From left: Kaijing Yan, executive chairman of Tasly Holding Group; Henry Sun, president and CEO of Tasly Pharmaceuticals; Ed Schutter, president and CEO of Arbor Pharmaceuticals; Naifeng Wu, president of Tasly Holding Group; at the Tasly-Arbor signing ceremony for a US clinical co-development and commercialization agreement, in Rockville, MD on Sept ember 14, 2018.

TASLY PHARMACEUTICALS

Seeks Final US Approval for T89 Drug

Tests show it can reduce chronic stable angina.

Tasly Pharmaceuticals Inc, is nearing the end of what has been a long road of testing to get approval from the US Food and Drug Administration (FDA) for its T89 drug, a multiple components traditional Chinese medicine (TCM).

Also known as Dantonic, the drug has been shown to have few adverse side effects and to effectively reduce the frequency of chronic stable angina — a form of chest pain that most often occurs with activity or emotional stress and causes the heart to need more oxygen.

In March 2018, the US subsidiary of China-based Tasly Group, announced the test results of its three-herb composition drug T89 in a Phase 3 global clinical trial.

The results indicated that T89's pharcological functionalities in improving blood circulation, booting energy metabolism level, and reducing blood thickness made the drug to express clinically significant benefits.

The findings are also significant in the general public health because an increasing number of patients, particularly those with advanced chronic coronary artery disease, experience frequent chest pain and therefore, impaired their daily activities and reduced quality of life.

"It could create a new pattern of pharmaceutical R&D and industrialization of a class of new drug led by T89, a multi-component innovative Chinses Medicine (iCM), and gradually establish the regulatory requirements of international iCM technology and standards," said Henry Sun, president and CEO of Tasly's US subsidiary, Tasly Pharmaceuticals, Inc.

In September 2018, Tasly US and the US-based pharma Arbor Pharmaceuticals, Inc announced cooperation in future clinical development and regulatory approval required by the FDA for T89, and co-marketing the drug in the US.

T89 is sold as a prescription drug in China, Vietnam, Pakistan, South Korea, India, and the United Arab Emirates, and reportedly is taken by about 10 million people every year.

Before being put into production and commercialization in the US, other steps must be taken for the drug: communications and negotiations with key opinion leaders, insurance companies, political lobbyists and other stakeholders, and choosing a right name for the product and branding it in a targeted market.

"This cooperation is a symbol of T89, the innovative Chinese Medicine (iCM) finally moving from clinical research to global marketing. T89 will bring the pharmaceutical industry to be more interested in iCM worldwide," said Shirley Chai, head of administration at Tasly Pharmaceuticals, Inc.

Because T89 is different from common chemical or biological drugs, launching T89 on the market in the future could clarify functions of multi-herbal medicines in training physicians, said Chai.

Based on the acceptance of Tasly's data from previous T89 trials, Arbor will contribute up to $23 million for clinical research and regulatory approval and obtain the exclusive right of selling T89 in the US.

Tasly will receive another payment up to $50 million and a share of the gross profits up to 50 percent after the drug is on the market.

This extensive strategic cooperation significantly made Tasly benefit from transformation in marketing of T98 and the more intensive conduction of research in this field.

To Sun, the greatest challenge in the future extensive strategic cooperation with Arbor would be "to make innovative Chinese Medicine (iCM) rank among the world's medicines along with chemical drugs and biological drugs, forming the triple pillars of modern medicine".

Tasly Pharmaceutical Group Co Ltd is based in the city of Tianjin and was established in 1994, to produce traditional Chinese medicine.

In February 2017, it announced plans to form a joint venture with American multi-level marketing company Herbalife.

Tasly US seeks to treat serious diseases with chemical-free products.

Tasly Pharmaceuticals' office building in Rockville, Maryland.

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>
> *Henry Sun*
> President and CEO of Tasly Pharmaceuticals

10 MILLION

Number of people worldwide who takes T89 every year

"T89 can be a reference experience for the commercialization of innovative Chinese Medicine (iCM), ultimately more iCM will be gradually accepted globally to serve the purpose of filling the therapeutically gaps and lead to new treatments for patients," said Sun.

He said that he expects the future success of T89 will bring innovation to TCM because it will resolve many regulatory issues by working with the FDA and be significant in improving the models and development of new drugs in China.

"Tasly will continue to explore the unique theoretical framework and empirical methodologies of iCM, along with advanced technologies to fulfill unmet clinical needs and make sure iCM can stand rigorous assessment in the modern clinical setting worldwide," said Sun.

T89 is the world's first compound Chinese herbal drug to have passed US FDA regulated multi-center phase 3 clinical trials.

By conducting more clinical research and cooperating with multiple companies and institutions, Tasly is seeking to put T89 on a path to open the door for the globalization of modernized iCM.

Tasly's development of T89 presents significant scientific evidence of the long-term practice of Traditional Chinese Medicine, which can heal the body with pure, natural herbs as effectively as chemical and synthetic drug compounds.

According to Tasly, at least 34 countries' national health regulatory authorities have approved its herbal based pharmaceutical products. ❑

TASLY PHARMACEUTICALS
Rockville, Maryland