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Huya CEO Mireille Gingras On Partnering To Develop Chinese Compounds In The West: An Interview With PharmAsia News

San Diego-based Huya Bioscience partners with Chinese research institutions and companies to identify preclinical and clinical-stage compounds, including traditional Chinese medicines to license for ex-China development. CEO Mireille Gingras recently spoke with *PharmAsia News* about Huya's partnership efforts in China. Prior to founding Huya, Gingras was founder and chief operating officer of MIR3, a software company developing online treatment programs for neuro-addictive diseases.

PharmAsia News: *Could you first talk about how Huya decided to target China as a source for compounds?*

Mireille Gingras: Sure. This is my third company, and before starting this I had a consulting company. What we did was we in-licensed and out-licensed compounds for large pharma and mid-sized biotech companies. We looked everywhere where everybody was looking, which was in Europe and actually spent a year in Japan looking over there, too, and found that most of the pools there were depleted. And then we ended up going to China to meet, to look for a compound for one of our clients and found this phenomenal science. At the time the IP was not as strong as we would have liked it to be but the science was very good, and I thought maybe there would be more opportunity there.

That's how we started Huya two years ago, basically because we thought there would be more opportunity. I spent over 80 percent of the time in the past three years there just meeting these different institutes and universities and companies, developed relationships and found that there was a lot of opportunity.

PharmAsia News: *Do a lot of these compounds stem from traditional Chinese medicines?*

Gingras: Some of them do. Some of them are what we call NCEs, and some of them are what we called purified compounds so they are derivatives from the earth, but then they can become a new chemical entity because they are purified.

PharmAsia News: *You mentioned IP originally not being so great. Have you seen a change?*

Gingras: Absolutely. No, there has been a big change in terms of IP and development over the years so it has become better. And the principal investigators know that they have to do certain filings and they have to be protected with a patent.

PharmAsia News: *Are there specific changes in IP law and regulations that you would like to see improved or changed?*

Gingras: I think that everybody is working and making sure that their IP is protected, so I think that's come a long way than it was when we first started there three years ago.

PharmAsia News: *Can you talk about your partnership model in China?*

Gingras: Our business model is that we will partner up with a Chinese company or institute in China, and we will develop it. They will develop it in China, and what we will do is bring it over to the U.S. and develop it here in the U.S. And what we like to do is have a relationship with the company in China so that we can work with them. As they develop it in China, we can follow and develop it in the U.S. So basically we have a validation either in animals or in humans because we know that it works.

That is how we like to partner, and we've done this, so … we own the compound fully. Sometimes, depending on the case, we will own all of the rights worldwide or we will own ex-China.

In two cases now, we are working with a compound that we in-licensed, which is an oncology compound from a private

company in Shenzhen. And we are working with them and developing that compound.

The second one is with the Shanghai Institute of Materia Medica, which is a cardiovascular compound which has gone through four Phase I's and now is going into a Phase II. We are developing [the oncology compound] here in the U.S., and we have had two very successful pre-IND meetings. What I mean by "successful" is that the [U.S.] FDA has basically approved our plans moving forward to go into the clinic. But not only that, they approved the Chinese data as supportive data.

And this was a huge milestone for Huya because this was something that we weren't sure which way the FDA was going to go. But they welcomed it and thought that it could be used as supportive data. …

PharmAsia News: *Was that for your histone deacetylase inhibitor HBI8000?*

Gingras: That's correct - HBI8000. That's the one that we relicensed from Chipscreen in Shenzhen. The CEO there is Xian-Ping Lu, and we've been working with him.

We just finished our clinical trials in China, Phase I, and we are now going to go into the clinic [in the U.S.]. By the end of this year we are submitting an IND.

So we work very quickly, and from the time that we licensed it to where we are now has been a very short period of time because we have a team that just focuses on moving the compound forward. That's one of the things that Huya does is reduce the risk by taking on the risk and moving it to the clinical stage here in the U.S. so that we can eventually partner it up with a bigger pharma in a later stage like Phase II.

