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Valley fever cure a step closer

FDA hopes to lure commercial developer

Kerry Fehr-Snyder
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The federal government is backing the first potential cure for valley fever, a serious lung disease that has spiked in recent years and afflicted thousands of Arizonans.

The University of Arizona announced Tuesday that the Food and Drug Administration has granted so-called orphan-drug status to nikkomycin z, a drug acquired by UA in 2005. That will make it easier for the drug to be developed and tested by a pharmaceutical company.

Four drugs have been approved for treatment of valley fever, which is caused by inhaling a fungus that lives in desert soil. But none kills the fungus outright, relying instead on a patient's immune system to stop it from growing.

Nikkomycin z has been shown to kill the fungus in mice. The FDA backing will provide financial and other support to take the research to a higher level, including tax credits and market exclusivity for a commercial partner to test the drug and bring it to market.

"The fact that this drug is going forward is exciting," said Dr. John Galgiani, director of UA's Valley Fever Center for Excellence.

Whether the drug is effective on people won't be known for several years.

To speed up findings, the FDA grants "orphan status" to compounds aimed at treating relatively rare diseases, those affecting fewer than 200,000 people a year, that struggle to win attention and resources.

Valley fever has long plagued Arizona and other arid Southwestern states. In 2004, the latest year with official counts, 3,665 cases were reported in the state. The incidence rate hit record levels: 63 cases per 100,000 residents, compared with 14 a decade earlier, Arizona Department of Health Services records show. Early reports indicate 2006 may set a record.

But health experts believe the number of infections is much higher. The Valley Fever Center for Excellence estimates there are about 150,000 new cases throughout the country each year.

In the most serious ones, patients, especially the elderly, develop pneumonia and other health problems. The disease is not contagious and is rarely fatal, with about 35 dying a year. One in three patients shows symptoms, and about 10 percent of them require treatment with anti-fungal medications.

Several years ago, officials at the federal Centers for Disease Control and Prevention mapped new Phoenix-area cases and found that most occurred in outlying areas, where dirt was being disturbed to build new homes and businesses.

"As the state grows, I think, this disease is only going to become more and more of a problem," Galgiani said.

Galgiani has applied for a federal grant worth upward of \$1 million over three years

to test and develop nikkomycin z. A decision on the application is expected this summer.

Even in the best-case scenario, the drug likely won't be available for use by patients for at least five years. But that is about a third of the typical time it takes to bring a pharmaceutical drug to market.

In addition to orphan-drug status, the Valley Fever Center for Excellence has enlisted help from two other UA-affiliated groups: the Bio5 Institute and the Critical Path Institute.

C-Path is developing new ways to get the drug approved by the FDA more quickly. It also is starting a registry of patients with valley fever to track how the disease manifests itself and any side effects to treatments.

"Until you have that, you can't design a trial to better treat it," said Raymond Woosley, chief executive officer of C-Path.

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