Arcus Biosciences and Taiho Pharmaceutical Co., Ltd. Jointly Announce Taiho’s Exercise of Its Option for an Exclusive License to Zimberelimab (AB122) for Its Territories in Japan and Other Asian Countries

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Taiho’s in-licensing facilitates global development and commercialization of zimberelimab as a monotherapy and as a combination backbone for Arcus’s and Taiho’s oncology portfolios

Zimberelimab exhibits clinical activity and a safety profile consistent with those of currently approved anti-PD-1 therapies

Broad development program delivering randomized data in 2020 for zimberelimab in multiple novel combinations, including with AB154, Arcus’s anti-TIGIT antibody, and with AB928, the first and only dual A2a/A2b adenosine receptor antagonist in the clinic

HAYWARD, Calif.--(BUSINESS WIRE)-- Arcus Biosciences, Inc. (NYSE:RCUS), an oncology-focused biopharmaceutical company working to create best-in-class cancer therapies, and Taiho Pharmaceutical Co. Ltd., (“Taiho”), today announced Taiho’s exercise of its option to exclusively license zimberelimab, an anti-PD-1 monoclonal antibody, from Arcus Biosciences for commercialization in Japan and certain other territories in Asia (excluding China). This is Taiho’s second exercise of an Arcus program and follows their 2018 decision to license AB928, the first and only dual A2a/A2b adenosine receptor antagonist in the clinic.

This press release features multimedia. View the full release here:
“We are happy to expand our collaboration with Arcus, with their ability to produce exceptional molecules and to thoughtfully execute on unique trial designs,” said Masayuki Kobayashi, President and Representative Director at Taiho. “This next stage in the partnership between our two companies further reinforces Taiho’s commitment in developing and delivering new treatment options to patients in need.”

“Taiho has been a great partner for Arcus, and we highly value the long-term relationship that we have built with our colleagues at Taiho,” said Terry Rosen, Ph.D., Chief Executive Officer of Arcus. “This second option exercise provides additional opportunities to fully leverage the therapeutic potential of our portfolio of clinical programs. We look forward to multiple AB928 and zimberelimab expansion study readouts starting in mid-2020 and to early randomization data prior to the end of the year.”

Zimberelimab has demonstrated a favorable safety profile as monotherapy and in combination with other agents, including AB928 and AB154. Zimberelimab is part of a broad development program with Arcus’s lead asset, AB928, in clinical studies that include prostate, colorectal, non-small cell lung, pancreatic, triple negative breast and renal cell cancers. In addition, zimberelimab is currently in a randomized Phase 2 study for the treatment of first-line metastatic non-small cell lung cancer, evaluating zimberelimab in combination with AB154, Arcus’s anti-TIGIT monoclonal antibody, with and without AB928.

Arcus licensed zimberelimab in 2017 from WuXi Biologics to provide flexibility and optionality for clinical development of innovative precision combination regimens and potential commercialization. Arcus holds worldwide rights to zimberelimab excluding China and Thailand. Gloria Biosciences, which licensed the rights to zimberelimab for China, recently presented data from its independent development of zimberelimab that demonstrated impressive anti-tumor activity in classical Hodgkin’s lymphoma. In January 2020, Gloria Biosciences submitted its application to the Chinese National Medical Products Administration (NMPA) to seek marketing approval in this indication.

In December 2019, Arcus received a payment from Taiho for the exercise of its option to license zimberelimab, and Arcus is eligible to receive additional clinical, regulatory and commercialization milestones of up to $275 million, as well as royalties on net sales, for this program.

About Zimberelimab

Zimberelimab, an anti-PD-1 monoclonal antibody, was in-licensed by Arcus to enable the development of precision combination regimens with full line-of-sight to the commercialization of innovative therapies for all patients who may benefit. Clinical studies with zimberelimab have demonstrated clinical activity and a safety profile that are consistent with those of currently approved anti-PD-1 therapies. The most advanced study with zimberelimab is a randomized Phase 2 study for the treatment of first-line metastatic non-small cell lung cancer, evaluating
zimberelimab in combination with AB154, an anti-TIGIT monoclonal antibody, with or without AB928, the first and only dual A2a/A2b adenosine receptor antagonist in the clinic. Zimberelimab is also being evaluated as a monotherapy in a tumor-agnostic, biomarker-selected Phase 1b trial for cancers with no approved anti-PD-1 treatment options.

