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Reverse Innovation In China: An Interview With HUYA CEO Mireille Gillings

Eight years ago, HUYA's CEO Mireille Gillings began screening compounds developed in China to bring them to global markets. Nowadays, the company says it has a database with more than 12,000 compounds and 2,000 biomarkers from China.

SAN FRANCISCO – For decades, pharmaceutical companies brought innovative drugs developed in the West to China. Now, as China's government invests billions to spur local innovation, HUYA Bioscience International LLC is trying to bring innovation from China to global markets.

Through its eight offices and 80 scouts across China, the company has established a database with 12,000 compounds and 2,000 biomarkers developed by a large network of research institutes and universities in the country. HUYA screens these projects and licenses selected compounds from Chinese partners to develop them to Phase II outside of China and then finds partners to bring these projects to Phase III and commercialization.

The company has in-licensed four compounds in oncology and cardiovascular disease and has many others in due diligence in additional therapies like fibrosis and hepatitis C. Given the momentum, HUYA will expand its office in Shanghai Zhangjiang Hi-tech Park this month.

HUYA's CEO Mireille Gillings sat down with PharmAsia News' China Bureau during the annual JP Morgan Healthcare Conference in San Francisco to discuss HUYA's business model and innovation they found in China.

PharmAsia News: *Could you please introduce HUYA's business model? I think HUYA is one of the first international companies to look at compounds from China. What led you to the idea?*

Mireille Gillings: I went to China eight years ago looking for a compound for Alzheimer's. My PhD is in neurobiology so I could always speak science, and that's the international language. I met with the PIs [principal investigators] at the Shanghai Institute of Materia Medica and found that the science was excellent but the IP needed a bit of work. At that time I spoke to other PIs and scien-

tists and predicted that China would be the next hot spot for innovation and innovative science. I believe I was right because the biopharma industry in China is now booming, and HUYA has the first mover advantage with our eight offices in China and a very large team of scouts.

Our offices are located coastally and inland, strategically positioned so that our scouts can go talk to all the PIs and scientists about their projects. The HUYA scouts are very high qualified; they have PhDs and they understand the science so they can talk about it to the PIs and share the information with the rest of the HUYA teams. Our China co-headquarters are in Shanghai and we have offices in Beijing, Guangzhou, Shenzhen, Hangzhou, Chengdu, Taizhou and Wuhan (*"California's Huya And China Medical City Create Alliance To Develop Chinese Pharmaceutical Projects"* — *PharmAsia News, Jul. 20, 2010 11:03 AM GMT*).

All of the information from China is sent to our co-headquarters in San Diego, where most of our drug development experts are located.

Our model is to reduce the risk and the cost of drug development. We do that by working with our Chinese partners as they develop their compound for China and we develop for ex-China. We are true partners because we use the data from China to help us develop in Japan, Europe or the U.S., and then we share the benefits of our development experience with our partners in China. We also give validation to them as the originator of the innovative product. So it's a win-win for the Chinese and for us.

PharmAsia News: *What do you think of the quality of science in China?*

Gillings: That's what HUYA is about – we believe in the Chinese product opportunities. We have four programs



HUYA CEO Mireille Gillings

currently in development and we have validated Chinese data for those programs in a number of different ways. In one case we replicated the Chinese data in specialized efficacy studies in collaboration with the **University of Toronto**. For another project we collaborated with a top lab at the **University of Michigan** to perform critical safety studies, and again the Chinese findings were confirmed and extended. And we are now working with the Salk Institute to advance the Chinese PI's data on the mechanism of action for a molecule with highly interesting efficacy.

We've also given multiple proposals to U.S. FDA, and FDA has told us that they would use the Chinese data as supportive data. However, we replicated the Chinese data for our U.S. IND package (including toxicology, PK) without any problems. Importantly, we also replicated the human clinical data from China in a U.S. Phase I trial with our partner **Quintiles Inc.**

So yes, we do believe in the Chinese compounds, the Chinese opportunities and the researchers and the PIs. You do hear people's skepticism but it's not only about China – you have that everywhere. We continue to replicate and validate data from China, and we have done it over and over so we are confident in the quality there.

PharmAsia News: *A lot of big pharmas are looking to China for discovery projects. Do you think it brings competition to you because they have so much cash (“Sanofi Signs Two New Research Partners To Its List Of China Collaborations” — PharmAsia News, Oct. 16, 2012 8:28 PM GMT)?*

Gillings: Well, I believe that, again, it's based on the relationships. Also at HUYA we are different from big pharma because we believe in the science, the innovation. We believe and we take the risk by investing in our Chinese partners, even at an early stage. Many big pharma companies prefer to invest in a later stage where there is less risk. Although they may do more early stage investing, we have been building relationships with PIs and proving ourselves in China since 2004. We continue to work with

our partners to identify and in-license novel programs and we are developing our current in-licensed programs for global markets.

