KIRA PHARMACEUTICALS ANNOUNCES FIRST PARTICIPANT DOSED IN PHASE 1 CLINICAL TRIAL FOR P014, A BIFUNCTIONAL BIOLOGIC MEDICINE

CAMBRIDGE, MA and SUZHOU, JIANGSU (February 2, 2021) – Kira Pharmaceuticals, a global biotechnology company pioneering a new generation of complement-targeted therapies to treat immune-mediated diseases, announced today that the first healthy volunteer has been successfully dosed in a first-in-human Phase 1 clinical trial for its lead investigational therapy P014. This randomized, double blind, placebo-controlled study will evaluate the safety, tolerability, pharmacokinetics (PK) and pharmacodynamics (PD) of escalating single and multiple doses of P014. These data will guide dose selection as well as provide essential supportive information for the design of trials for patients living with complement-mediated diseases.

P014 is a bi-functional, first-in-class biologic with a unique mechanism of action. Designed to block two separate rate-limiting steps in the complement activation cascade critical for disease development, P014 provides a powerful and selective approach to inhibit the complement system. P014 has also been engineered to have an extended half-life and potency, with the opportunity for subcutaneous administration at home by the patient.

“Today marks a pivotal milestone for Kira Pharmaceuticals as we transition into a clinical stage company,” said Frederick Beddingfield, MD, PhD, CEO at Kira Pharmaceuticals. “The data generated from this Phase 1 study will provide important information about P014’s safety and tolerability profile as well as biomarkers and ex-vivo surrogate measurements of drug efficacy data that will inform our understanding of how the drug is impacting target biology. These data will be invaluable as we consider P014 for treatment of a range of complement-mediated diseases.”

Founded by some of the foremost experts in complement biology, Kira Pharmaceuticals has designed its LOGIC drug discovery platform (Lead identification, Optimization and

attribute Generation, In vivo Confirmation) to overcome the inherent challenges of complement drug discovery. The complement system is a key driver and amplifier of inflammation and tissue damage in many human diseases but is complex and has been historically difficult to target. Kira's LOGIC platform improves target selection and validation and the design and development of therapies with superior efficacy and longer lasting inhibition.

About Kira Pharmaceuticals

Kira Pharmaceuticals is a biotechnology company developing complement-targeted therapies to treat immune-mediated diseases. Enabled by its LOGIC drug discovery platform, the company is committed to advancing first-in-class and best-in-class therapies to transform the lives of patients with complement-driven diseases. With offices in Cambridge, Massachusetts and an R&D center in Suzhou, China, Kira Pharmaceuticals is committed to establishing a global footprint and advancing life-changing therapies to patients around the world.

For more information, please visit www.kirapharma.com.

科越医药宣布双功能生物药 P014 在一期临床第一个健康志愿者成功给药

美国马萨诸塞州剑桥和中国江苏省苏州（2021 年二月二日）科越医药，一家致力于研发新一代补体靶向药物来治疗免疫介导疾病的全球生物技术公司，今天宣布第一名受试者已在人类第 1 阶段的临床试验中接受了 P014 的研究治疗。这项随机，双盲，安慰剂对照的临床研究将评估逐步增加单剂量和多次剂量 P014 的安全性，耐受性，药代动力学（PK）和药效学（PD）。这些数据将为后续临床实验设计和剂量选择提供重要的信息。

P014 是一款具有独特的作用机制，旨在同时抑制上游和下游的补体靶点的全球首创双功能生物药。P014 通过调节对疾病发展至关重要的补体活化级联中的两个单独的限速步骤，以此为补体抑制提供一种强有力且可能更加有选择性的精准治疗方法。P014 还设计有更长的半衰期和效力，以及皮下注射的给药方式，从而让患者有可能在家中实现自我给药。

“今天我们过渡到临床阶段标志着科越医药的重要里程碑，” 科越医药首席执行官贝丁菲尔德博士（Frederick Beddingfield, MD, PhD）说。 “从第一阶段研究中获得的数据将提供有关 P014 的安全性和耐受性的宝贵信息，以及重要的生物标志物和体外实验数据。这些数据将对我们理解 P014 的靶向作用机理和评估其治疗一系列补体介导疾病的潜力有重要价值”

科越医药由补体生物领域的几名顶级专家联合创立，公司已设计出自己的 LOGIC 药物发现平台（先导物识别、优化和属体生成、体内确认），用于克服补体药物开发过程中的各种挑战。在人类的许多疾病中，补体系统是炎症和组织损伤的一个关键驱动因素和放大器，但是，补体系统本身却很复杂，而且一向难以被靶向攻破。科越的 LOGIC 平台具有卓越的功效和更持久的抑制作用，从而改善了靶标的选择和验证以及疗法的设计和开发。

关于科越医药

科越医药是一家临床阶段生物技术公司，致力于开发针对补体介导疾病的免疫疗法。公司凭借自己的 LOGIC 药物发现平台，致力于推进首创疗法及同类最佳疗法，以此彻底改善补体驱动型疾病患者的生活。科越医药在美国马萨诸塞州剑桥市设有办事处，

并且在中国苏州和上海设有研发中心，以此致力于建立全球足迹，在全球推广能够改善患者生活的疗法。
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