# Announcement of Chengdu Kanghong Pharmaceutical Group Co., Ltd. on stopping the global multi-center clinical trial of Conbercept ophthalmic injection

Stock code: 002773 Stock abbreviation: Kanghong Pharmaceutical Announcement Number: 2021-023

The company and all members of the board of directors guarantee that the information disclosed is true, accurate and complete, and there are no false records, misleading statements or major omissions.

Chengdu Kanghong Biotechnology Co., Ltd., a wholly-owned subsidiary of Chengdu Kanghong Pharmaceutical Group Co., Ltd., launched in May 2018 on "a multi-center, double-blind, randomized, dose range trial to evaluate the treatment of Conbercept ophthalmic injection "Efficacy and safety in patients with neovascular age-related macular degeneration" clinical trial project (hereinafter referred to as "PANDA trial"). On September 25, 2020, the PANDA trial completed the 36th week primary endpoint visit for all subjects .

Since the beginning of 2020, unfavorable factors such as global public health emergencies and changes in the external environment have caused great difficulties and impacts on clinical research. Although the company has added a lot of manpower and financial resources to this end, it retains and protects the tested patients to reduce adverse effects, and strives to make the PANDA trial progress on time. However, the company cannot know the benefits of each group of subjects before unblinding and the



Mylan v. Regeneron, IPR2021-00880 U.S. Pat. 9,669,069, Exhibit 2112 4/13/2021

actual impact is more difficult to assess. The phased analysis that has now been unblinded shows that the impact of global public health events on this study has greatly exceeded the company's expectations. Factors including various control measures introduced by various countries have caused a large number of subjects to fall off, lose follow- up, and exceed the window, which is fully in line with PANDA trial dosing regimen cases have gradually decreased to less than 40% of the enrolled cases. In particular, the obstacles of international shipping and travel restrictions have made it extremely difficult to control the quality of experimental drugs that need to be distributed throughout the cold chain, and to go to the hospital for onsite clinical inspections and inspections. In addition, as many as 68 trial centers, more than half of the subjects' vision changes from baseline after injection are equal to or even lower than zero, which is very different from the previous clinical research of the trial drug and the large amount of real world use experience.

On April 9, 2021, the PANDA Experimental Science Steering Committee held a special meeting to conduct a mid-term review based on the data generated in the above environment. The committee believes that during the global public health event, a large number of subjects deviated from the prescribed dosing regimen of the trial; Conbercept showed good safety in the trial; in the subgroup analysis of Asian population, 1mg Kang The curative effect of the dose group of praxicept injected once every three months may be better than the overall performance. At the same time, we are deeply concerned about the possible impact on the supply of trial drugs and the cold chain, and it is recommended to carry out follow-up investigations and studies. However, the committee believes that the PANDA trial has failed to achieve the expected goals and recommends that the company stop the PANDA trial. The company believes that clinical trials are a complex system engineering, and the results of the trials are affected by many factors. Especially for the impact of sudden global public health events on clinical trials, there is currently no universal assessment and correction method. Its significant impact on the PANDA test cannot be fully evaluated under current cognitive conditions. However, considering many risks such as the complex international situation in which global public health events are still spreading and the uncertain external environment, continuing to advance the PANDA trial has been unable to obtain results with registration value. In particular, considering the clinical benefits of the tested patients and the protection of the interests of investors, the company decided to respect the professional evaluation and recommendations of the Scientific Steering Committee and stop the global PANDA trial after careful research.

The analysis and investigation of the PANDA trial is still in progress. The company will carefully analyze the trial data and the reasons behind the clues, and continue to communicate with the regulatory agencies of various countries. The company will prudently advance the follow-up related work after ensuring that there are corresponding effective measures.

The company will perform its information disclosure obligations in a timely manner regarding subsequent progress. Investors are kindly requested to make cautious decisions and pay attention to investment risks.

Special announcement.

The Board of Directors of Chengdu Kanghong Pharmaceutical Group Co., Ltd.

April 9, 2021

Stock code: 002773 Stock abbreviation: Kanghong Pharmaceutical Announcement number: 2021-022

Chengdu Kanghong Pharmaceutical Group Co., Ltd.

Announcement on the resolutions of the eighth meeting of the seventh board of directors

The company and all members of the board of directors guarantee that the information disclosed is true, accurate and complete, and there are no false records, misleading statements or major omissions.

The eighth meeting of the seventh board of directors of Chengdu Kanghong Pharmaceutical Group Co., Ltd. (hereinafter referred to as the "Company") was held on April 9, 2021 in the company's conference room. The notice of the meeting was temporarily issued to all directors by Mr. Ke Zunhong, the chairman of the board. This time the board of directors should have nine directors, and actually nine directors (including: directors Mr. Wang Lin, Mr. Yin Jinqun, independent directors Mr. Zhang Qiang, Mr. Qu Sancai, and Mr. Zhang Yu participated by communication). The meeting was chaired by the chairman of the board, Mr. Ke Zunhong . The company's supervisors, secretary of the board of directors and some senior management personnel attended the meeting as non-voting delegates, which complied with the relevant provisions of the "Company Law" and the "Articles of Association".

The meeting passed the following resolutions by means of written ballot and communication:

1. The meeting reviewed and passed the "Proposal on Stopping the Global Multi-center Clinical Trial of Conbercept Eye Injection" with 9 votes in favor, 0 votes against, and 0 abstentions.

The PANDA Trial Scientific Steering Committee believes that during the global public health event, a large number of subjects deviated from the trial's prescribed dosing regimen; Conbercept demonstrated good safety in the trial; subgroup analysis in Asian populations Among them, the efficacy of the 1 mg conbercept injection once every three months in the dose group may be better than the overall performance. At the same time, we are deeply concerned about the possible impact on the supply of trial drugs and the cold chain, and it is recommended to carry out follow-up investigations and studies. However, the committee believes that the PANDA trial has failed to achieve the expected goals and recommends that the company stop the PANDA trial.

The company believes that clinical trials are a complex system engineering, and the results of the trials are affected by many factors. Especially for the impact of sudden global public health events on clinical trials, there is currently no universal assessment and correction method. Its significant impact on the PANDA test cannot be fully evaluated under current cognitive conditions. However, considering many risks such as the complex international situation in which global public health events are still spreading and the uncertain external environment, continuing to advance the PANDA trial has been unable to obtain results with registration value. In particular, considering the clinical benefits of the tested patients and the protection of the interests of investors, the company decided to respect the professional evaluation and recommendations of the Scientific Steering Committee and stop the global PANDA trial after careful research.

# **CKET LARM** Find authenticated court documents without watermarks at <u>docketalarm.com</u>.

# DOCKET A L A R M



# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## **Real-Time Litigation Alerts**



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

### **Advanced Docket Research**



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## **Analytics At Your Fingertips**



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

#### API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

#### LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

#### FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

#### E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.