One of the other things that differentiate HUYA from big pharma is that we will help the PIs by providing feedback and advice on their programs. For example we can explain the FDA or EMA requirements and help them design the studies required by the regulatory agencies. We also try to keep an open mind and make suggestions to improve programs that may be too early for licensing. We describe specific studies that could add value to their program, and sometimes they come back to us with the results and we then move forward with them.

The PIs and the scientists appreciate the fact that we spend the time to help them, and I believe this significantly differentiates HUYA from the big pharma. It's really the guanxi [“relationship” in Chinese] – it's all about the relationships.

PharmAsia News: *And you are also looking at traditional Chinese medicine (“Quick Take: AstraZeneca Pursues Traditional Chinese Medicine As New Source For R&D” — PharmAsia News, Dec. 18, 2012 5:18 PM GMT)?*

Gillings: Yes. Two of our cardiovascular compounds are derived from TCM. One is a synthetic analog of a TCM-derived compound, and the other is a small molecule purified from a TCM extract. The latter is another example where we validated the Chinese data: We purified the molecule from extract and confirmed its identity, then used the molecule in efficacy studies. That confirmation was extremely important for us and gave us the confidence to continue moving the program forward.

PharmAsia News: *After you in-licensed these compounds, what do you do with them?*

Gillings: We will generally develop compounds until Phase IIa, and then we will find a partner to help bring them to Phase III and commercialization. Our business model is not to do commercialization but to partner a program once we de-risk it. We invest in it from the stage we get it, whether it is preclinical or Phase I (usually preclinical), and take it through to Phase II and then partner. It is very attractive for our partners – the risk is lower because we have taken the risk to replicate and extend the China data and bring the program to clinical proof of concept.

PharmAsia News: *You have partner like Quintiles to do the clinical trials. How do you run partnerships with these CROs? What kind of work do you want to keep in-house and what kind of jobs do you want to out-license to them (“San Diego's Huya Signs Six New Deals With Chinese Scientific Partners, Looks To Fast Forward Global Drug Development” — PharmAsia News, Feb. 14, 2011 11:21 PM GMT)?*

Gillings: Well, as you have said, in the case of Quintiles it was a partnership where we worked together to advance the program jointly. Again, HUYA's business model is to partner to efficiently advance compounds to the next stage.

We have different types of partners: We have preferred CRO partners that we work with to do IND-enabling work, and we use pharma and academic partners for pre-clinical efficacy and safety studies.

PharmAsia News: *As you mentioned eight projects you are working on right now, can you talk about some of them, just maybe a good sample for our readers how you get a compound in-licensed?*

Gillings: We focus on three areas now: oncology, cardiovascular and metabolic diseases. We have programs in each of these categories, ranging from preclinical to Phase II clinical stage. We also have a number of programs in due diligence and we will decide which to in-license based on our selection criteria.

Our team in San Diego has expertise in our focus therapeutic areas and follows an efficient system to evaluate and prioritize projects for in-licensing. They are in constant contact with the scouts and management team in our Chinese offices. They work continually with the HUYA staff and the Chinese PIs to see how best we can collaborate with them, their institute or biotech company.

There are an increasing number of biotech companies emerging in China, founded by returnees as well as nationals. The Chinese government is putting a lot of money towards the formation of these companies because they want to see the industry grow. I predicted that eight years ago when I went to China and saw all this wonderful talent. Nobody else was there, now everybody's going to tap into the brain power and the enthusiasm of the Chinese PIs, not only the returnees but also the nationals.

PharmAsia News: *Eight years ago you were concerned about IP in China. Right now do you think it's a comfortable situation? What changes have you seen here?*

Gillings: There have been some improvements. Firstly, when you read the top-tier journals, there are more and more Chinese authors and Chinese citations. So the Chi-

nese are taking a much bigger share of the publications and are being cited much more than before. The graphs showing growth in Chinese publications and citations look like a hockey stick. The same is true for patents. The Chinese investigators are learning how to protect their technology. And I think it's just going to get better.

PharmAsia News: *What's your prediction for China in the next five years?*

Gillings: I think that the biopharma industry in China is booming and that growth is going to continue. The government is continuing to allocate funds to grow this industry and I believe they're going to be one of the leading countries. I also believe that the innovation is going to improve and there will be more novel programs coming out of China.

PharmAsia News: *Is HUYA also developing compounds in China?*

Gillings: No, but we help our partners with study design, which works very well because if there are certain criteria that we know are needed for the regulatory filings in the U.S., Europe or Japan, we explain that to our partner so they may incorporate those points in their study so that we can use the resulting data for global development. As I mentioned before, we can share our data with them so it's really a true collaboration. And I think that's another differentiator between HUYA and the big pharmas.

A lot of the Chinese PIs that I've met want to see their drug on the market. They're proud of what they've done and they want to see it through. With HUYA they get that, while if they work with the big pharmas, they may not.

Really there are enough compounds to go around for everybody. There's so much innovation and so much good work. I really believe in the Chinese innovation and their ability to make an impact on global health care.

By Jialing Dai

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