About AB928

AB928, the first and only dual A2a/A2b adenosine receptor antagonist in the clinic, is designed to maximally inhibit the adenosine-driven impairment of tumor-infiltrating lymphocytes (mainly T cells and NK cells) and myeloid cells (dendritic cells, macrophages), mediated by A2a receptor and A2b receptor, respectively. A2b is also upregulated in certain tumors, such as in KRAS-mutated cancers. As a result, AB928 may uniquely block adenosine’s immunosuppressive and cancer cell-intrinsic effects. Developed specifically for the oncology setting, AB928 achieves high penetration of tumor tissue, robust potency in the presence of high adenosine concentrations, and minimal shift in potency from non-specific plasma protein binding. AB928 has demonstrated a favorable safety profile with a variety of combination regimens and exhibits pharmacokinetics / pharmacodynamics consistent with once-daily dosing. AB928 is currently being evaluated in several Phase 1b/2 studies across multiple indications.

About the Taiho Agreement

Arcus and Taiho entered into an option and license agreement in September 2017 pursuant to which Arcus granted Taiho an exclusive option, over a five-year period, to in-license the development and commercialization rights to clinical-stage product candidates from Arcus’s portfolio for Japan and certain other territories in Asia (excluding China). Taiho is obligated to pay an option exercise payment for each option exercise, with the amount dependent on the development stage of the applicable Arcus program for which the option is exercised. In addition, Taiho is obligated to pay to Arcus clinical, regulatory and commercialization milestones of up to $275 million per program as well as royalties on net sales in Taiho’s territories.

About Arcus Biosciences

Arcus Biosciences is an oncology-focused biopharmaceutical company leveraging its deep cross-disciplinary expertise to discover highly differentiated therapies and to develop a broad portfolio of novel combinations addressing significant unmet needs. AB928, the first and only dual A2a/A2b adenosine receptor antagonist in the clinic, is being evaluated in several Phase 1b/2 studies across multiple indications, including prostate, colorectal, non-small cell lung, pancreatic, triple negative breast and renal cell cancers. AB680, the first CD73 small-molecule inhibitor in the clinic, is in Phase 1/1b development for the treatment of first-line metastatic pancreatic cancer. AB154, an anti-TIGIT monoclonal antibody, is in randomized Phase 2 development for the treatment of first-line
metastatic non-small cell lung cancer in combination with zimberelimab and AB928. Zimberelimab (AB122), Arcus’s anti-PD1 monoclonal antibody, is being evaluated in a Phase 1b study as monotherapy for cancers with no approved anti-PD1 treatment options, as well as in combinations across the portfolio. For more information about Arcus Biosciences, please visit www.arcusbio.com.

About Taiho Pharmaceutical

Taiho Pharmaceutical, a subsidiary of Otsuka Holdings Co., Ltd., is an R&D-driven specialty pharma focusing on the three fields of oncology, allergy and immunology, and urology. 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/.

Forward-Looking Statements

This press release contains forward-looking statements. All statements other than statements of historical facts contained herein, including, but not limited to, any potential benefits from Taiho's option exercise of zimberelimab and the timing of any data or other anticipated milestones in Arcus's clinical trials, 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, uncertainties and other important factors that may cause Arcus's actual results, performance or achievements to differ significantly from those expressed or implied. Factors that could cause or contribute to such differences include, but are not limited to, the inherent uncertainty associated with pharmaceutical product development and clinical trials, delays in clinical trials due to difficulties or delays in the regulatory process, enrolling subjects or manufacturing or supplying product for such clinical trials, the emergence of adverse events or other undesirable side effects, and changes in the competitive landscape for our programs. Risks and uncertainties facing Arcus are described more fully in Arcus's quarterly report on Form 10-Q for the quarter ended September 30, 2019 filed on November 5, 2019 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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