proven by a number of companies

An antibody drug developer with three platform technologies

AbClon is an antibody drug company that develops novel drugs by discovering antibodies that target different domains of disease proteins. The company has built an extensive pipeline using its three platform technologies: NEST (monoclonal antibody platform), AffiMab (bispecific antibody platform), and CAR-T. The company has licensing deals with Shanghai Henlius Biotech and Green Cross LabCell and is currently working on four joint research projects with Yuhan.

Key technologies and candidates

1) NEST platform

The NEST platform focuses on the development of antibodies targeting new epitopes. The lead NEST platform candidate, AC101, targets HER2 genes and is being developed for the treatment of HER2-overexpressing gastric and breast cancers. AC101 is expected to be more effective than existing HER2 cancer therapies, such as Herceptin and Perjeta, by binding to different epitopes. Preclinical studies showed that a combination of Herceptin and AC101 was more effective than a Herceptin/Perjeta combination.

AbClon licensed out the China/Hong Kong rights and global rights for AC101 to Shanghai Henlius Biotech in 2016 and 2018, respectively. Recently, Shanghai Henlius Biotech initiated a Phase 1 trial on AC101 as a monotherapy for solid tumor patients with HER2 overexpression. Shanghai Henlius Biotech, the antibody drug subsidiary of China's Shanghai Fosun Pharmaceutical (2018 revenue of W4tr), is currently conducting clinical trials on seven antibody drug candidates and five biosimilar candidates. It is also believed the Chinese company will begin studies on a combination therapy of AC101 and its Herceptin biosimilar candidate.

Aside from AC101, other NEST platform candidates, such as AC103 (colorectal cancer/head and neck cancer), AC104 (solid tumor/eye disorders), AC106 (lung cancer/colorectal cancer), and AC203 (rheumatoid arthritis), are expected to enter clinical trials.

FY (Dec.)	12/14	12/15	12/16	12/17	12/18	12/19F
Revenue (Wbn)	2	2	3	4	4	15
OP (Wbn)	-2	-3	-2	-2	-2	5
OP margin (%)	-100.0	-150.0	-66.7	-50.0	-50.0	33.3
NP (Wbn)	-3	-10	-2	-1	-1	4
EPS (W)	-636	-1,705	-262	-235	-122	574
ROE (%)	209.0	-181.8	-12.6	-10.1	-4.7	19.8
P/E (x)	-	-	-	-	-	93.8
P/B (x)	-	-	-	25.7	15.6	16.9
Dividend yield (%)	-	-	-	0.0	0.0	0.0

Note: All figures are based on consolidated K-IFRS; NP refers to net profit attributable to controlling interests
Source: Company data, Mirae Asset Daewoo Research estimates

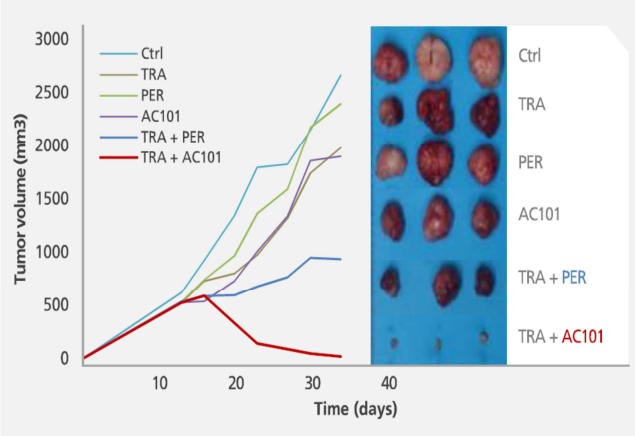
2) AffiMab platform

The AffiMab platform develops bispecific antibodies, which have recently been gaining much attention. The lead AffiMab platform candidate is AM201, which is being developed as a treatment for rheumatoid arthritis. Around half of patients resistant to TNF-α inhibitors, such as Remicade and Humira, respond well to interleukin-6 receptor inhibitors (brand name Actemra). AM201 is a bispecific antibody that simultaneously inhibits TNF-α and interleukin-6 receptors. In an animal study, AM201 was found to be more effective than the best-selling rheumatoid arthritis drug, Humira. Preclinical package data has been completed, paving the way for potential licensing deals.

AM105 is an antibody that targets EGFR and CD137 (4-1BB) to treat colorectal cancer. It is believed that AM105 has addressed the toxicity issue of existing CD137 monoclonal antibody therapies through bispecific antibodies. A Phase 1 trial is set to begin soon.

