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Onyx, Bayer End Court Fight By Signing New Collaboration

By Mari Serebrov
Washington Editor

The latest long-running dispute over the outgrowth of a collaboration agreement has come to an end – with another agreement.

More than a week into a jury trial in a U.S. district court over rights to regorafenib, Bayer Healthcare and Onyx Pharmaceuticals Inc. ended their dispute Tuesday with a new agreement on the late-stage cancer compound that Onyx claimed was an offshoot of the companies' joint development of Nexavar (sorapenib), a blockbuster cancer drug.

The new agreement recognizes regorafenib as a Bayer compound and gives the company, a subsidiary of Bayer AG, of Leverkusen, Germany, the final decision-making authority for global development and commercialization of the multikinase inhibitor. But Onyx didn't come away empty-

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Shield Launches Phase III of Ferric Iron Drug in Anemia

By Nuala Moran
***BioWorld Today* Correspondent**

LONDON – Shield Therapeutics Ltd. dosed the first patients in two Phase III studies of its lead product, ST10, for the treatment of iron deficiency anemia, just four months after closing its first round of venture funding.

"We've had a good 18 months," CEO Carl Sterritt told *BioWorld Today*. "We started to design the protocol about a year ago, and with the funding we were able to go ahead identifying all the centers and getting it all up and running,"

The international, double-blind, placebo-controlled trials are testing ST10 twice daily as a treatment for iron deficiency anemia in patients with ulcerative colitis or Crohn's disease, respectively. Each of the studies will enroll 120 patients who cannot be treated with existing oral iron replacement therapies, with the primary endpoint defined

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ASHG 2011

In Paradox, Complex Data Can Simplify Statistical Headaches

By Anette Breindl
Science Editor

MONTREAL – It may be the annual meeting of the American Society of Human Genetics. But scientists here devoted a lively discussion yesterday morning to what will be needed in addition to genetics to wrest greater clinical significance from genomewide association studies (GWAS).

GWAS have led to an explosion of known genes that are associated with complex traits. In 2007, a paltry seven such associations had been reported in the scientific literature. By the end of 2010, that number had risen to more than 1,200.

But that rise, to date, has not been accompanied in any sort of simple way by a corresponding increase in understanding about the biology of those genetic variants – let alone therapeutic approaches.

Partly, of course, that is because the genetic variants

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NewCo News

With $50M in Hand, Hua Aims To License Drugs for China

By Trista Morrison
Staff Writer

Hua Medicine Ltd. made headlines last month with the news that it had raised $50 million in start-up funding from a blue-chip syndicate including Arch Venture Partners, Fidelity, Venrock, Sino-Alliance International Ltd. and WuXi PharmaTech Corporate Venture.

But while it was clear Hua was up to something big, it was less clear exactly what that might be. Reports were long on praise for the Shanghai-based company's plan to become "the leading, fully integrated biotech company in China," but short on details of how it would achieve that status.

"We're just now coming out of stealth mode," admitted

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Hua

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John Choi, Hua's chief strategy and business officer.

Hua was founded in mid-2010 by Li Chen, Ge Li and Jack Baldwin. Chen, who previously co-founded Roche AG's research center in China, is credited with building much of the biopharma ecosystem in Shanghai. Li, as chairman and CEO of Chinese clinical research giant WuXi PharmaTech, is heralded as one of China's most successful health care entrepreneurs. Baldwin also is a serial entrepreneur: After 30-plus years with Merck and Co. Inc., he helped found WuXi, Pharmacopeia Inc. and Vitae Pharmaceuticals Inc.

The trio saw an opportunity to build a Chinese biotech company that could in-license drugs, leverage China's notoriously capital-efficient development resources to advance them through the pipeline and tap its founders' connections to ensure successful commercialization in China.

That vision clearly resonated with investors. Bryan Roberts, general partner at Venrock, explained that Hua's appeal lies in a convergence of factors. First, economic growth in China is leading to the creation of what is expected to be a massive health care market. Second, the Chinese government is willing to help foster innovation through substantial grants, tax breaks and other incentives. Third, the return of Western-trained sea turtles – like Choi, a former venture capitalist and hedge fund manager – means there are people in China with the expertise to pull it off.

So what exactly is Hua doing with its $50 million? Choi said the company has cycled through hundreds of assets and identified several it plans to license. Details should be available in the next few months, but Choi told *BioWorld Today* the company is looking at a preclinical neurology asset, a clinic-ready drug for metabolic disease and a new drug application-ready primary care drug.

For the former two assets, Hua would in-license worldwide rights and take over development, with the goal of out-licensing ex-Asia rights after proof of concept. For the later-stage compound, Hua plans to in-license only Chinese rights.

The company is also looking at joint ventures, subsidiaries and other deal structures that would allow it to build its pipeline. Different drug developers have "different ways of wanting to commercialize drugs in China," said Venrock's Roberts, so Hua plans to be flexible.

At the end of the day, Hua's business model doesn't look all that different from U.S.-based biotech start-ups focused on in-licensing, advancing and potentially commercializing drugs.

The difference, Choi explained, is that there is "high competition for limited assets" in the U.S., and once a license is obtained, drug development is more expensive.

China also presents a unique opportunity for commercialization because its regulatory, pricing and distribution hurdles make it a difficult market for U.S. or European drug companies. Choi explained that even if a drug already is approved in the U.S., it has to complete pharmacokinetic and Phase III trials in China to gain Chinese approval. Then the drugmaker must negotiate target pricing at the central government level, complete a price auction process at the provincial level, get the drug listed in individual hospitals at the local level and obtain reimbursement at the national and provincial levels.

Given the complex process, most drug developers "need a China partner that knows the landscape well," Choi said – and Hua is hoping to be that partner of choice.

Choi noted that most of the drug firms in China thus far have been focused on generics – only more recently have some started to get into development. Venrock's Roberts agreed. "Outside of traditional Chinese medicine, the market is pretty green field," he said.

Yet Hua isn't the only biotech seeking to capitalize on the opportunity to commercialize drugs in China. Start-up Ascletis Inc., of Hangzhou, China, pulled in a whopping $100 million in Series A funding this spring to license late-stage and commercial programs for the Chinese market, as well as to discover and develop new drugs for oncology and infectious diseases. (See *BioWorld Today*, April 7, 2011.)

And Foster City, Calif.-based SciClone Pharmaceuticals Inc. built its own China sales force to support hepatitis drug Zadaxin (thymalfasin), which never made it to market in the U.S. but has found success overseas. The firm has done so well in China that it in-licensed other products to add to its sales bag and is expected to report about $135 million in revenues this year. In April, SciClone strengthened its hand in China with the acquisition of Shanghai, China-based specialty pharmaceutical firm NovaMed Pharmaceuticals Inc., which markets 18 products and boasts a 450-person China sales organization. (See *BioWorld Today*, April 20, 2011.)

Roberts predicted more biotechs will start to jump on the China bandwagon. "It sounds like there will be a lot of wheat and chaff sorting over the next five years or so," he said. ■

U.S. Patent Disclosures

• **AgonOx LLC**, of Portland, Ore., received U.S. Patent No. 7,959,925, titled "Trimeric OX40 Immunoglobulin Fusion Protein and Methods of Use," which covers both a range of compositions of OX40 Ligand Fusion Proteins and methods of use.

• **Allon Therapeutics Inc.**, of Vancouver, British Columbia, was granted a patent covering the compositions of matter for the D-isomer of NAP (davunetide), which is known as AL-408 in the firm's pipeline.