



NEWS RELEASE

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

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TOKYO & HAYWARD, Calif.--(BUSINESS WIRE)-- Taiho Pharmaceutical Co., Ltd. ("Taiho") and Arcus Biosciences, Inc. (NYSE:RCUS, "Arcus") announced that Taiho exercised its option to develop and, if approved, commercialize casdatifan (International Nonproprietary Name; development code: AB521), an investigational small molecule HIF (Hypoxia Inducible Factor)-2 α inhibitor, in Japan and certain other territories in Asia (excluding mainland China). This option exercise is based on a 2017 option and license agreement between Taiho and Arcus. This is the fifth option exercise by Taiho to an Arcus program.

In exchange for the exclusive license to casdatifan, 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.

Casdatifan is an investigational small molecule compound developed by Arcus. Arcus is currently conducting an ongoing global, registrational Phase 3 study, PEAK-1,* comparing the combination therapy of casdatifan and a VEGFR-targeted tyrosine kinase inhibitor (TKI) to monotherapy using a VEGFR-targeted TKI alone in patients with clear cell renal cell carcinoma (ccRCC). Japan is also expected to participate in the study starting in the first half of 2026.

*PEAK-1: A Randomized, Placebo-Controlled, Double-Blind, Multicenter Phase 3 Trial of Casdatifan and Cabozantinib Versus Placebo and Cabozantinib in Patients with Advanced Clear Cell Renal Cell Carcinoma

Through this collaboration, Taiho and Arcus are committed to delivering casdatifan as a potentially innovative new medicine to patients and healthcare professionals as swiftly as possible.

About Casdatifan (AB521)

Casdatifan is a small-molecule inhibitor of HIF-2 α , a master switch that turns on hundreds of genes in response to low oxygen levels; when oxygen levels return to normal, HIF-2 α is turned off. In a majority of people with the most common form of kidney cancer (clear cell renal cell carcinoma), this shut-off mechanism is deficient and HIF-2 α remains activated even in the presence of oxygen, causing normal kidney cells to become cancerous. Casdatifan is designed to provide deeper and more durable inhibition of the HIF-2 α pathway.

About clear cell renal cell carcinoma (ccRCC)

Kidney cancer is a disease with a rising worldwide incidence estimated at 400,000 new cases annually, and a worldwide mortality rate approaching 175,000 deaths per year. Current projections suggest incidence continuing to increase over the next decade, emphasizing the urgency of addressing this significant global health trend. ccRCC is the most common type of kidney cancer in adults, making up 75-80% of all cases.¹

About the 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 five Arcus programs in Japan and certain other territories in Asia (excluding mainland China): (1) casdatifan, HIF-2 α inhibitor announced today; (2) etrumadenant, a dual A2a/b adenosine receptor antagonist program in 2018; (3) zimberelimab, the anti-PD-1 program in 2019; (4) domvanalimab, the anti-TIGIT program in 2021, and (5) quemliclustat, CD73 inhibitor program in 2024.

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’s 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 therapies for people with cancer. In partnership with industry collaborators, patients and physicians around the world, Arcus is expediting the development of first- and/or 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 advanced multiple investigational medicines into registrational clinical trials including domvanalimab, an Fc-silent anti-TIGIT antibody being studied in combination with zimberelimab, an anti-PD-1 antibody, for upper gastrointestinal and non-small cell lung cancer, casdatifan, an HIF-2 α inhibitor for clear cell renal cell carcinoma, and quemliclustat, a small-molecule CD73 inhibitor for pancreatic cancer. For more information about Arcus Biosciences' clinical and preclinical programs, please visit www.arcusbio.com.

Arcus 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 development plans for casdatifan, including the conduct of PEAK-1 in Japan; ability to deliver casdatifan as an innovative new medicine; and realization of any potential benefits from this transaction such as the receipt of future milestones and royalties, 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 or delays in conducting or completing clinical trials due to difficulties or delays in the regulatory process, enrolling subjects or supplying investigational or standard of care products for such clinical trials, all of which may be exacerbated by unfavorable global economic, political and trade conditions; the unexpected emergence of adverse events or other undesirable side effects with casdatifan; changes in the competitive landscape; and the inherent uncertainty associated with pharmaceutical product development and clinical trials. Risks and uncertainties facing Arcus are described more fully in the "Risk Factors" section of Arcus's most recent periodic report filed with the U.S. Securities and Exchange Commission. 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.

The Arcus name and logo are trademarks of Arcus Biosciences, Inc. All other trademarks belong to their respective owners.

1) Padala S. et al. Epidemiology of Renal Cell Carcinoma. World J Oncol. 2020 May 14;11(3):79–87. doi: 10.14740/wjon1279

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