BofA SECURITIES

China Healthcare

Takeaways from expert call on innovative drugs going abroad

Industry Overview

In 2023, many Chinese big pharma and biotech companies announced license-out deals/new FDA approvals. We hosted an expert call with Dr. Ye Hua, founder and CEO of BioNova Pharmaceuticals, to share his views on the biotech development and the global opportunities.

Products going abroad has become a trend

According to Dr. Hua, there are two types of "going abroad" – products going abroad and companies entering abroad. According to him, difficulties persist for the companies to go abroad, while products going abroad have become a trend. In 2023, the total upfront and other payments received by the China companies from license-out deals reached over US$5bn. In the future, he expects this trend to continue as the global market can fund products development and provide enough profits. In China, due to the weak financing environment in the past few years, there are challenges for the biotech fundings to support development. In addition, with the price cut from the NRDL negotiation, there is likely little profit for the innovative drugs in China after their launch. Therefore, it is important for the drugs to go abroad.

Challenges on going abroad

First, the product needs to be innovative. It should be the best- or better-in-class version to enter the developed market. Otherwise, the product can only be approved in other developing countries, such as ASEAN, and Dr. Hua doubts the profitability in such markets. The second challenge is MRCT. The clinical data from MRCT is very important for out-licensing and MRCT typically cost a large amount for the biotech companies. Moreover, the company's operating structure and IP management are challenges for the products to enter the overseas markets.

Advantages of big pharma/biotech on innovations

Currently, the Chinese big pharma companies usually have solid cash flows and they can take risks on developing new target or first-in-class products. While for the biotech companies, they usually have unique platforms to develop better-in-class products.

Problems in domestic market

Previously in China, there were protections against global innovative products, so that the many domestic pharma companies do not have to compete against. In addition, many so-called "innovative" drugs or me-worse products can still be approved in China. Moreover, the major regulators of the domestic healthcare system – NMPA and NHSA, have two different targets. For NMPA, it is to encourage the development of drugs and increase the innovation and safety of drugs; while for NHSA, it is to cut drug prices and improve drugs' accessibility. The different targets have led to conflicts in policies.

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FDA: Food and Drug Administration

MRCT: Multi-Regional Clinical Trials

NMPA: National Medical Products Administration

NHSA: National Healthcare Security Administration

NRDL: National Reimbursement Drug List

ASEAN: The Association of Southeast Asian Nations

Refer to important disclosures on page 3 to 4.
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