

High-Tech Pioneer

USF biotechnology spin-off pioneers new cancer and viral disease drug development.

IRX THERAPEUTICS, A PRIVATELY HELD company that started with technology licensed exclusively through USF, is on a fast track to help in the battle against cancer and viral disease. The company's lead product for cancer treatment, IRX-2, or citoplurikin, is now in advanced clinical trials. And, after raising another \$25 million through stock offerings, bringing its total in private financing to \$65 million, the company's future looks bright.

IRX-2 is aimed at stimulating a coordinated cellular immune response to enable a patient's immune system to fight disease while improving survival and quality of life. The product contains multiple natural cytokines, a category of signaling proteins used in cellular communication, including interferons, natural proteins produced by the immune system.

Citoplurikin has been tested in phase one and two clinical trials where the drug was being tested for safety in increasingly larger numbers of volunteers with head

and neck cancer. Reports said the drug was "well tolerated" with no major side effects and a clinical response rate of 38 percent as overall survival doubled to 48 months. The company is planning phase three trials where its efficacy in treatment will be further tested.

Citoplurikin has been given "fast track" and "orphan drug" status by the U.S. Food and Drug Administration (FDA). The fast track designation is a formal mechanism to interact with the FDA and is intended for products with claims that it addresses an unmet medical need. The benefits of fast track include scheduled meetings to seek FDA input into development plans, the option of submitting a new drug application in sections rather than all components simultaneously, and the option of requesting evaluation of studies using surrogate. Orphan drug status is a special status for drugs aimed at treating rare diseases.

According to John W. Hadden II, president and CEO of IRX Therapeutics, the new funding will be used to further develop its cancer and viral disease product platform. "USF, the USF Research Foundation and USF's Division of Patents and Licensing have been supportive partners since the company's founding," says Hadden.

Those at USF who have helped get IRX Therapeutics off the ground are excited about its potential and the potential for its products to help fight disease and improve the lives of those with diseases such as cancer and some viral diseases.

"IRX Therapeutics is a great example of the success that occurs when strong technology is coupled with experienced and capable management," says Valerie Landio McDevitt, director of USF's Division of Patents and Licensing. "These are the kinds of successes USF is focused on facilitating."

— Randolph Fillmore



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