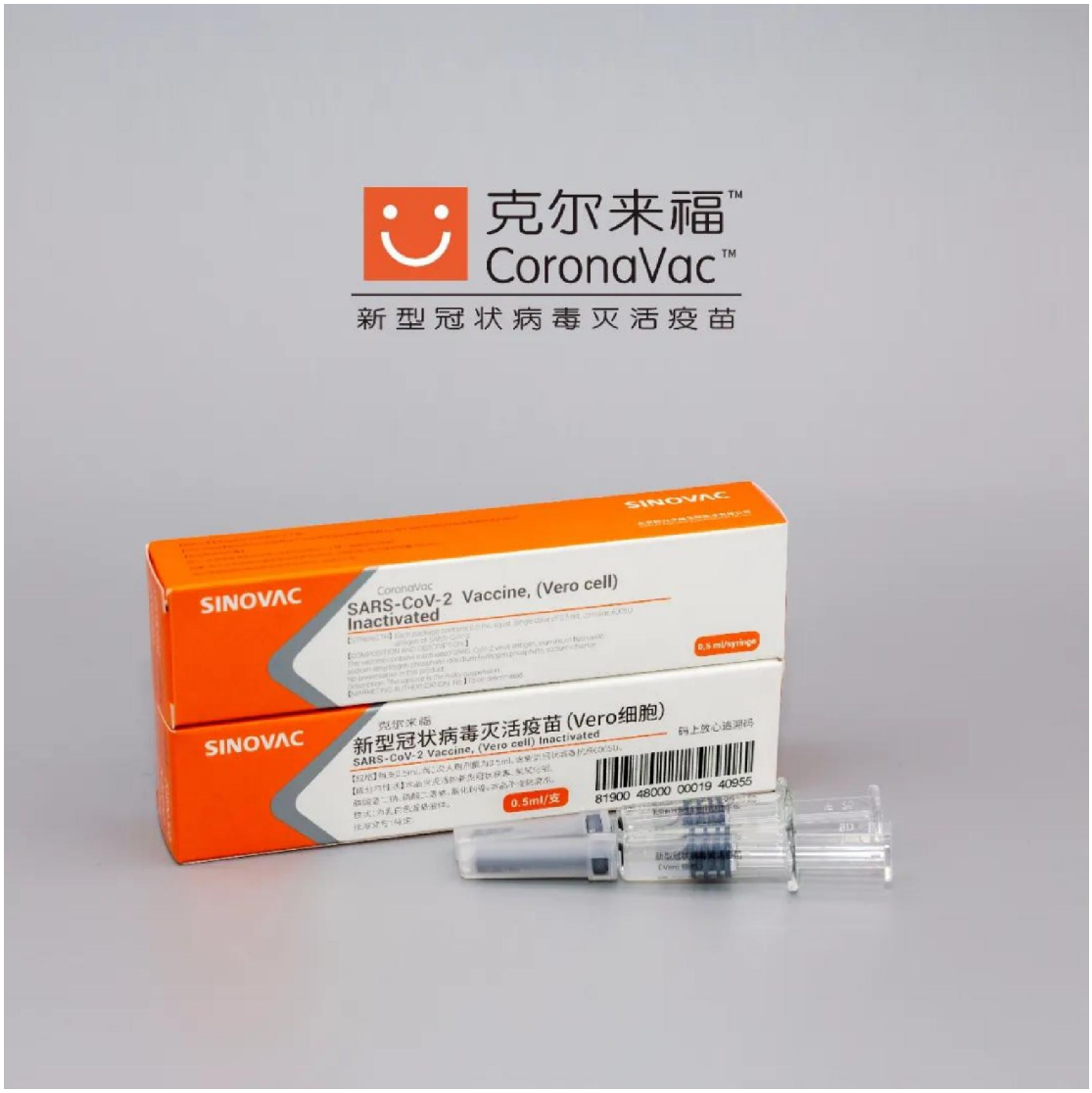
科兴中维新型冠状病毒灭活疫苗 I/II期临床研究揭盲，初步结果显示该疫苗具有良好的安全性和免疫原性

近日，科兴控股生物技术有限公司（“科兴”）旗下北京科兴中维生物技术有限公司（“科兴中维”） 研制的新型冠状病毒灭活疫苗克尔来福™（“新冠疫苗”） Ⅰ/Ⅱ期临床研究（0,14 程序）盲态审核暨揭盲会在京举行。初步结果显示该疫苗具有良好的安全性和免疫原性。

