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## Can Ancient Herbs Treat Cancer?

By Coeli Carr

The Chinese herb Ban Zhi Lian may not be in everyone's lexicon, but to the 80 women with stage IV metastatic breast cancer, who are participating in the second phase of the BZL101 clinical trials, it represents hope and life.

For Bionovo, the drug discovery and development company in Emeryville, Calif., that's behind BZL101, there's hope too. The trial is the first FDA-validated clinical study of a potential cancer drug derived from a Chinese medicinal herb, says Dr. Mary Tagliaferri, a co-founder of the company, former practicing acupuncturist and a breast-cancer survivor. "Sixty-two percent of chemotherapy drugs come from natural products, and plants have been the basis of almost every new class of medication," she says. "It makes sense that these plants can act as anticancer agents."

Tagliaferri's interest in Ban Zhi Lian, which has traditionally been used to treat swellings, sores and fever, was sparked in 1996 by a fellow acupuncturist, Isaac Cohen, who would later become a co-founder of Bionovo. At that time, Cohen had been treating, for a decade, women who were battling breast cancer with conventional medicines and had run out of treatment options. "In their exhaustion and desperation, they were trying to find an alternative treatment that was not so harsh," says Cohen, who often prescribed herbs to be prepared as teas to ease the side effects of chemo and hormone therapy. But the patients' oncologists, says Cohen, discouraged them from trying anything new. "They'd say Chinese medicine was quackery and that there was no evidence it worked," he says. Still, Cohen observed that many of the women to whom he gave Chinese herbs, including Ban Zhi Lian, responded well to the herbs and even experienced a relatively good quality of life. "At first I chucked it to luck," he says. "But then you see it's not just luck. And then you ponder why."

Cohen's early observations about Ban Zhi Lian may have started out as a hunch, but they may hold up. In 1996, Cohen and Tagliaferri, along with Dr. Debu Tripathy, then a breast cancer specialist at the University of California, San Francisco, co-founded the Complementary and Alternative Medicine program at the university's Carol Franc Buck Breast Care Center. Over the next several years, the trio amassed enough

evidence about the herb's anticancer properties — in lab tests of animals and breast-cancer cells, BZL101 caused apoptosis or cell death, according to Tagliaferri — to get a green light from the FDA to begin clinical trials.

The researchers conducted Phase I trials at Buck and at the Cancer Research Network in Plantation, Fla. Their 21 participants had stage IV metastatic breast cancer, which had continued to progress despite an average of four rounds of standard treatment, including chemo and hormone therapy. The patients took 12 g a day of Ban Zhi Lian, a dose that's three times more concentrated than the amount found in a cup of brewed tea. After about a year, 25% of the patients saw stabilization in their disease for 90 days, and 19% for 180 days. The experimenters say BZL101 works by preventing cancer cells from undergoing glycolysis, a process of glycogen breakdown that accounts for as much as 85% of cancer cells' energy supply.

In 2002, Tagliaferri and Cohen left Buck to establish Bionovo, where they began Phase II trials of BZL101 in April 2006, expanding their studies to 10 hospitals and breast cancer centers, including the University of Chicago Medical Center, Duke University Medical Center and the M.D. Anderson Cancer Center in Houston. Bionovo expects the second phase of trials to conclude by early 2008.

Women with breast cancer have typically sought Chinese medical herbalists for relief from the side effects of chemotherapy and radiation or to strengthen and balance their immune systems; some have even hoped for a cure. Some women may have been helped; others not. But with so many variables — the broad range of patients, quality and potency of the herbs available, types of formulations prescribed and the expertise of the herbalist — outcomes in informal settings were never a sure thing. And it's the same kind of variability that has made clinical research so problematic. "Even though people are very interested in herbal therapy and a lot of people take herbs, research in herbal therapy is difficult because you're dealing with a mixture of compounds," says Tripathy, who is now a clinical professor of internal medicine at the University of Texas Southwestern Medical Center in Dallas. During the research phase, Tripathy says, scientists often attempt to isolate one particular molecule or compound from the herbal extract — and the anticancer activity is lost. "There are herbal extracts in which the anticancer activity is actually due to the synergy between many of the compounds contained in that extract," he says.

Tripathy also says that companies like Bionovo have a tough time getting funding either from the private sector or from pharmaceutical companies: "In the absence of controlled clinical trials, people are skeptical and say 'There's no evidence this works,'" he says. Bionovo, which expects to begin Phase III trials in 2009, hopes to upset this way of thinking. And, says Tagliaferri, the company is studying about two dozen other Chinese herbs with anticancer potential.

The FDA at least is eager to see more studies of botanical treatments of cancer. "We're not opposed to Chinese medicine," says Dr. Shaw Chen, botanical review team leader at the FDA. "We just like to see clinical studies that meet our standards." Chen agrees it can be tough to study the pharmacological activity of botanical compounds or to ensure consistency in quality, but Bionovo's efforts, if fruitful, may help pave the way for other research. "A successful application to market for a cancer drug based on Chinese

medicine will be encouragement to the industry," he says. "I think the industry is watching for the first success story."

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