PRESS RELEASE 15 January 2019
For Immediate Release

Successful completion of Pre-IND meeting with FDA

Oslo, Norway and New Brunswick, NJ (15 January 2019) – Kaydence Pharma AS, a development stage pharmaceutical company, is pleased to report that it has successfully completed a pre-IND (Investigational New Drug) meeting with the US Food and Drug Administration (FDA). At the meeting, the FDA addressed questions regarding key components of the planned IND application and the clinical/regulatory pathway for MQ7, Kaydence Pharma's novel drug candidate for the treatment of arterial stiffness in stable renal transplant recipients with subclinical vitamin K deficiency.

"As a result of this informative meeting, we reached agreement with the FDA on the non-clinical requirements for the IND for MQ7 supporting the planned first-in-human (FIH) study. We also achieved alignment on key components of the design for the FIH study, including the ability to conduct the study in the target patient population. In addition, the FDA provided input and guidance on our clinical and regulatory development pathway. Importantly, the FDA has agreed to meet with us following completion of the FIH study to continue discussions regarding the Phase 2 and Phase 3 development programs" said Dan Rosenbaum, CEO of Kaydence.

Currently, there are no FDA approved treatments for arterial stiffness, a condition that is highly prevalent in patients with chronic kidney disease/renal transplant. Arterial stiffness is associated with decreased renal allograft function and increased risk for cardiovascular morbidity and mortality in renal transplant recipients.

About MQ7
MQ7, a pharmaceutical formulation of the vitamin K2 subtype menaquinone 7, enables the activation of a potent, local inhibitor of vascular calcification, matrix Gla protein (MGP), thereby inhibiting arterial stiffness. A substantial proportion of patients with chronic kidney disease, including those with renal transplant, do not have sufficient levels of vitamin K (subclinical vitamin K insufficiency) to allow the activation of MGP such that vascular calcification can be inhibited. In general, inactive MGP is associated with reduced kidney function and increased risk for cardiovascular morbidity and mortality. Further, subclinical vitamin K insufficiency has been associated with reduced allograft function, graft failure, and all-cause mortality in renal transplant recipients.

About Kaydence Pharma AS
Kaydence Pharma AS is a pharmaceutical company focused on development of MQ-7 for conditions associated with arterial stiffness in patients with subclinical vitamin K deficiency.

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