这项随机、双盲、安慰剂对照的Ⅰ/Ⅱ期临床研究负责机构为江苏省疾病预防控制中心（江苏省公共卫生研究院），研究的目的是评价不同剂量的新型冠状病毒灭活疫苗按照 0，14 程序或 0，28 程序接种健康受试者的安全性、耐受性和免疫原性，确定疫苗的免疫程序和免疫剂量。截至目前，I/Ⅱ期临床研究受试者共 743 人已全部完成接种，现有数据显示疫苗具有良好的安全性与免疫原性。

此次揭盲的 0，14 程序Ⅰ/Ⅱ期安全性数据显示，疫苗不良反应以 1 级为主，主要表现为接种部位轻度疼痛，个别受试者出现乏力及低热等，无严重不良反应报告。Ⅱ期临床研究 0,14 天程序免疫原性结果显示，全程免疫 14 天后中和抗体阳转率均超过 90%，表明疫苗具有良好的免疫原性。相关研究结果将尽快以学术论文形式与全球分享。



上述结果支持科兴中维的新冠疫苗开展 III 期临床研究。公司计划于近日向国家药品监督管理局提交Ⅱ期临床研究报告和Ⅲ期临床研究方案，争取尽快启动Ⅲ期临床研究和疫苗应用，以期尽早发挥疫苗作为全球公共产品在疾病防控中的作用，为中国乃至全球应对新冠疫情贡献力量，造福人类命运共同体。

科兴中维于 2020 年 1 月初开始关注新冠疫情并着手疫苗研制的各项前期准备工作，随后于 1 月 28 日正式启动名为“克冠行动”的新型冠状病毒疫苗研制项目，按照国务院应对新型冠状病毒肺炎疫情联防联控机制科研攻关组疫苗研发专班部署，在国家疫苗研发专班、科技部、国家卫健委、国家药监局、工信部等有关部门及北京市政府的大力支持下，联合浙江省疾控中心、中国医学科学院医学实验动物研究所、中国疾控中心等单位推进疫苗研制工作，于 2020 年 4 月 13 日获批临床，并随后于 4 月 16 日在江苏启动成人组（18 至 59 岁）Ⅰ/Ⅱ期临床研究。该项目得到科技部“国家重点研发计划”、北京市科委“市科技计划”项目及大兴区生产条件支持。

关于科兴

科兴控股生物技术有限公司（“科兴”）是一家总部位于北京的生物高新技术企业，目前在纳斯达克全球精选市场（NasdaqGS：SVA）上市。公司通过全资子公司科兴控股（香港）有限公司（“香港科兴”）拥有北京科兴生物制品有限公司（“北京科兴”）、科兴（大连）疫苗技术有限公司（“大连科兴”）、北京科兴中维生物技术有限公司（“科兴中维”）和北京科兴中益生物医药有限公司（“科兴中益”）四家企业。科兴以“为人类消除疾病提供疫苗”为使命，致力于人用疫苗及其相关产品的研究、开发、生产和销售，为疾病预防控制提供服务。

公司上市产品主要包括：预防用生物制品 1 类新药——肠道病毒 71 型灭活疫苗（益尔来福®），中国第一支通过 WHO 预认证的甲肝灭活疫苗（孩尔来福®），流感病毒裂解疫苗（安尔来福®），水痘减毒活疫苗，甲型乙型肝炎联合疫苗（倍尔来福®）以及腮腺炎减毒活疫苗等。此外公司还曾先后研制出全球第一支 SARS 冠状病毒灭活疫苗（完成 I 期临床）、中国第一支大流行流感（H5N1）疫苗（盼尔来福®）以及全球第一支甲型 H1N1 流感疫苗（盼尔来福.1®），为中国乃至全球疾病预防控制做出了贡献。

科兴正在开发一系列新产品，包括 Sabin 株脊髓灰质炎灭活疫苗、23 价肺炎球菌多糖疫苗、四价流感裂解疫苗、新型冠状病毒灭活疫苗及多个联合疫苗等。

科兴主要在中国销售疫苗，同时也在国际市场寻找增长机会。公司的产品在中国以外的 30 多个国家注册。

科兴中维是香港科兴于 2009 年独资组建的生物高新技术企业，注册资本 960 万美元。科兴中维专业从事人用疫苗及其相关产品的研究开发与技术服务，为重大传染病防控提供技术支撑。公司依托集团多年来在疫苗研发和产业化上的优势，逐步形成了以企业为研发主体、产学研相结合的研发模式，构建了多个技术平台，各平台的专业技术优势互补，交叉渗透，推动公司研发稳步、高效地前进。

