

Southern Research's leukemia drug put on fast track

By **DAVE PARKS**
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Human trials of a leukemia drug developed by Southern Research Institute have been so impressive that the Food and Drug Administration has put the medication on the fast track for possible approval.

"It does look pretty good," said Jack Secrist, vice president of drug discovery at Southern Research. "This is a drug that could help a lot of folks."

If all goes well, the drug, clofarabine, could be approved by this fall for patients diagnosed with acute myelogenous leukemia or acute lymphocytic leukemia.

In a clinical trial of 29 children with advanced leukemia, injections of the drug triggered one complete remission and nine partial remissions, which allowed seven of the children to undergo further treatment with bone marrow transplants.

"The response in some kids is great," Secrist said.

The children all had been treated with other cancer drugs, and their leukemia was still out of control, he said. Clofarabine was a last hope.

In December, the FDA put the drug on the fast-track, which will speed up the process for approval if further clinical trials are successful, Secrist said. Much of the clinical trial work is being done at the M.D. Anderson Cancer Center in Houston, he said.

The drug's trip from the lab bench to the bedside of patients has taken more than a decade, Secrist said. It was initially discovered in the 1980s at Southern Research by Secrist and another well-known researcher,

DRUG: Attacks DNA in cancer cells

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John Montgomery. It was first synthesized in a Southern Research lab by Anita Fowler, a chemist.

Secrist said researchers believed they had found something significant because the drug was effective in fighting cancer in mice. Still, Secrist said, the cost of fully developing the clofarabine was prohibitive for Southern Research.

So development and commercialization rights for clofarabine were sold to Bioenvision Inc., a drug company in Europe. Bioenvision has taken on a North American development partner, ILEX Oncology Inc., which conducted the successful clinical trial in the United States.

Southern Research still holds a patent on the drug and will receive royalties if it reaches the marketplace. Secrist said the royalties probably won't amount to much at first, since clofarabine would be used in a limited number of cases.

But, Secrist said, the drug may also be effective against other, more common cancers, as indicated in animal studies. The drug works by attacking DNA in cancer cells.

Bioenvision and ILEX have started clinical trials for patients suffering from advanced solid tumors. These patients will get an oral form of the drug.

Secrist said clofarabine is a good example of the caliber of work that is being done at Southern Research.

Two other cancer drugs discovered at Southern Research are in early stages of development. In addition, five cancer drugs already approved by the FDA and on the market were developed at Southern Research.