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The best medicine – prevention – may be coming to cancer

By Anette Breindl, Science Editor

Cancer Prevention Pharmaceuticals Inc. and Swiss specialty pharma company Tillotts Pharma AG, a wholly owned subsidiary of Tokyo-based Zeria Pharmaceutical Co. Ltd., signed a licensing agreement for European and Japanese rights to develop and commercialize CPP-1X/sulindac for the treatment of the orphan disease familial adenomatous polyposis, and other gastrointestinal conditions.

Specific terms were not disclosed, but will include up-front and milestone payments, and could total more than $100 million.

CPP-1X/sulindac is in Phase III trials for the treatment of familial adenomatous polyposis, and Tillotts is interested in the drug as part of its focus on gastroenterology.

To the team at Cancer Prevention Pharmaceuticals, of Tucson, Ariz., though – as the company's name might suggest – the real promise of the compound is not so much in what it can treat, as in what it can prevent – the progression to colon cancer that is all-but-inevitable in patients with the disorder.

"We are trying to follow the paradigm that has worked so well in the cardiovascular and neurovascular space . . . treat cholesterol instead of a heart attack, treat high blood pressure instead of a stroke," Cancer Prevention CEO Jeffrey Jacob told *BioWorld Today*.

That's not to say that familial adenomatous polyposis itself is not serious. Sufferers develop colon polyps – sometimes hundreds of them – that can necessitate colon removal surgery and colostomy bags, a fate that is always hard but particularly brutal for teenagers, which is the age when the disease typically manifests itself.

Colon cancer is all-but-certain to follow unless the colon is removed, with an average age of 39 at diagnosis. According to data from the National Cancer Institute, for the general population, average lifetime risk of developing colon cancer is around 5 percent, and 90 percent of those cases occur in people who are older than 50.

It is that transition to outright cancer that CPP-1X/sulindac is aimed at preventing, at least in the initial indication. A Phase III trial is testing the ability of the drug to prevent the "occurrence and/or recurrence of problematic polyps and tumors." The team hopes to have data from the trial in two to 2 .5 years.

A much larger trial, sponsored by the National Cancer Institute and run by the Southwestern Oncology Group, is looking at the drugs' ability to prevent recurrence in colon cancer patients more generally. That trial, which will enroll more than 1,000 patients as opposed to the roughly 150 in the familial adenomatous polyposis trial, is expected to take around five years to complete.

Earlier-stage clinical trials are looking at preventing recurrence of neuroblastoma, in which relapse is very likely after initial treatment successes.

Jacob said that from his team's perspective, there is no basic difference between preventing the initial occurrence of a cancer and preventing its recurrence. Preventing the initial occurrence is realistic only in groups that are known to have a high risk of developing cancer, such as familial adenomatous polyposis patients do for colon cancer, at least for the time being.

But he noted that statins, too, were first tested in patients with extremely high risk of heart attack, and their use was gradually expanded.

Notably, the company's initial investors and business advisors includes Daniel von Hoff, who is better known for working at the absolute opposite of the cancer spectrum, using molecular profiling to make treatment decisions for metastatic patients who have run out of options, sometimes after more than a dozen treatments. (See *BioWorld Today*, April 22, 2009.)

Jacob said that von Hoff was "a friend, advisor and investor," and that his involvement was emblematic of the belief of many in the field – even those whose practical work is centered elsewhere – that ultimately, "a better way to go is to move upstream. Treat predisease and pre-relapse," Jacob said, "instead of waiting until it is too late." //