Akeso, Inc.

(Stock code: 9926)

August 2020 Newsletter

Company Development Overview

On August 17, 2020, Akeso, Inc. ("Akeso", "Company", "we", "our" or "us"; stock code: 9926) announced the consolidated results for the six months ended June 30, 2020 ("Period"). Since the listing date, the Company has made significant progress with respect to the product pipeline and business operation.

Product Pipeline and Business Operation Development

Within the Period, the research and development expenses of the Company increased by approximately 95.4% to RMB240.7 million compared to those for the six months ended June 30, 2019. The Company added 9 new pipelines and launched 20 new clinical trials (40 in total). Besides, 7 investigational drugs obtained the Investigational New Drug (IND) approvals, and 2 investigational drugs obtained approvals to initiate registrational trials from the National Medical Products Administration of the PRC ("NMPA") and the Food and Drug Administration of the United States ("FDA"), respectively. The NMPA accepted the new drug application of the potentially best-in-class humanized monoclonal antibody against PD-1 developed by the Company in house, for the treatment of patients with relapsed or refractory classical Hodgkin's lymphoma. Based on the fast-to-market strategy, the Company's first-in-class PD-1/CTLA-4 bi-specific antibody AK104 has obtained the Fast Track Designation (FTD) from the FDA, for the monotherapy treatment of patients with recurrent or metastatic cervical cancer. Furthermore, the commercialization manufacturing base in Guangzhou is under construction, and the Company expects to complete facility construction and commence operation by the beginning of 2021. Besides, the Company plans to build a commercial operation team of approximately 300–500 personnel by the end of 2021.

Monthly Capital Market Performance

In August, major security firms reiterated "Overweight", "Buy" or "Outperform" ratings on the Company, including Morgan Stanley, JPMorgan Chase & Co. ("JPM"), Jefferies Group LLC ("Jefferies Group"), BOCOM International Holdings Company Limited ("BOCOM Int'l") and China International Capital Corporation Limited ("CICC"), and recognized the Company's long-term growth potential on the basis of the Company's fundamental strengths.

Firm	Date	Rating	Target Price (HK$)
Morgan Stanley	August 20	Overweight	37.90
	August 18	Overweight	37.90
	August 13	Overweight	37.90
JPM	August 21	Overweight	33.00
	August 18	Overweight	33.00
Jefferies Group	August 18	Buy	50.00
BOCOM Int'l	August 19	Buy	45.89
	August 18	Buy	45.89
	August 5	Buy	45.89
CICC	August 19	Outperform	39.94

On August 11, Loncar Investments announced that August 10 marked the semi-annual rebalance and reconstitution of the China BioPharma ETF's (Nasdaq: CHNA) underlying index, and Akeso, Inc. was among the 14 newly added companies to the Loncar China BioPharma Index (LCHINA). The LCHINA, launched by the Loncar Investments, is an index of 50 securities that have a strategic focus on advancing China's biopharmaceutical industry. On August 14 and 28, the Hang Seng Indexes Company Limited announced and updated the quarterly index review results of the Hang Seng Family of Indexes, respectively. The Company will be selected as a constituent stock of the Hang Seng Composite Index, the Hang Seng Healthcare Index and the Hang Seng Hong Kong-Listed Biotech Index, and the changes will take effect on 7 September, 2020.

Since listing, the Company's stock has risen nearly 82.63% from the IPO price of HK$16.18 as of the closing price of HK$29.55 on Monday, August 31, 2020, and the Company's trading volume has been healthy. The Company's daily average stock trading volume in August was around 1.83 million shares, indicating that the Company's trading volume maintains at a high level among other listed biotech companies in Hong Kong.

Recent Developments

Inclusion of the Shares of the Company as a Constituent Stock of Hang Seng Index Series

Published on August 18, 2020 | [Operational Highlights]

Based on quarterly review on the Hang Seng Index Series announced by the Hang Seng Indexes Company on August 14, 2020, the Company will be selected as a constituent stock of the Hang Seng Composite Index, the Hang Seng Healthcare Index and the Hang Seng Hong Kong-Listed Biotech Index, with effect from September 7, 2020.

[View details]

PD-1/CTLA-4 Bi-specific Antibody Novel Drug (AK104) Obtained FTD from the FDA for Treating Advanced Cervical Cancer

Published on August 13, 2020 | [Oncology][AK104 (PD-1/CTLA-4)]

The PD-1/CTLA-4 bi-specific antibody novel drug (AK104) independently developed by the Company has obtained FTD from the FDA for treating advanced cervical cancer. This represents another significant development after receiving the approval from the FDA in April 2020 to initiate a registrational clinical trial of AK104 monotherapy as second-line therapy in patients with recurrent or metastatic cervical cancer.

[View details]

PD-1/VEGF Bi-specific Antibody Novel Drug (AK112) Obtained IND Approval from the NMPA for Treating Advanced Solid Tumor

Published on August 11, 2020 | [Oncology][AK112 (PD-1/VEGF)]

The PD-1/VEGF bi-specific antibody (AK112) independently developed by the Company has obtained IND approval from the NMPA to advance to phase Ib of clinical trial for advanced solid tumors in China. Recently, PD-1/PD-L1 antibody in combination with VEGF blocking agents has shown promising developments in lung cancer, kidney cancer, liver cancer and various other tumor indications, and some of these trials have been approved by FDA, indicating that bi-specific antibodies against these two targets may have a higher chance of success.

[View details]

About Akeso

Akeso, Inc. (9926.HK) is a biopharmaceutical company dedicated to the research, development, manufacturing and commercialization of new innovative antibody drugs that are affordable to patients worldwide. Since our establishment, the Company has established an comprehensive in-house drug development platform (ACE Platform), encompassing fully integrated drug discovery and development functions, including target validation, antibody drug discovery and development, process development, and GMP-compliant commercial scale manufacturing. The Company has also successfully established a bi-specific antibody drug development technology platform (Tetrabody Technology Platform). The Company currently has a pipeline of over 20 innovative investigative drugs for the treatment of major diseases like cancer and autoimmune diseases, 9 of which have entered clinical stage, including two first-in-class bi-specific antibody drugs (PD-1/CTLA-4 and PD-1/VEGF). The Company's vision is to become a global leading biopharmaceutical company through research and development of break-through new drugs that are first-in-class and best-in-class therapies.

Product Overview

Oncology is one of our focused therapeutic areas. Our products in advanced clinical development stage include a PD-1/CTLA-4 bi-specific antibody (AK104), a PD-1 antibody (penpulimab (AK105)) and a PD-1/VEGF bi-specific antibody (AK112).

We have strategically developed an expertise in immunology since our inception and we have one of the richest innovative biologics pipelines targeting autoimmune diseases among China-based biopharmaceutical companies. In this therapeutic area, we have two drug candidates currently in clinical trials (an IL-12/IL-23 monoclonal antibody (AK101) and an IL-17 monoclonal antibody (AK111)), one drug candidate with IND approved in Australia (AK120, an IL-4R antibody), and one more in IND-enabling stage (AK114, an IL-1 beta antibody).

In addition to oncology and immunology, we have several compounds targeting diseases in other therapeutic areas. For instance, we have discovered and are developing ebronucimab (AK102) (PCSK9), which has strong commercialization capabilities in the cardiovascular therapeutic area.

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