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Huya Targeting China to Accelerate Drug Production

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Risk reduction has always been an attractive business practice, but it has an especially sweet-sounding ring for drug firms looking to bring new medicines onto the market.

Biotechnology and pharmaceutical companies have long sought to reduce the risk of adverse side effects, which can cost a business millions in investment dollars, and, often, its future if it has invested in a single drug candidate that fails.

Drugs being developed in China today are offering U.S. companies a means of mitigating risk before conducting lengthy and often expensive Western clinical trials.

The theory goes that if a Western life sciences company can in-license a drug already proven safe and effective in human trials in China, it can easily duplicate those studies in the United States and then submit the data to the FDA for speedier approval.

“If you can pick up a drug that has already demonstrated some effect in people overseas that, obviously, is a good model,” said Eckard Weber, a partner with Domain Associates LLC, a local venture capital firm .

San Diego-based Huya Bioscience, which focuses on therapies in the areas of oncology, cardiology, inflammation and infectious diseases, says partnerships forged with Chinese academic research institutes have allowed it to tap into novel Chinese compounds already proven in human trials.

By in-licensing those compounds developed in China, the company said it has been able to alleviate the financial burden and risks involved with studying those same compounds on its own.

The Chinese institutes gain access to commercialization rights in China while Huya obtains rights to develop and market the drug in the U.S.

While the idea may seem at odds with conventional wisdom — the FDA has yet to approve a drug tested and proven in China only — gains have been made in recent times that suggest Chinese drug trials could have a place in U.S. regulatory processes.

The FDA recently indicated a willingness to accept preclinical and clinical data generated in China during talks with Huya for HBI-8000, the company’s investigational cancer drug licensed from Chipscreen Biosciences in China.

Huya plans to submit an investigational new drug application with the FDA in the third quarter of the year.

Mireille Gingras, president and chief executive officer of Huya, called the FDA’s willingness to accept the ancillary data “a huge milestone” for the company.

So far, Huya’s partnerships in China have yet to bring a drug to the market. But a new anti-arrhythmic compound, called HBI-3000, is about to be tested in humans in the U.S. following the successful completion of three Phase I studies in China.

Overseas Success

Huya has established working relationships with the Zhangjiang Hi-Tech Park in Shanghai, home to more than 360 biotechnology companies, as well as the Beijing-based China Pharmaceutical Technology Transfer Center and the Singapore-Hangzhou Science and Technology Park.

It also has a team in China charged with scouring the biotech landscape for promising drug candidates.

“It’s a burgeoning industry that is very exciting and developing very quickly,” Gingras said.

Huya’s strategy has been to address needs on both sides of the Pacific — the need for new, untapped sources of pre-clinical and clinical stage compounds by U.S. companies and China’s need for forging Western relationships and building knowledge of drug development.

Although China has made enormous gains in its manufacturing and drug testing processes, industry observers say it has much to learn from the United States in terms of building new life sciences companies and bringing drugs to the market for profit.

“We have to make more contact to learn how to improve our pharma research,” said Dr. Xiaoliang Wang, who visited Huya last week from China’s Institute of Materia Medica, Chinese Academy of Medical Sciences and Peking Union Medical College, one of the primary institutions for drug research in China.

Wang, who heads the Chinese institute, said its relationship with Huya allows it to see the Western process at work.