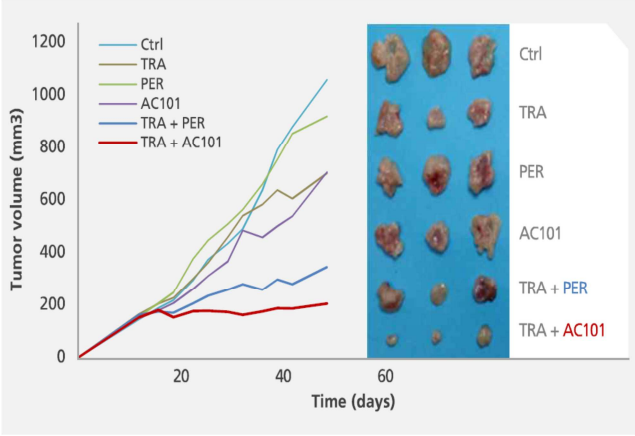
Other AffiMab candidates in the pipeline include AM101 (targets HER2/EGFR in gastric cancer), AM102 (targets HER2/IGF-1R in breast cancer), AM106 (targets PD-L1/LAG-3 in colorectal cancer), and AM107 (targets PD-1/TIM-3 in melanoma).

Table 1. AC101 shows superior efficacy on stomach cancer animal model



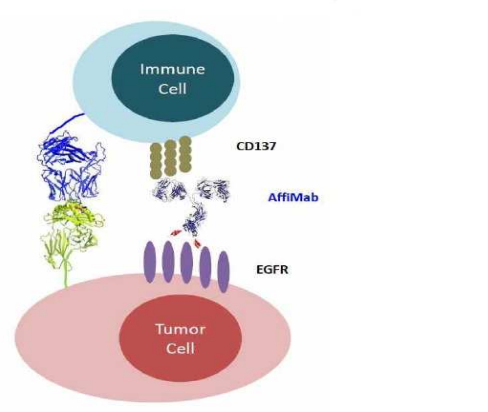
Source: AbClon, Mirae Asset Daewoo Research

Table 2. AC101 shows superior efficacy on breast cancer animal model



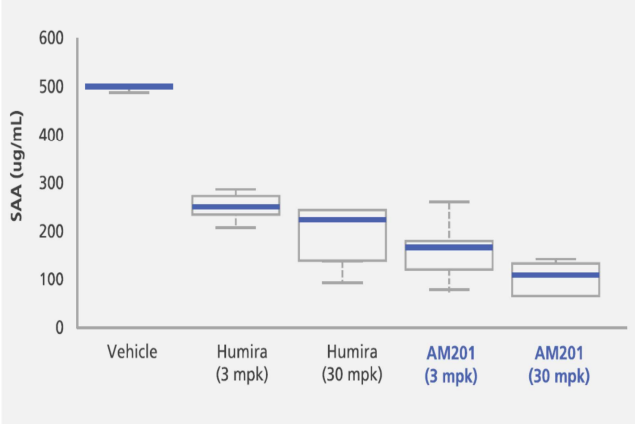
Source: AbClon, Mirae Asset Daewoo Research

Table 3. The concept of Double antibody AM105



Source: AbClon, Mirae Asset Daewoo Research

Table 4. Double antibody AM201 shows superior efficacy to Humira on inflammation animal model



Source: AbClon, Mirae Asset Daewoo Research

3) CAR-T platform

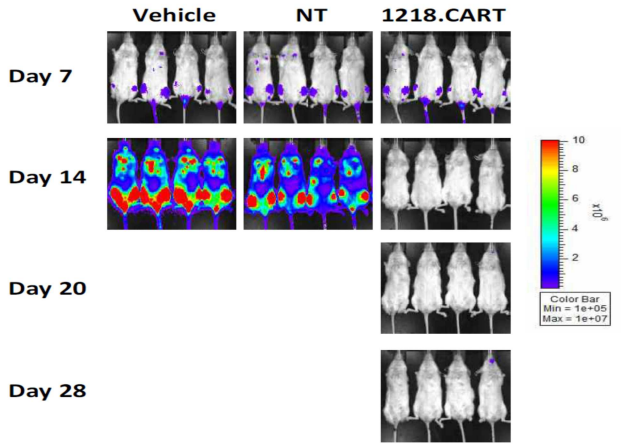
AbClon is currently developing classical CAR-T therapies and switchable CAR-T therapies. The company's classical CAR-T therapy is a blood cancer treatment that targets CD19 by binding to different domains than existing treatments, like Yescarta and Kymriah. Because the therapy is being developed as a humanized antibody, and not a mouse antibody, it is also expected to have lower immunogenicity. The company recently developed a candidate agent and is currently building the necessary production facilities. The company plans to launch a Phase 1 trial by the end of the year.

