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China's Hua Medicine Licenses Worldwide Rights To Roche Diabetes Compound, More Deals On The Way

Chinese startup Hua Medicine kicks off its in-licensing strategy with an IND-ready glucokinase activator from Roche.

SHANGHAI - Shanghai-based biotech startup Hua Medicine Ltd. announced Dec. 20 an agreement to in-license Roche's glucokinase activator (GKA) program for type 2 diabetes for global development.

It is Hua Medicine's first in-licensing deal, with more expected shortly, according to the company.

Roche first started to work on GKA in the mid-1990's and demonstrated efficacy in lowering blood glucose levels of diabetic patients in clinical trials by using a previous generation of GKA compounds, according to Hua Medicine. The Chinese company is licensing a more advanced generation of the GKA candidate, which has been further optimized for safety and efficacy and is now IND-ready in the U.S.

In China, Roche has completed all preclinical studies and developed a manufacturing process for the drug.

The deal should not be a shock to China watchers. Hua Medicine's CEO Li Chen was formerly chief scientific officer of Roche's R&D center in China and played an important role in helping to develop the compound in China.

"We plan to file a Clinical Trial Application in China in March or April 2012 and hope to launch the Phase I trials by the end of next year in China," Chen told PharmAsia News in an interview.

Under the agreement, Hua Medicine will receive full preclinical and clinical documentation for Roche's GKA program, active pharmaceutical ingredient for Roche's compound, RO5305552, and rights to potential back-up compounds.

Roche has granted Hua Medicine exclusive development, manufacturing and worldwide sales and marketing rights with the rights to also sub-license. In return, Roche received an undisclosed upfront payment, and is eligible for milestones and potential royalties if compounds reach the market.

"As a part of its global R&D strategy, Roche was seeking an external partner to continue this compound development, because it is a really good molecule," Chen said. "They chose Hua, because Hua is a China innovation company, and because many preclinical development data for this compound have been generated at the Roche R&D Center China and through many partnerships in China."

"This is also one of the reasons we will do clinical trials first in China," added Chen, who outlined plans to complete Phase II trials by 2014 or 2015.

Plenty Of Competition

GKA is a novel, small molecule activator of the glucokinase enzyme, which plays a key role in regulating carbohydrate metabolism. By increasing the enzyme's activity, GKA has the potential to help lower elevated blood glucose levels seen in diabetes.

Currently, there are no GKAs on the market, which provides Hua Medicine with a potential first-in-class opportunity. However the area of research is competitive, with others ahead of Hua, though Hua may be able to turbo charge development given China's trial recruitment advantages, including a large, treatment-naïve population, and a patient base centered near large hospitals. China has roughly 92 million diabetics compared to 25 million in the U.S., according to Hua.

Competitors in the space include Eli Lilly & Co., which appears to be the farthest along with a GKA in Phase II, LY2409021, obtained through a licensing deal with OSI Pharmaceuticals (now Astellas Pharma Inc.) in 2007. Others in the space include Forest Laboratories Inc., with GK1-399 in Phase I, obtained from TransTech Pharma Inc. in 2010; and Amgen Inc. with AMG 151, also in

Phase I, which was in-licensed from Array BioPharma Inc. (*"Amgen Pays Array $60 Million Upfront For Its Phase One Type 2 Diabetes Compound" — "The Pink Sheet" DAILY, Dec. 15, 2009 5:00 AM GMT*).

However, one major competitor, AstraZeneca PLC, recently discontinued development of two GKA compounds, including one in Phase II, according to a pipeline update posted to its website in July. It is unclear why the compounds were terminated, although AZ has been conducting a comprehensive portfolio review under new R&D head Martin Mackay, which has led to the culling of roughly 10% of its clinical compounds (*"AstraZeneca Rebuilds Its R&D, With Payers In Mind" — "The Pink Sheet," Jul. 4, 2011 4:00 AM GMT*).

Backed By $50 Million, More Deals Are Coming

Hua Medicine is on the leading edge of a new kind of Chinese company, which is looking to take advantage of major trends in the industry.

With Big Pharma cutting back on R&D in response to the patent cliff, significant costs savings available in China, and huge unmet medical needs in China and around the world, Chinese entrepreneurs have been launching startups looking to in-license compounds from multinationals. Many of these startups are also establishing in-house research teams to discover new medicine internally.

A key differentiator is that several are also led by senior management, like Hua Medicine's Chen, who have significant experience working for Western pharmas. Hua has attracted $50 million from American venture capitalists, including Arch Venture Partners, Venrock and Fidelity Ventures, as well as Chinese VC Shanghai Alliance Investment Ltd. and the corporate venture arm of Chinese CRO giant WuXi PharmaTech Inc. (*"Meet China's New Innovators: Hua Medicine Looks To Take Flight With U.S. Venture Backing (Part 1)" — PharmAsia News, Sep. 19, 2011 2:00 PM GMT*).

Another example is the oncology-focused BeiGene Ltd. ,which scored a $20 million investment from Merck & Co. Inc. and recently in-licensed two compounds from Johnson & Johnson (*"As Management Talent Moves To China Startups, Will Industry See More In-Licensing Deals?" — PharmAsia News, Oct. 25, 2011 12:00 PM GMT*).

Ascletis Inc. has also generated considerable buzz. The U.S.-China hybrid was founded by a former VP of global HIV drug discovery for GlaxoSmithKline PLC, and is backed by $100 million raised by angel investors, led by real estate billionaire Jinxing Qi, also a co-founder of Ascletis (*"Ascletis Opens Its $100 Million Wallet - Breaks Ground On China Facility, Sets Sights On In-Licensing" — PharmAsia News, Oct. 26, 2011 11:00 AM GMT*).

A key challenge for all of these startups is how to identify promising compounds to in-license, particularly as Western pharmas are more likely to hold on to development rights for their highest-potential candidates.

Hua's Chen notes he has established an experienced team to screen compounds. He has set three criteria for in-licensed projects:

1. **First-in-class, innovative products around the world or in China;**
2. **Compounds that address large unmet medical needs in China and the rest of the world; and**
3. **Compounds that can be developed in China.**

Using these three criteria, his team has screened more than 200 compounds already and found 10 that hit the sweet spot, Chen said.

The CEO is helped by a portfolio advisory board, led by John J. Baldwin, who is also a co-founder of Hua Medicine and on its board of directors. Baldwin spent more than 30 years at Merck on the R&D side, helping to develop several compounds like the glaucoma treatments Trusopt and Cosopt. He also was a founder and chief scientific officer for both Pharmacopeia and Vitae Pharmaceuticals Inc. and is a co-founder and member of the board of directors of WuXi.

Another member of the portfolio advisory board, Christopher Walsh, is a professor of neurology at Harvard Medical School. Hua is also backed by an experienced board of directors, which in addition to Chen and Baldwin, includes Robert Nelson from Arch Venture, Bryan Roberts at Venrock, Daniel Auerbach at Fidelity and Ge Li, CEO of WuXi.

Closing the deal with Roche on GKA is just the first of many steps Hua plans to take, Chen said, explaining that he is in discussions to in-license several late stage clinical development compounds for China. Unlike the Roche deal, those compounds would be for China rights only, according to Chen.

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