

HOPE

THE CHRISTUS STEHLIN FOUNDATION FOR CANCER RESEARCH

SEPTEMBER 2008

VICTORY!!

FDA APPROVES
OUR CANCER
FIGHTING
DRUG FOR
CLINICAL TRIALS

CHRISTUS STEHLIN FOUNDATION
REACHES A MILESTONE

On July 31, 2008, The CHRISTUS Stehlin Foundation for Cancer Research received extremely exciting news from the U.S. Food & Drug Administration (FDA). The Foundation's 2,800-page Investigational New Drug (IND) application for the promising anticancer drug CZ48 was approved with minor changes.

With this approval, the Foundation can launch Phase I (human) trials – another step in the journey to offer this potentially lifesaving drug, which the Foundation discovered in 1995, to people suffering from cancer.

continued on page 2





continued from page 1

Overcoming Tremendous Odds

According to Robert Anderson, Executive Director of the Foundation, the FDA approval represents a remarkable accomplishment, since past records show that for every 5,000-10,000 compounds discovered, only 250 make it to pre-clinical phases, and only 5 are approved by the FDA for clinical (human) studies.

Making the go-ahead even sweeter is the knowledge that well over 50% of IND applications for oncology products are either put on hold or receive queries from the FDA for further information. The CHRISTUS Stehlin Foundation application sailed through with just two minor changes.

“This approval represents years and years of hard work from our devoted staff, and the financial and emotional support of loyal friends and organizations who believed in our work,” commented Bobby. “We are extremely proud, but also humbled by the responsibility, and very grateful for the opportunity.”

One drug company’s chart (below), developed in 2007 from a number of sources, shows for every 5-10,000 oncology drugs discovered, only five (less than one-tenth of one percent) win approval from the FDA to enter clinical trials.

Leaves of Promise

The FDA approval was for CZ48, a derivative of extracts from a Chinese tree, the Camptotheca Acuminata, which more than 45 years ago showed potent anticancer activity against a mouse leukemia. The Stehlin Foundation has been researching cancer treatment with the Camptothecin family of compounds since late 1988.

Since 1995, when the CZ48 compound was identified, research has continued at the Foundation to improve efficacy and reduce toxicity. The staff has tested the compound against 22 different human cancers transplanted to the Foundation’s famous “nude mice.” Their research has shown that CZ48 exhibits a broad spectrum of activity again breast, lung, colon, pancreas and bladder carcinomas, melanomas and DSRCT sarcomas, with a striking lack of toxicity.

CZ48 is also remarkable in that it can be taken orally. Pre-clinical studies indicate that it has very few side effects. This makes its appeal even stronger for human cancer treatment.

“We have always felt that CZ48 holds tremendous promise as a cancer treatment, which is why we have worked so diligently to make it available,” said Dr. Beppino Giovanella, Laboratory Director at the CHRISTUS Stehlin Foundation. “With CZ48 we bring to life the vision of The Stehlin Foundation – utilizing both research bench and physician’s office to improve the treatment of the patient suffering from cancer.”

Next Steps

The initial manufacturing process for CZ48 has already been completed, producing a sufficient amount of the drug to treat 75 patients during the Phase I clinical testing. The purpose of a Phase I study is to determine (1) toxicity, and (2) starting doses for Phase II studies, designed to determine the effectiveness of the drug.