Unlike traditional CAR-T therapies, which directly recognize and attack cancer cells, switchable CAR-T therapies are designed to combat cancer cells by using mediums ("switches"). The biggest advantage of switchable CAR-T therapies is that patients whose cancers reoccur or spread after receiving CAR-T can be treated simply by injecting an antibody switch, rather than developing or administering a new CAR-T. It can also artificially suppress side effects caused by CAR-T overactivity, such as cytokine release syndrome (CRS).

AbClon's AT501 is a switchable CAR-T therapy targeting ovarian cancer. AT501 uses cotinine to create CAR-T cells and combines cotinine with HER2-targeting affibody to use as the switch. A preclinical study found varying cytotoxicity activity depending on the amount of switch used. A Phase 1 trial is expected to begin next year.

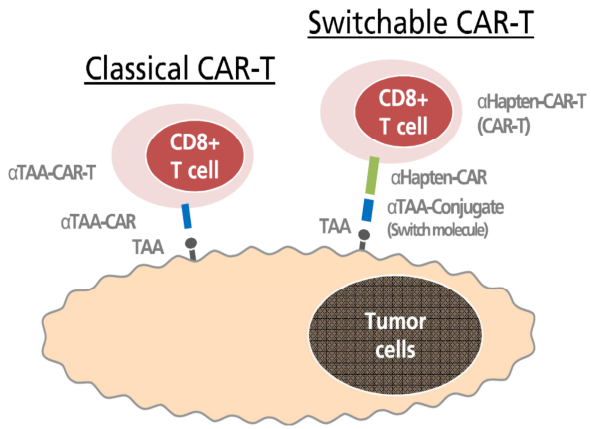
Of note, AbbVie licensed Calibr's switchable CAR-T technology in June 2018.

Table 5. Classical CAR-T shows outstanding results on Hematologic malignancy mouse model



Source: AbClon, Mirae Asset Daewoo Research

Table 6. Next generation version: Switchable CAR-T



Source: AbClon, Mirae Asset Daewoo Research

Technology proven by a number of companies

AbClon's robust antibody development technology has already been validated by a number of companies.

1) Under its October 2016 deal with AbClon to license rights to AC101 in China (including Hong Kong, Macao, and Taiwan), Shanghai Henlius Biotech was given the option to secure global rights to the antibody. After two years of numerous tests, including preclinical studies, the company exercised its option to acquire the global rights in November 2018, right before the start of the Phase 1 trial. We believe this demonstrates Shanghai Henlius Biotech's confidence in the efficacy and potential success of AC101.

2) AbClon has also gained recognition from Yuhan. The two companies signed their first joint development agreement in April 2016, and since then have inked three more deals. The fourth deal was for collaboration on a bispecific antibody for immuno-oncology. The anti-TIGIT antibody presented by Yuhan at the April American Association for Cancer Research (AACR) meeting was licensed from AbClon.

3) Green Cross LabCell uses AbClon's antibody in its development of CAR-NKs. The company, which is currently engaged in a Phase 2 trial for an NK cell therapy, is developing a CAR-NK treatment that combines AbClon's antibody with NK cells. In late January, Green Cross LabCell agreed to pay W3bn in milestones to AbClon to license its new HER2 antibody technology and plans to use it to develop a gastric cancer treatment. Green Cross LabCell's CAR-NK cell therapy was the first CAR-NK cell therapy project to receive a government grant in Korea.

Table 1. AbClon pipeline

Platform	Pipeline	Phase	Note	Partner
NEST	AC101	Phase 1 clinical trial	Combination therapy trial expected	Shanghai Henlius Biotech
AffiMab	AM201	Nonclinical	TNF-α/IL-6 double antibody	
	AM105	Nonclinical	EGFR/4-1BB double antibody	
	AM106	Nonclinical	PD-L1/LAG-3 double antibody	
	AM107	Nonclinical	PD-1/TIM-3 double antibody	
CAR-T	AT101	Nonclinical completed	Targeting initiation of phase 1 trial by year-end	
	AT501	Nonclinical in progress	Targeting initiation of phase 1 trial by next year	Seoul National University
Collaboration	AY101	Nonclinical completed	Targeting initiation of phase 1 trial by next year	Yuhan Corporation

Source:

APPENDIX 1

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Equity Ratings Distribution & Investment Banking Services

	Buy	Trading Buy	Hold	Sell
Equity Ratings Distribution	83.52%	8.24%	8.24%	0.00%
Investment Banking Services	82.61%	4.35%	13.04%	0.00%

* Based on recommendations in the last 12-months (as of March 31, 2019)

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