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Cellceutix makes strides with Kevetrin cancer drug

Startup pharma company runs a tight ship on path to crucial human testing

By Martin Desmarais

BEVERLY, Mass. -- In the pharmaceutical industry, the process of getting drugs to market is typically a long, research-intensive one, often with a billion-dollar price tag. Upstart Cellceutix Pharmaceuticals Inc. is aiming to slash this expenditure and has made great gains in doing so with its Kevetrin for drug-resistant cancers.

Cellceutix was started in May 2007 by Krishna Menon and George Evans and has focused on Kevetrin, a pharmaceutical compound developed by Menon, since its start -- producing some impressive test results in the lab so far. In fact, Cellceutix is now readying for the main goal of any pharmaceutical company -- getting Food and Drug Administration approval for human testing. This step puts all drug companies on the path to where they want to be -- having patients using their products.

According to Evans, Cellceutix chairman and chief executive officer, the hope is to get Kevetrin into human clinical trials by next spring. The company is about to start some final toxicity studies in animals, which will last for several months and clear the final hurdle to get the product into humans. Cellceutix has signed a deal with the U.S. arm of German drug manufacturer Girindus to produce Kevetrin for testing out of Girindus America Inc.'s facility in Cincinnati.

Human trials for a drug typically have three phases, which can be spread out over at least five years. Evans anticipates that the first phase of human trials for Kevetrin will last one year.

Having human trials on the horizon is a tremendous accomplishment for a pharmaceutical company that currently only has three employees. Both Menon and Evans admit, however, that the company will have to receive some funding to increase the company size and staff to support human trials. Still, both view Cellceutix as way ahead of the curve in what they have spent to get their drug to where it is. While other small pharmaceutical companies may spend in the \$10 million range to get a drug through phase 1 clinical trials, Menon said Cellceutix, which has received some small private backing to date, can get through this stage under that price tag.

Partnering with a larger drug company is also a typical option for a small drug maker such as Cellceutix. According to Evans, that is an option but the company would like to get through phase 1 trials before such a deal.

What is really building excitement for Cellceutix are test results showing Kevetrin's effectiveness fighting drug-resistant cancers, such as lung and breast cancer. Originally, Cellceutix was targeting Kevetrin toward the treatment of head and neck cancer, but test results also showed effectiveness against lung cancer, which caused the company to lean in that direction with its product.

"There is just not that much available [to treat lung cancer]. It is one area of great medical need," said Evans. "It's turned out to be something that is even more exciting than head and neck cancer."

Recent tests also showed similar effectiveness combating breast cancer.

At the end of the day, both Menon and Evans say that human trials and the FDA may initially lead to the disease Kevetrin will be focused on for treatment and approval, but having a drug that can be applied in different areas will be great in the long run.



Evans points out that is not unusual for cancer drugs to get initial approval to treat one area, such as lung cancer, and then get broader and broader approvals to treat other areas that the drug shows signs of combating. "We would ultimately try to get approval for a range of these indications," he said. "We have potential in a number of different areas and we will try to exploit these areas."

A shift of focus for a drug, initially targeted to treat one type of problem, but found to also treat another, is not unusual for the pharmaceutical industry. Well known examples include Viagra and Rogaine, both of which were initially targeted to treat diseases unrelated to the effects the drugs have now become famous for.



While many pharmaceutical companies spend billions getting a drug to market, Cellceutix and co-founder Krishna Menon, above, are hoping to take a less expensive path with their drug.

Evans "It is not unusual to start at one thing and then find another use," said Evans. "That is the nature of the beast. That is how the pharmaceutical industry works."

In addition to Kevetrin, Cellceutix is also working on another drug for the treatment of psoriasis. All told the company has rights to about seven compounds.

"It is important to have a couple of things going because of the nature of the risk in the pharmaceutical industry," Evans said. "You have to try and spread the risk a little bit.

Despite the small size of Cellceutix and the focus on Kevetrin, Menon still finds time to work in the lab or collaborate with other scientists to develop new ideas and compounds. "It is important to keep generate new ideas because it is a new idea business," said Evans.

Menon, Cellceutix's president and chief scientific officer, has worked in drug development for several decades. Originally trained as a veterinary surgeon, Menon began his career as a chief government veterinarian in Jamaica in the 1970s. He then worked as a director of agriculture for the Cayman Islands.

In 1982, he took a job with the Dana Farber Cancer Research Institute. In 1984, he earned a doctoral degree in pharmacology from Harvard University and became a research scientist at Dana Farber, a job that lasted until 1990. From 1991 to 1993 he was a senior research scientist focusing on cancer at Bayer Pharmaceuticals.

After a year operating his own veterinary oncology and drug development consultancy practice, Menon joined Eli Lilly & Co. as group leader of cancer research and clinical development, and was involved in the pre-clinical development of Gemzar and Alimta, drugs which have gone on to billions of dollars in sales.

Evans has more than 25 years experience in the pharmaceutical industry. He worked in a number of positions for Pfizer Inc., ending his career there as general counsel for Pfizer's worldwide prescription drug unit, and a member of the unit's leadership team. He is a graduate of Williams College and Columbia University's law and business schools.

Menon and Evans met through a mutual colleague at a time when Menon was trying to decide what to do with the pharmaceutical compound he had created that would become Kevetrin. He said he initially though he would sell the compound, but Evans' expertise opened up the possibility of starting a pharmaceutical company to develop it.

Both are very happy with the way things have turned out so far with Cellceutix.

"We are highly satisfied ... The most important thing in this industry is the data. You have to have data that shows good strong results," Evans said. "We are in a very good situation now. We have strong data in an area that is very hard to treat.

"We are pretty comfortable the results we have are good," he added. "They are exciting results in an area where there is very little out there to help patients. So I think we are very well positioned."

And both have high expectations for the future.

"The next year is very important because we are doing human trials. It is a very, very important year," Menon said.

"Once you start to see results in people that gets to be pretty exciting," Evans added.