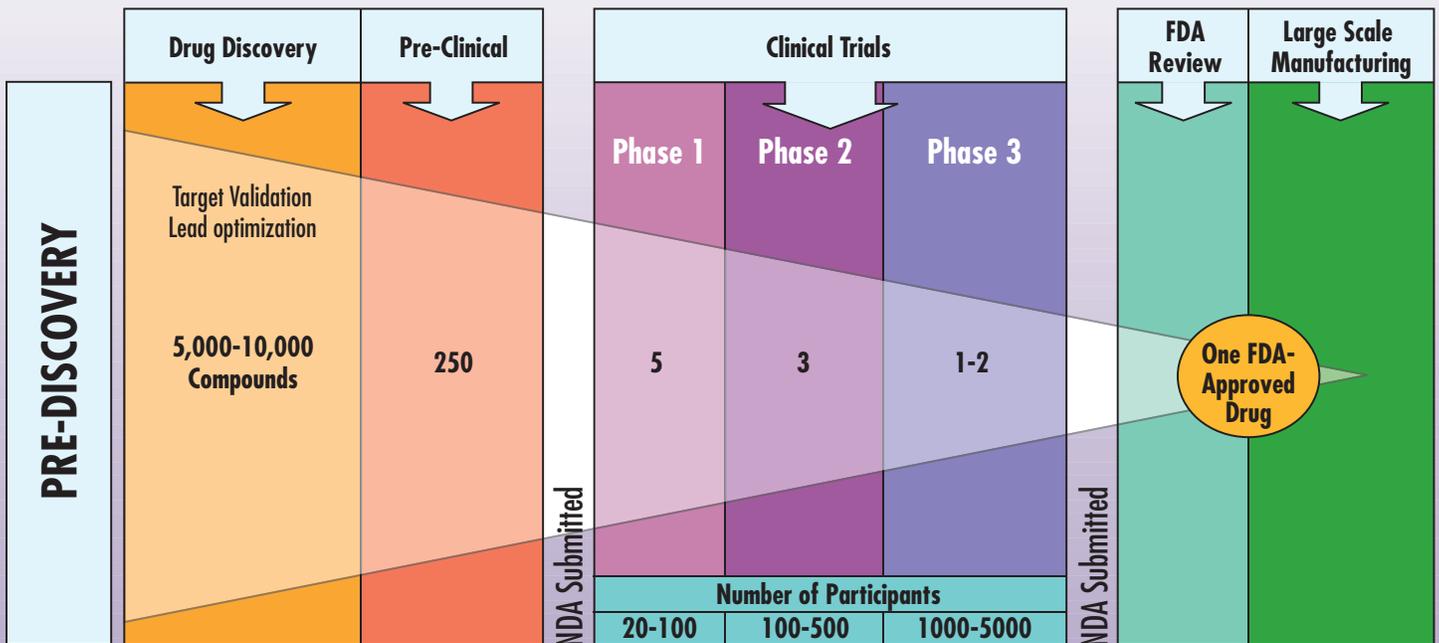
The clinical trials will be conducted at the Vanderbilt-Ingram Cancer Center in Nashville and the University of New Mexico Cancer Center in Albuquerque. They are expected to last 12-15 months. In accordance with FDA regulations, patient accrual for the Phase I studies will be slow.

“We realize we won’t be able to help everyone with this study,” said Bobby Anderson. “The important thing, however, is that every step gets us closer to victory in the fight against cancer.”

CZ 48 BY THE NUMBERS

The CHRISTUS Stehlin Foundation IND application for CZ48

- Contained 2,823 pages
- Weighed in excess of 140 pounds
- Took over 10 months to prepare
- Drew from 13 years of ongoing investigational research
- Summarized 48 months of dedicated research





Making Progress – With a Little Help from Our Friends

“The Fab Four” to Rock the 28th Friends of the Stehlin Foundation Gala

Here we go again! Another great evening is on the docket for the 28th Annual Friends of the Stehlin Foundation gala, scheduled for Saturday, November 15, 2008, at the Westin Galleria.

What has been described as “the best party of the year” by Houston’s top society writers will certainly live up to its reputation this time, with a host of great auction items, terrific entertainment, and a dance band that will keep the crowd rocking until the wee hours.

This year’s theme, “With a Little Help from Our Friends,” was inspired by the headline act – the Fab Four, the premier Beatles tribute band in America, in its first-ever appearance in Texas.

The Fab Four will perform a 90-minute concert in two acts, featuring the early Beatles music in the first act, and Sgt Pepper and later Beatles music in the second. The Fab Four also brings an Ed Sullivan Master of Ceremonies impersonator to round out the show.

With their uncanny, note-for-note renditions of Beatles’ songs, the Fab Four has amazed audiences all over the world and earned admiring reviews, even from members of the original Beatles’ families. According to fans, they look like the Beatles as they perform classics like “Can’t Buy Me Love,” “Yesterday,” “A Day in the Life,” “Penny Lane,” “Here Comes the Sun,” and “Hey Jude.”

