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KAYOTHERA

KayoThera, Inc. Nominates First-in-Class, Oral Inhibitor of the Retinoid Pathway in Genetically Defined Oncology Indications as a Development Candidate

Unique safety profile positions KAYO-1609 as the first retinoid pathway inhibitor to enter Investigational New Drug (IND)-enabling studies

Company expects to file IND application with the U.S. Food & Drug Administration (FDA) by the end of 2024

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SEATTLE--(BUSINESS WIRE)--KayoThera, Inc. ("KayoThera"), an early-stage therapeutics company developing first-in-class, oral, small molecule inhibitors of the retinoid pathway, today announces that it has selected KAYO-1609 as its first drug development candidate. KAYO-1609 has demonstrated a differentiated safety profile across a variety of species with ideal drug-like properties. Preclinical studies in multiple models of cancer support the potential of KAYO-1609 in the treatment of genetically-defined cancers based on the molecule's mechanism of action. With the nomination of KAYO-1609 as the development candidate, KayoThera is well-positioned for IND-enabling studies, clinical planning, and partnering activities.

Retinoid signaling is known to both inhibit helper CD4 T cells that mediate tumor cell destruction, and cause maturation of regulatory T cells that dampen the immune system's response to cancer. Retinoid signaling further forces differentiation of monocytes into tumor-associated macrophages that can promote tumor growth and metastasis. Collectively, these activities reduce the immune system's ability to detect and eliminate malignant cells. Inhibition of the amplified retinoid signaling found in unique tumor types could potentially restore or enhance the anti-tumor immune activity, enabling a unique approach to cancer immunotherapy in patients with few therapeutic options.

"Despite its known roles in blunting the body's anti-tumor immune defense, previous efforts to develop retinoid signaling antagonists have failed due to unacceptable toxicity in preclinical development," said Mark Esposito, Ph.D., vice president of R&D, and co-founder of KayoThera. "The discoveries on which KayoThera was founded enable the development of orally available, small molecule inhibitors of this important signaling pathway that have very favorable safety profiles. The preclinical safety and efficacy data generated to date in studies of KAYO-1609 are exceptionally promising, and we intend to move as rapidly as possible toward initiating human clinical trials of this novel molecule in genetically-defined cancers."

KAYO-1609 has demonstrated excellent safety and tolerability, with no dose-limiting toxicities observed in studies across five different species. Preclinical studies also have identified a dose-responsive biomarker for target engagement that is expected to facilitate the IND-enabling studies. KayoThera expects to initiate IND-enabling studies of KAYO-1609 in the

third quarter of 2023 and anticipates filing an IND application with the FDA by the end of 2024. Following acceptance of the IND, the company plans to initiate a human clinical trial of KAYO-1609 in patients with genetically-defined cancers that are most likely to demonstrate clinical benefit based on the mechanism of action of KAYO-1609.

"The selection of KAYO-1609 as our lead oncology development candidate is the most recent demonstration of the significant progress, we have made over the past few months to position KayoThera for success," said Kendall Mohler, Ph.D., chief development officer and board member of KayoThera. "In May we announced the expansion of our pipeline into the cardiometabolic disease space, with a focus on Type 2 diabetes and in July we strengthened our financial position with multiple grants and the expansion of our Series A financing. Taken together, we now have the financial resources to advance exciting and differentiated candidates in cancer and Type 2 diabetes, diseases with significant unmet clinical need that are associated with significant mortality and morbidity. We are committed to developing retinoid signaling pathway inhibitors as novel therapeutic modalities that can improve outcomes for patients living with these and other serious diseases."

About KayoThera Inc

KayoThera, Inc. is an early-stage therapeutics company focused on the development of first-in-class, oral, small molecule inhibitors of the retinoid pathway. This pathway plays a critical role in a variety of serious diseases, including cardiometabolic diseases and cancer. KayoThera is developing therapies to treat diabetes and late-stage and metastatic cancers including breast, lung, pancreatic, colorectal, brain, and kidney cancers. The company was founded based on discoveries from Dr. Mark Esposito's post-doctoral research at Princeton University and professor Yibin Kang, PhD. For more information, visit www.kayothera.com.

About Accelerator Life Science Partners

Accelerator Life Science Partners (ALSP) is an early-stage life science accelerator and investment firm that creates and builds next generation biotechnology companies centered on innovative science. ALSP catalyzes the development and commercialization of breakthrough biotechnology innovations by providing a holistic toolkit and leveraging its network and entrepreneurial expertise to accelerate the establishment and operation of early-stage biotechnology companies. ALSP's portfolio companies are backed by renowned life science investors and are comprised of industry-leading, transformative companies, including KayoThera, Inc., Lodo Therapeutics (acquired by Zymergen, now Ginkgo BioWorks), Petra Pharma (acquired by a global pharmaceutical company), Proniras Corporation, and Rodeo Therapeutics (acquired by Amgen Inc.). For more information, please visit www.acceleratorlsp.com.

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