

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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JOSEPH GAMBLE

The new tracking device detects movements characteristic of individuals with dementia.

tracked by Ultra Wideband (UWB) sensor technology installed in the rooms and hallways. The results show changes in movement speed and directions of travel.

“Our results so far clearly show movement pattern differences for each person and stability in an individual’s patterns across days,” says Kearns. “Those normal movement patterns, and changes in movement patterns, can be analyzed by computer programs and may ultimately give

“real time” updates to ALF administrators to warn them of a resident’s impending departure.”

Kearns, whose research is funded by the Johnnie Byrd Alzheimer’s Center and Research Institute, says the study’s findings will be published soon and on-going studies are aimed at perfecting the monitoring technology.

– Randolph Fillmore

Safe Return

A NEW TRACKING SYSTEM—developed specifically for tracking patient movements and identifying potential wanderers or those who may be about to wander from their assisted living facility (ALF)—may help family members and caregivers to breathe a bit easier.

William D. Kearns, a professor in the Department of Aging and Mental Health in the Louis de la Parte Florida Mental Health Institute at USF, and colleagues have adapted sensor technology to detect various movements characteristic of individuals with dementia. They currently have an ongoing study to test the system’s effectiveness.

According to Kearns, about 140,000 Floridians are being cared for in nursing homes or ALFs.

“In the past five years, the number of residents in these facilities with dementia has increased from 40 percent to 60 percent,” he says. “It’s estimated that six million Americans have dementia and during their illness 60 percent may wander, which can lead to injury or death.”

The study will gather movement data from 30 residents who move about in congregate areas within their ALF, says Kearns. During waking hours, each resident wears a tag shaped like a wristwatch and their movements are



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