

Interview: Amy Huang    General Manager, OBI Pharma, Taiwan



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In an exclusive interview, Amy Huang, general manager of OBI Pharma, shares her plans to bolster the international development of the company and further strengthen its expertise throughout the drug development process. She also elaborates on the key next steps that lie ahead for OBI Pharma  s flagship immuno-oncology therapy, Adagloxad Simolenin, as the company also expands its R&D focus to the antibody field.

At the 2016 American Society of Clinical Oncology (ASCO) Annual Meeting on 4th June 2016, OBI Pharma presented the results of a Phase II/III trial of the investigational immunotherapy Adagloxad Simolenin in patients with metastatic breast cancer. Although the study did not meet its originally designed primary endpoint, it did show interesting efficacy for some specific patients. As general manager of OBI, what makes you believe these results are promising?

Although the study did not meet the primary efficacy endpoint of progression-free survival, Adagloxad Simolenin is an extremely innovative product and proudly stands as a frontrunner in immunology. As a matter of fact, the KOLs and experts that we met at the annual meetings of ASCO and the European Society for Medical Oncology (ESMO) encouraged us to move forward on the development of our product and start global trials, because they believed that this vaccine can really be a benefit to cancer patients and our vaccine is well-tolerated with no major safety concerns.

Our understanding of these results is that our product is inefficient for patients with late stage metastatic cancer who do not have enough time to produce enough of the necessary antibodies. Nevertheless, patients who demonstrated an immune response (IgG or IgM) showed a highly

significant improvement in progression-free survival â?? and this represented around 50 percent of the patients involved in the trial. This is one of our key investigations and we strongly believe that this product can benefit certain types of cancer patients, who can produce enough antibodies to fight the progression of the disease.

This study has taught us a lot about the properties of Adagloxad Simolenin and we are now collaborating with international regulatory agencies to design the protocol for its global phase III study and identify the patient population that will see the greatest response to our therapy. On 24 January 2017, we received formal approval from the CFDA to conduct a phase III clinical trial, while on 20 January 2017, we met with the US FDA for an End-of-Phase 2 (EOP2) meeting. We are also meeting with the EMA in Europe. Global phase III trials are expensive, and we want to take our time so we can do it right and further assist physicians in their efforts to more effectively treat metastatic breast cancer.

Would OBI consider cooperating with major multinational companies for this global phase III trial?

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We have the ambition to become a global biopharmaceutical company, and we already have a commercial presence in the US and Asia in general. With the expansion of our pipeline, however, we have become more open to forming new collaborations. We still want to keep important commercial rights; and we are also keen to increase our productâ??s speed of development, so we are implementing a flexible partnership strategy and are ready to negotiate with other leading pharmaceutical companies.

In the meantime, I am trying to attract more global and experienced talent to support the company. We will, for example, expand our office in San Diego and set up larger medical and clinical teams to supervise our upcoming trials. As for R&D, our main lab is in Taipei but I am thinking we may need to open another lab to support OBIâ??s long-term growth.

You mentioned the expansion of OBIâ??s pipeline. What is OBIâ??s current R&D strategy?

Over the past three years, OBI has enriched its R&D focus to become a two-pillar company, broadening our pipeline â?? which was essentially focused on immunotherapies â?? to now also encompass antibodies.

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In the meantime, we have been strategically strengthening the companyâ??s research capacity. Historically, OBI was mostly focused on development: for example we in-licensed OBI-822 [*the previous name of Adagloxad Simolenin, e.d.*] from Memorial Sloan Kettering Cancer Center (MSKCC) and concentrated our efforts on designing and advancing its phase II and III trials.

Over the last five years, we have been building our in-house capacity for translational medicine and our own pharmacology division. Although two-thirds of our employees are working in R&D, we want to further expand OBIâ??s research footprint by more than five times, hiring mainly local but also some global talent. Given our tremendous investments in the R&D field, I expect a lot of innovation coming out of our companyâ??s pipeline in the upcoming years.

What do you see as the most important success factors to further propel the companyâ??s growth over the upcoming years?

I think we need to build a high-performance team and to choose the right leaders for all our different divisions. For example, I recently recruited a new COO, who has a great expertise fund raising globally. As we move towards the goal of becoming an international biotech, we need to find people who will broaden our company's expertise – which already stands as a great challenge – and also further enhance OBI's capacity in other areas to ensure our global trials are advancing as swiftly as expected.

What do you want to have achieved within the next five years?

Over the next five years, we want to move briskly forward with the phase III breast cancer study for Adagloxad Simolenin. We hope to license out important regions and build strong relationships with other multinational pharma and biotech. We also hope to in-license innovative products that enhance and expand our product pipelines, so we are actively seeking innovative products and targets. Finally, we are open to growing inorganically, and hope to raise further funding in Taiwan and overseas to fuel new research, new clinical trials, and M&A opportunities.

What is OBI Pharma's positioning on the global stage?

OBI is committed to the research and development of third-generation pharmaceutical products focused beyond proteins and small molecules. In the grand scheme of things, we want OBI to become a leader when it comes to changing the way doctors treat cancer.

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