FDA Approves First TCM Drug for Phase II Clinical Trials

An anti-cancer drug, called Kanglaite Injection, made by China’s Zhejiang Kanglaite Pharmaceutical, is the first TCM drug approved by the FDA for clinical trials on humans. The US-based company Oncoherb* has been designated to conduct the Phase II clinical trials.

The US Food and Drug Administration (FDA) has recently given approval to a China-made anticancer herbal drug for clinical tests on humans. According to China’s State Administrative Bureau of Traditional Chinese Medicine (TCM), this is the first time a TCM drug has been approved for clinical trial in the US, a new avenue for TCM to enter the global market.

In China, the drug has been tested in various clinical trials on over 200,000 cancer patients. The results show that the drug is effective in treating cancer and has minor side effects.

The drug, called Kanglaite injection, was invented by China’s Zhejiang Kanglaite Pharmaceutical Co Ltd, which is located in Hangzhou, the capital city of eastern China’s Zhejiang province. Previously, the herbal injection has already gone through a four-month clinical trial on 15 to 18 volunteers at a hospital in Salt Lake City, Utah, USA.

All the data will be studied and analyzed before new rounds of clinical trials are allowed to start and before it is licensed for sale, according to Dr. Li Dapeng, the drug researcher for Kanglaite.

Dr. Li said that data from the first group, who received the injection as part of the clinical trials, has shown that the drug is effective and safe.

Kanglaite is developed from the liquid distilled from the seeds of the herb called Job’s tears (Yiyiren). It is able to kill cancer cells by enhancing the immune system of the human body.

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The drug’s active components and its production techniques and formula have been patented in the US, Japan and the EU countries. The sales volume of the drug ranks first in the Chinese market among all anti-cancer western drugs and TCM.

Although China’s history of herbal application dates back to over 5000 years ago, the country’s herbal export accounts for less than 5 percent of the world market. Experts hope the FDA’s approval for Kanglaite is a new start for commercialization and globalization of TCM drugs, which is one of the key issues of China’s State 9th Five-year Development Program.

* Oncoherb to Begin FDA Phase II Trial Of Kanglaite

The US biopharmaceutical company, Oncoherb Inc. announced on 25 July 2001 the details of its collaboration with a well-known US cancer center in New York on an FDA Phase II human trials for the herbal drug Kanglaite, at a symposium on Modernization of Traditional Chinese Medicine. The symposium featured a talk about Medical Reform and TCM Modernization in China by Mr. Ren Dequan, deputy director-general of China’s State Drug Administration (SDA). Mr. Ren also commented on the challenges for TCM after China has joined the WTO. Dr. Albert Wai-Kit Chan, president and CEO of Oncoherb, spoke on the Introduction to TCM Development in the US.

The herbal extract has demonstrated efficacy against non-lobular lung cancer in clinical trials conducted in China, where it is a prescription drug. Oncoherb expects to begin selling the new drug 31 months from the start of the clinical trials. Studies have indicated that the drug may also be useful in the...
International Mongolian Medical Conference to be Held in Inner Mongolia

An international academic conference on Mongolian medicine will be held in Hohhot, the capital of China’s Inner Mongolia Autonomous Region. The conference is co-sponsored by the Inner Mongolian government and China’s State Administrative Bureau of traditional Chinese medicine.

Some 300 Chinese and foreign experts, scholars and health officials will attend the conference. An exhibition on the achievements of Mongolian medicine and new Mongolian medical products will be held during the three-day conference.

At a recent press conference, the organizers said they hope the conference will promote Mongolian medicine, which has been proven effective in treating heart and brain vascular diseases, diabetes and hepatitis.

Medicated Plasters from Taiwan may be Detrimental

Most medicated plasters contain herbal medicine. Medicated plasters are among the top products in the developing market for Chinese medicines. But Taipei City’s Bureau of Health recently said that an inspection conducted by the bureau and the National Laboratories of Foods and Drugs, showed that about 60 percent of Taiwan’s medicated plasters have failed to meet the standards stipulated by regulations governing the pharmaceuticals industry.

The inspection showed that 65 percent of medicated plasters produced in Taiwan contain butylated hydroxytoluene (BHT), an antioxidant and food preservative. About 44 percent do not carry labels indicating the exact contents. About 28 percent contain the chemical diphenhydramine hydrochloride, an antihistamine drug, along with some herbs, while regulations clearly state that herbal medicine plasters should not contain any such chemicals.

Studies have shown that such chemicals may be a carcinogen. The bureau said that the lack of information about the BHT used makes it difficult to determine whether the amount of BHT present is harmful to human health. Diphenhydramine hydrochloride is used to treat allergies and inflammations. It can cause drowsiness and fatigue. Users of products containing this chemical must be informed of possible dangers when driving or when operating heavy machinery.

There are no official statistics indicating the popularity of medicated plasters in Taiwan, but the Industrial Development Bureau of Taiwan’s Ministry of Economic Affairs has broadly estimated that Taiwan has an annual market for one billion medicated plasters.

The official said that with the market for medicated plasters growing, the government is working on upgrading the quality of the products to ensure that the health of users is not adversely affected and to develop the market.
Selected Titles in Biotechnology

Dynamical Modeling in Biotechnology
Lectures Presented at the EU Advanced Workshop
edited by Franco Bagnoli & Stefano Rufio (Università di Firenze, Italy)

The power of modelization in physics and in engineering is not in doubt, while in the biotechnological field many theoretical studies stop at the description level. It is time for theoretical modelization to enter the field of biotechnology, and that needs people with both physical and biological knowledge.

This book introduces interested scientists with varied backgrounds to active research in different areas broadly related to what has come to be called “dynamical modeling in biology.”

Readership: Biotechnologists.

324pp  Dec 2000
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FROM BIOTECHNOLOGY TO GENOMES
The Meaning of the Double Helix
by Philippe Goujon (Université Catholique de Lille, France)

Aimed at scientists and non-specialised readers alike, this book retraces the source of national and international biotechnology programmes by examining the origins of biotechnology and its political and economic interpretation by large nations. With a foreword by André Goffeau, who initiated the European Yeast Genome Project, the book describes the achievements of the first genetic and physical maps, as well as the political and scientific genesis of the American Human Genome Project.

Readership: Students, professors, science historians, science policymakers, physicians and those in the biotechnology industry.

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