October 10, 2023-

Notice of the Completion of Investigational New Drug Application for the treatment of Central Retinal Artery Occlusion (CRAO) in the United States

We are pleased to inform that we have successfully submitted the Investigational New Drug Application (IND) for our ongoing development of KUS121 for the treatment of Central Retinal Artery Occlusion (CRAO) to the United States regulatory authority, the Food and Drug Administration (FDA).

Moving forward, if we do not receive any notifications such as a clinical hold from the FDA within 30 days from the IND submission, we will be granted permission to commence the Phase II clinical trials. Our company will then proceed with the Phase II trials, with a primary focus on assessing the safety, effectiveness, and dosing of KUS121. These trials are planned to be conducted at multiple research facilities in the U.S., commencing in early 2024.

We are committed to expeditiously and efficiently progress through this trial with the support of the Japan Agency for Medical Research and Development (AMED) and utilizing grants from the "Promotion of Drug Discovery Support Projects - Pre-Designation Support for Orphan Drug Development" program.