科兴中维承担了国家重大新药创制专项 2 项、北京市科技计划 2 项，已取得中国发明专利授权 12 项。公司研制的 23 价肺炎多糖疫苗已成功完成临床研究并在北京科兴实现产业化。目前公司正在进行新型冠状病毒疫苗及多个联合疫苗品种开发和产业化建设。

Sinovac Announces Positive Preliminary Results of Phase I/II Clinical Trials for Inactivated Vaccine Candidate Against COVID-19

Beijing-June 13, 2020 — Sinovac Biotech Ltd. ("Sinovac" or the " Company")(Nasdaq: SVA), a leading provider of biopharmaceutical products in China, today announced positive preliminary results of phase I/II clinical trial for the Company's COVID-19 vaccine candidate, named CoronaVac, which showed favorable immunogenicity and safety profiles.

The phase I/II clinical trials were designed as randomized, double-blind and placebo-controlled studies. In total, 743 healthy volunteers, aged from 18 to 59 years old, enrolled in the trials. Of those, 143 volunteers are in phase I and 600 volunteers are in phase II. There have been no severe adverse event reported in either the phase I or phase II trials. The phase II clinical trial results show that the vaccine induces neutralizing antibodies 14 days after the vaccination with a 0,14 day schedule. The neutralizing antibody seroconversion rate is above 90%, which concludes the vaccine candidate can induce positive immune response.

The Company expects to submit a phase II clinical study report and a phase III clinical study protocol to China's National Medical Products Administration (NMPA) in the near future and commence application of phase III clinical trials outside of China. As previously announced on June 11, 2020, Sinovac is collaborating with Instituto Butantan in Brazil to prepare and conduct a phase III clinical study. The Company expects to share the full data on our clinical trials with the public through academic publications.

Mr. Weidong Yin, Chairman, President and CEO of Sinovac, commented, "Our phase I/II study shows CoronaVac is safe and can induce immune response. Concluding our phase I/II clinical studies with these encouraging results is another significant milestone we have achieved in the fight against COVID-19. We have started to invest in building a manufacturing facility so that we can maximize the number of doses available to protect people from COVID-19. Like with our other vaccines, we are committed to developing CoronaVac for global use as part of our mission of supplying vaccines to eliminate human diseases."

As announced previously, Sinovac's development of a vaccine against COVID-19 began in January 2020 in partnership with leading academic research institutes in China. The Company received approval from China's NMPA on April 13 to conduct phase I/II studies on its inactivated vaccine candidate against COVID-19 in China.

About Sinovac

Sinovac Biotech Ltd. is a China-based biopharmaceutical company that focuses on the research, development, manufacturing and commercialization of vaccines that protect against human infectious diseases.

Sinovac's product portfolio includes vaccines against enterovirus71 (EV71), hepatitis A and B, seasonal influenza, H5N1 pandemic influenza (avian flu), H1N1 influenza (swine flu),

varicella vaccine and mumps. Healive, the hepatitis A vaccine manufactured by the Company, has passed the assessment under WHO prequalification procedures in 2017. The EV71 vaccine, an innovative vaccine developed by Sinovac against hand foot and mouth disease caused by EV71, was commercialized in China in 2016. In 2009, Sinovac was the first company worldwide to receive approval for its H1N1 influenza vaccine, which it has supplied to the Chinese Government's vaccination campaign and stockpiling program. The Company is also the only supplier of the H5N1 pandemic influenza vaccine to the government stockpiling program.

The Company is developing a number of new products including a Sabin-strain inactivated polio vaccine, pneumococcal polysaccharides vaccine, a quadrivalent influenza vaccine and a SARS-CoV-2 (commonly referred to as COVID-19) vaccine. Sinovac primarily sells its vaccines in China, while also exploring growth opportunities in international markets.

The Company is registering its products in over 30 countries outside of China. For more information please see the Company's website at www.sinovac.com.

Safe Harbor Statement

This announcement may include certain statements that are not descriptions of historical facts, but are forward-looking statements. These statements are made under the "safe harbor" provisions of the U.S. Private Securities Litigation Reform Act of 1995. These forward-looking statements can be identified by terminology such as "will," "expects," "anticipates," "future," "intends," "plans," "believes," "estimates" and similar statements. Forward-looking statements involve risks, uncertainties and other factors that could cause actual results to differ materially from those contained in any such statements. In particular, the outcome of any litigation is uncertain, and the Company cannot predict the potential results of the litigation it filed or that could be filed against it by others. Additionally, the triggering of a shareholder rights plan is nearly unprecedented, and the Company cannot predict the impact on the Company or its stock price should its rights plan have been triggered.