REGULATORY NEWS - 6th APRIL 2022

U.S. FDA Accepts for Priority Review New Drug Application of Futibatinib for Advanced Cholangiocarcinoma

“This is a very important step towards our goal to deliver futibatinib to patients awaiting potential new treatment options,” says Teruhiro Utsugi, Senior Managing Director at Taiho Pharmaceutical. “The Taiho group, working as one, will continue to do its utmost to deliver this agent to those in need.”

FDA Partial Clinical Hold for TakeAim Leukemia Study of Emavusertib (CA-4948)

"We are committed to ensuring the safety of patients in our studies and to working collaboratively with the FDA to develop therapies that meaningfully improve and extend patients' lives," said James Dentzer, Chief Executive Officer of Curis. "Given the clinical profile of emavusertib observed to date, we are hopeful that the study can be resumed soon, after appropriate review. We continue to be confident in the potential of emavusertib to address the high unmet need of patients with AML or MDS."

BLA application submitted to the US Food and Drug Administration for Mirvetuximab Soravtansine in Ovarian Cancer

“The BLA submission for mirvetuximab soravtansine is a key inflection point on our journey to delivering a safe and effective treatment option to patients with platinum-resistant ovarian cancer and moves us one step closer to transforming ImmunoGen into a fully-integrated oncology company,” said Mark Enyedy, ImmunoGen’s President and Chief Executive Officer. “Platinum-resistant ovarian cancer is an area with high unmet need, and we look forward to working with FDA to secure mirvetuximab soravtansine’s first approval and bringing this novel therapy to patients as quickly as possible.”