PharmAsia News: *In those pre-IND conversations with FDA, did the agency approach the data differently than if it had come from the U.S.? Did they have specific concerns?*

Gingras: What we do is we replicate and extend all of the studies that were done in China. So like I said they were happy to accept the Chinese data as supportive data. So that's how the FDA accepted it.

China doesn't have GLP and GMP, so we have to replicate and extend the studies here in the U.S.

PharmAsia News: *Huya announced in March the establishment of a clinical advisory team for the anti-arrhythmic compound HBI-3000 (PharmAsia News, March 11, 2008). Can you talk about their role in the development process?*

Gingras: Yes. So for example with 3000 we have a clinical development team that is in house that we work with. Some of them are consultants and some of them are employees, and together we are developing 3000 from our headquarters in San Diego. Then we also have a clinical advisory team that is composed of Eric Topol and Ben Lucchesi, Denis Roy, Peter Kowey. These are really the top experts in cardiovascular, and they are very excited about our drug development. Peter Kowey and Ben Lucchesi were with us when we went to the FDA and had the pre-IND meeting with the FDA.

PharmAsia News: *You mentioned the quality of science in China. How much of that is due to Chinese scientists returning from abroad to work in China?*

Gingras: It is a very young, growing, booming industry, biotech industry. It's untapped. And the pool there is going to become increasingly bigger. You have all of these Chinese returnees. They call themselves "sea turtles" because they got their degrees in the U.S., spent the 10 years in research and development in the big pharmas, and now they are back. And they are actually doing it themselves and doing a lot of the development work. I think that because of their training they are doing the same type of research and development in China as they would be doing anywhere else. So that part is globally the same.

PharmAsia News: *Last year Huya signed a deal with Organon, now a part of Schering-Plough, to help the company identify compounds in China for neurology, immunology and oncology (PharmAsia News, Jan. 12, 2007). Do you see Huya focusing more on identifying compounds for customers or identifying compounds and then developing them internally yourself?*

Gingras: The relationship that we have with Schering-Plough is a partnership relationship where they are interested in some different therapeutic areas. And then based on that if there is a compound that they find interesting and exciting and want to pursue, we go into an alternative business arrangement where we have a co-development type of

relationship to further the compound along.

PharmAsia News: *Is Huya's first inclination to find someone like that to partner with? Or do you have the resources to develop compounds yourself?*

Mireille Gingras: Both. We have the resources to develop it, and we also want to have strategic partners such as Schering-Plough so that once we have the opportunities and we have brought it along to a certain point we can partner up with the bigger pharmas so that we can bring it to market.

PharmAsia News: *Do you have plans to expand beyond China and perhaps look for promising compounds elsewhere in Asia?*

Gingras: Sure. Eventually that's something that we would be interested in doing, but right now our focus is in China. We have offices in Beijing, in Shanghai, in Hangzhou and we are going to open one in Shenzhen. So we are really focused on working with a lot of the science parks and the incubators to help these companies that are doing the R&D to get to the clinical stages since we have validated the model twice now. They have seen what we have done with the Shanghai Institute of Materia Medica, and they have seen what we have done with Chipscreen that now this gives them the opportunity to say, "Hey, we'd like you to do the same thing with us." We have gotten extremely positive feedback from these incubators and these science parks because they want to be able to see how they can move their compounds along.

PharmAsia News: *As Chinese life sciences companies move up the R&D value chain, do you expect to see your relationships with these companies changing?*

Gingras: I would hope that the basis of the relationships that we've done would just enable us to do more work together with different opportunities and compounds. So I see it as becoming more positive since they've had the experience to work with us. And in some cases we've helped design and helped with the [clinical trial] protocol and given a lot of input so that not only are they successful for developing the drug in their market and in China, but also having it done in a way so that it's accepted globally, so that they also get the credit from ex-China and the rest of the world if we're successful. So I think that having a relationship and developing these things between us will enable us to continue and to do more of these types of deals.

- *Daniel Poppy* (d.poppy@elsevier.com)

[Editor's note: PharmAsia News will host a webinar Aug. 27 for pharmaceutical and medical device firms entitled "Anti-Bribery Compliance in China - Avoiding the Pitfalls." For more information, please click here.]