

Qurient Announces U.S. FDA Clearance of IND Application for Q901, a Novel Cancer Therapy

Phase 1/2 clinical study in patients with advanced solid tumor expected to start in Q2/2022

Dortmund, Germany, and Seongnam-Si, Korea, February 9th, 2022 - Qurient Co. Ltd. (KRX: 115180), a clinical stage biotech company, announced that the U.S. Food and Drug Administration (FDA) has cleared its investigational new drug (IND) application for Q901, a small molecule oncology drug candidate targeting cyclin dependent kinase 7 (CDK7).

The company plans to enroll up to 70 patients with advanced solid tumors in a Phase 1/2 clinical study taking place in the United States. The goal of the study will be to determine the maximum tolerated dose, dose-limiting toxicities, and the recommended Phase 2 dose of Q901.

“IND clearance for Q901 is an important step forward in developing this novel drug candidate that may provide a new alternative treatment to patients with relapsed or refractory malignancies,” says Kiyeon Nam, CEO of Qurient. “We look forward to initiating the clinical study for Q901 and presenting additional nonclinical efficacy data of Q901 in various cancer models at an upcoming scientific meeting.”

Q901 is a highly selective CDK7 inhibitor that has been shown in *in vitro* studies to only inhibit CDK7 in the human kinome. CDK7 is a master regulator of cell cycle checkpoints and an essential component of the transcription machinery. Additional data from preclinical studies has demonstrated that selective inhibition of CDK7 specifically kills cancer cells with aberrant cell division cycle or transcriptional regulation. Nonclinical pharmacology studies of Q901 have demonstrated that the selective inhibition of CDK7 exerts tumor growth inhibition in a number of murine cell-derived and patient-derived xenograft models, including breast, ovarian, prostate, pancreatic, small-cell lung, and colorectal cancers.

Qurient licensed the CDK7 inhibitor program at lead stage from Lead Discovery Center (LDC) and the Max Planck Society and further optimized the program, completed the IND-enabling studies, and submitted the IND application.

“We are thrilled about the second CDK-selective inhibitor from the LDC pipeline to reach cancer patients. The nomination of Q901 for clinical development emphasizes the translational competence of LDC and represents an extremely important milestone,” adds Bert Klebl, CEO and CSO of the LDC. “Starting out with an early-stage and BMBF grant funded academic collaboration with two academic partners, and strongly supported by additional financing from the Max Planck Foundation, LDC has launched this journey to identify and generate mono-specific CDK7 inhibitors. After an initial animal proof-of-concept, the CDK7 assets were licensed to our strategic collaboration partner, Qurient. We respectfully appreciate our ongoing partnership with Qurient, who are now moving the second joint program, after Q702, forward to clinical trials. While licensing these projects and jointly starting the spin-off, QLi5, we have since built a sustainable and strong partnership with Qurient, with more to come, focusing on the translation of innovative biology and drug discovery programs from LDC’s academic network.”

“Qurient has proven to be the ideal partner for this project, and we are more than happy about the results of this strategic partnership,” says Jörn Erselius, Managing Director at Max Planck Innovation GmbH.

The CDK7 inhibitor project and other projects have been supported in part by private sponsors and charities, especially Max Planck Foundation, which supports many Max Planck research projects and researchers, including the most recent Nobel Laureates at Max Planck.

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About LDC

Lead Discovery Center GmbH was established in 2008 by the technology transfer organization Max Planck Innovation, as a novel approach to capitalize on the potential of excellent basic research for the discovery of new therapies for diseases with high medical need. The Lead Discovery Center takes on promising early-stage projects from academia and transforms them into innovative pharmaceutical leads and antibodies that reach initial proof-of-concept in animals. In close collaboration with high-profile partners from academia and industry, the Lead Discovery Center is building a strong and growing portfolio of small molecule leads with exceptional medical and commercial potential. The Lead Discovery Center sustains a long-term partnership with the Max Planck Society, KHAN-I GmbH & Co.KG and has formed alliances with Qurient, AstraZeneca, Apeiron, Bayer, Boehringer Ingelheim, Centessa, Merck KGaA, Daiichi Sankyo, Jemincare, Novo Nordisk e.g. In addition, LDC also works with leading translational drug discovery centers and with various investors to provide its assets for company creation. Further information at: www.lead-discovery.de.

About Qurient

Qurient is a clinical-stage biopharmaceutical company listed in Korea Exchange (KRX 115180). Qurient mainly focuses on development of novel therapeutics from discovery to human proof of concept stages through virtual R&D project management platform. Qurient currently has three programs in clinical development: Q301, a topical leukotriene inhibitor for atopic dermatitis, completed Phase 2b study; Telacebec (Q203), a first-in-class orally available cytochrome bc1 inhibitor for tuberculosis, completed Phase 2 study; and Q702, under Phase 1/2 study. A subsidiary of Qurient, QLi5 is developing immunoproteasome inhibitors targeting multiple Myeloma and diverse other indications. For more info, please visit www.qurient.com.

About Max Planck Innovation

Max Planck Innovation (MI) is responsible for the technology transfer of the Max Planck Society and, as such, the link between industry and basic research. With an interdisciplinary, team MI advises and supports scientists at Max Planck Institutes in evaluating their inventions, filing patents and founding companies. MI offers industry unique access to the innovations of the Max Planck Institutes. Thus, MI performs an important task: the transfer of basic research results into products that contribute to economic and social progress. Further information at: www.max-planck-innovation.com.