

July 9, 2024
Taiho Pharmaceutical Co., Ltd.
Arcus Biosciences, Inc.

Taiho Pharmaceutical Exercises Option for an Exclusive License to Quemliclustat in Japan and Certain Territories in Asia

Taiho Pharmaceutical Co., Ltd. (“Taiho”) and Arcus Biosciences, Inc. (NYSE:RCUS) today announced that Taiho exercised its option for quemliclustat (International Nonproprietary Name; development code: AB680), an investigational small molecule CD73 inhibitor, in Japan and certain other territories in Asia (excluding mainland China). This option exercise is based on an option and license agreement between Taiho and Arcus contracted in September 2017. This is the fourth option exercise by Taiho to an Arcus program.

In exchange for the exclusive license of quemliclustat, Taiho will make an option exercise payment, as well as additional payments upon achievement of clinical, regulatory and commercialization milestones, and, if any products from the program are approved, will pay royalties on net sales of such products.

Quemliclustat is an investigational small molecule CD73 inhibitor. In 2024, Arcus plans to initiate the global, registrational Phase 3 study PRISM-1, comparing quemliclustat plus chemotherapy to chemotherapy alone as a treatment for patients with previously untreated metastatic pancreatic ductal adenocarcinoma (mPDAC). Advancement to a Phase 3 study is based on overall survival results observed in the Phase 1b ARC-8 study that were presented earlier this year at the American Society of Clinical Oncology Gastrointestinal (ASCO GI) Cancers Symposium.

Through this collaboration, Taiho will further support the development and potential commercialization of quemliclustat and will operationalize the PRISM-1 study in Japan as part of its mission to deliver innovative drugs to patients and medical professionals.

About Quemliclustat

Quemliclustat is an investigational small molecule CD73 inhibitor. CD73 is the primary enzymatic producer of immunosuppressive adenosine in the tumor microenvironment, and high CD73 expression is associated with significantly poorer prognosis in several tumor types. Quemliclustat has been shown to block the production of adenosine. Once the immunosuppressive effects of adenosine are removed, activation of antitumor immune cells may be restored, resulting in cancer cell death.

In addition to the planned registrational Phase 3 study PRISM-1 by Arcus, quemliclustat is being co-developed by Arcus and Gilead Sciences in combination with other molecules within the companies’ portfolios with chemotherapy, including Phase 2 studies in lung and upper gastrointestinal cancers. Quemliclustat is an investigational medicine and is not approved for use globally.

About Taiho and Arcus Agreement

Based on the option and license agreement that Taiho and Arcus entered into in 2017, Taiho has obtained exclusive development and commercialization rights to a total of four programs in Japan and certain other territories in Asia (excluding mainland China): (1) quemliclustat, CD73 inhibitor program, announced today; (2) etrumadenant, a dual A2a/b adenosine receptor antagonist program in 2018; (3) zimberelimab, the anti-PD-1 program in 2019, and; (4) domvanalimab and AB308, both the anti-TIGIT program in 2021.

For other territories in the world, Gilead obtained the rights to commercialize in the U.S. and to co-promote with Arcus, and Gilead has exclusive rights to develop and commercialize outside the U.S.

About Taiho Pharmaceutical Co., Ltd. (Japan)

Taiho Pharmaceutical, a subsidiary of Otsuka Holdings Co., Ltd. (<https://www.otsuka.com/en/>), is an R&D-driven specialty pharma focusing on the fields of oncology and immune-related diseases. Its corporate philosophy takes the form of a pledge: “We strive to improve human health and contribute to a society enriched by smiles.” In the field of oncology, in particular, Taiho Pharmaceutical is known as a leading company in Japan for developing innovative medicines for the treatment of cancer, a reputation that is rapidly expanding through their extensive global R&D efforts. In areas other than oncology, as well, the company creates and markets quality products that effectively treat medical conditions and can help improve people’ quality of life. Always putting customers first, Taiho Pharmaceutical also aims to offer consumer healthcare products that support people’s efforts to lead fulfilling and rewarding lives. For more information about Taiho Pharmaceutical, please visit <https://www.taiho.co.jp/en>

About Arcus Biosciences

Arcus Biosciences is a clinical-stage, global biopharmaceutical company developing differentiated molecules and combination medicines for people with cancer. In partnership with industry collaborators, patients and physicians around the world, Arcus is expediting the development of first- and best-in-class medicines against well-characterized biological targets and pathways and studying novel, biology-driven combinations that have the potential to help people with cancer live longer. Founded in 2015, the company has expedited the development of multiple investigational medicines into clinical studies, including new combination approaches that target TIGIT, PD-1, the adenosine axis (CD73 and dual A2a/A2b receptor), HIF-2a, CD39 and AXL. For more information about Arcus Biosciences’ clinical and pre-clinical programs, please visit www.arcusbio.com.

Forward-Looking Statements

This press release contains forward-looking statements. All statements regarding events or results to occur in the future contained herein, including, but not limited to, Arcus’s receipt of milestones or royalties, the planning and initiation of additional clinical development activities, and realization of any potential benefits from this transaction, are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. All forward-looking statements involve known and unknown risks and uncertainties and other important factors that may cause our actual results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to: difficulties associated with the management of the collaboration activities or expanded clinical programs; data from ARC-8 may not be replicated in future studies evaluating the same investigational molecules or regimen, including PRISM-1; the unexpected emergence of adverse events or other undesirable side effects; the inherent uncertainty associated with the COVID-19 pandemic, including the duration and/or severity of the pandemic and actions by government authorities to contain or slow the spread of the virus; the inherent uncertainty associated with pharmaceutical product development and clinical trials; delays in Arcus’s clinical trials due to difficulties or delays in the regulatory process, enrolling subjects or manufacturing or supplying product for such clinical trials; and changes in the competitive landscape for Arcus’s programs. Risks and uncertainties facing Arcus are described more fully in its quarterly report on Form 10-Q for the quarter ended March 31, 2024, filed on May 8, 2024, with the SEC. You are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date of this press release. Arcus disclaims any obligation or undertaking to update, supplement or revise any forward-looking statements contained in this press release.

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