For the late-nighters, popular dance band **Collector’s Item** will enliven the dance floor with Mo-Town sounds. Plus, there is a special, top-secret act to take place during the intermission, put together by event planners extraordinaire Ward & Ames. Mum’s the word, but it’s a guaranteed hit.

Get ready for a wonderful night!

Come Together

The Friends of the Stehlin Foundation has produced the annual fundraising gala for the Stehlin Foundation for Cancer Research since 1981. A high-energy and tireless group, over the years they have **netted** over \$10 million to support the research and clinical projects of the CHRISTUS Stehlin Foundation.

This year’s chairs were introduced to the

CHRISTUS Stehlin Foundation through The Young Texans Against Cancer (YTAC), which co-sponsored two Friends’ galas in the recent past. YTAC was founded by a group of 44 20-40 year-olds in Houston who wanted to increase cancer awareness among their generation.



Andrea and Paul Stewart, chairs of the 2008 gala

Newlyweds Dr. Paul Stewart and Andrea Montgomery Stewart jumped right on board to co-chair the 2008 “With a Little Help from My Friends” event – even though YTAC is not a designated co-sponsor this year. Andrea, as a Founding Member of YTAC, saw this as a way to continue her efforts to spread the message across generations.

“We’re focused on creating an evening that is memorable and fun, and very successful in fundraising,” she said. “I’m delighted to introduce more people to the Stehlin organization and help them at this critical point in their history.”

All We Need is Love (and Ticket Sales)

Decorations for the Nov. 15 gala will draw from the era of the British Invasion, when the Beatles and the other bands and personalities from across the pond revolutionized the musical and pop scene. Think mini-skirts, Twiggy, paper flowers, beads and yellow

submarines.

“With a Little Help from Our Friends” sums up not only the theme of the party, but the purpose of the event, say its organizers. “We’re building on the support from the Friends in the past and hoping to make new friends who recognize the important contributions of the CHRISTUS Stehlin Foundation,” summarized co-chair Andrea Montgomery. “It’s the perfect combination of fun and fundraising.”

It Won’t Be Long Now

Proceeds from the Friends of the Stehlin Foundation galas traditionally go toward supporting cancer research at the Foundation, but this year the need is especially great.

As noted in the previous story, the upcoming Phase I (human) trials for the anticancer drug CZ48 represent a tremendous opportunity. However, the study will require 12-15 months and expenses of \$1.5 million (roughly \$30,000 per patient) – and costs are to be borne solely by the Stehlin Foundation.

We can make the future brighter for people suffering from cancer . . . “With a Little Help From Our Friends!” Please join us!





2008 scholarship recipients

Summer in the City

The 2008 recipients of the Educational Scholarship Program for the CHRISTUS Stehlin Foundation were just as exceptional as in other years. Just 10 high school and college students were selected from a field of more than 100 applicants to spend the summer at the Stehlin laboratory – conducting research, accompanying doctors on rounds and in surgery, and compiling their own presentations in preparation for careers in medical and biological sciences.

This year's group, however, had the distinction of working with the Stehlin staff on the preparation of the gigantic Investigational New Drug application to the FDA for the Camp-tothecin derivative CZ48. "I don't know what we would have done without them," summarized Executive Director Bobby Anderson. "They proofread, collated, assembled, and performed countless other tasks in addition to the hands-on research work that led to this huge achievement. We can't thank them enough."

The Educational Scholarship program began in 1980 as an opportunity for science-minded students to gain hands-on experience in medical research. The Foundation pays the students for their work and assists them in gaining acceptance at their choice of colleges and graduate schools.

The Summer 2008 Stehlin interns came from:

Colleges/Universities:

Alabama
Cornell
Rice
St. Thomas
SMU
Texas A&M
Trinity

High Schools:

Clear Brook
Kinkaid
Westbury

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Save The Date! Saturday, Nov. 15, 2008 featuring "The Fab Four"

Mark your calendars now for the 28th Annual Friends of the Stehlin Foundation Gala. You can't afford to miss out on what has proved to be the "best party of the year!"

VISIT THE CHRISTUS STEHLIN FOUNDATION ON THE INTERNET AT www.stehlin.org



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