Arcus Biosciences Provides Update on Clinical Programs, Including Key 2022 Milestones

1/10/2022

Six clinical-stage molecules targeting TIGIT, the adenosine axis (CD73 and dual A2a/A2b), HIF-2a and PD-1 continue to advance

- Multiple datasets are expected in 2022, including presentations planned for domvanalimab and etrumadenant in 1L PD-L1 high non-small cell lung cancer (NSCLC; ARC-7), quemliclustat in pancreatic cancer (ARC-8), and pharmacokinetic/pharmacodynamic data for AB521, Arcus's HIF-2a inhibitor
- Data from ARC-4, a randomized Phase 1/1b study in second- and third-line EGFR-mutation positive (EGFRm+) NSCLC, did not show differentiated clinical activity for the etrumadenant-based combination, and this setting has been de-prioritized
- Arcus and Gilead plan to initiate several new Phase 2 and Phase 3 studies evaluating intra- and cross-portfolio combinations targeting areas of high unmet need in 2022
- Arcus's cash position will nearly double to $1.4 billion upon receipt of option payments from Gilead in early Q1

HAYWARD, Calif.--(BUSINESS WIRE)-- Arcus Biosciences, Inc. (NYSE:RCUS), a clinical-stage, global biopharmaceutical company focused on developing differentiated molecules and combination therapies for people with cancer, today provided updates on clinical programs and key milestones anticipated in 2022.

“Our priorities for 2022 are clear and unambiguous—to flawlessly execute on the expansion of our global clinical programs which will include more than 10 randomized Phase 2 and 3 studies. We also expect to present
randomized datasets from ARC-7 and ARC-8 at medical meetings and generate early data for AB521 that will clarify its potential as a best-in-class molecule,” said Terry Rosen, Ph.D., Chief Executive Officer of Arcus Biosciences. “Our strong cash position and the support from our partner Gilead Sciences enable earlier investment to intelligently advance a broad development plan for our novel and potentially practice-changing combinations to treat cancer.”

Program Updates and 2022 Milestones

Anti-TIGIT program (domvanalimab and AB308)

Recent Updates:

- Taiho Pharmaceutical Co., Ltd., exercised its option for domvanalimab and AB308 in Japan and certain other territories in Asia (excluding China). In exchange for the exclusive license, 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.

Anticipated 2022 Milestones:

- Data from ARC-7, an ongoing randomized 150-patient three-arm study in first-line PD-L1≥50% NSCLC, including progression-free survival data, are expected to be presented in 2H22.
- In addition to ARC-10, an ongoing registrational study in 1L PD-L1≥50% NSCLC, we and Gilead plan to initiate two new Phase 3 studies in lung and gastrointestinal (GI) cancers, as well as additional clinical studies of domvanalimab-based combinations, in 2022.
- AstraZeneca and Arcus will initiate the PACIFIC-8 registrational Phase 3 study in January to evaluate domvanalimab plus durvalumab, an anti-PD-L1 antibody, in unresectable Stage 3 NSCLC with curative intent, where durvalumab is standard of care.
- Data from the Phase 1/1b ARC-12 study evaluating AB308, an Fc-enabled anti-TIGIT antibody, plus zimberelimab in advanced malignancies will inform future development plans.

Etrumadenant (A2a/A2b adenosine receptor antagonist)

ARC-4 Update:

- The randomized Phase 1/1b study ARC-4 did not show differentiated clinical activity for etrumadenant plus zimberelimab and pemetrexed/carboplatin compared to that of zimberelimab and pemetrexed/carboplatin in patients with metastatic, EGFRm+ NSCLC who progressed after one or more TKI therapies. Arcus is conducting exploratory biomarker analyses to assess whether sub-populations of patients in the study derive
benefit from etrumadenant-based treatment, such as those with PD-L1 high tumors. Final data from the study will be presented when available.

- All ongoing studies for etrumadenant will continue unchanged. These studies are in settings where encouraging clinical activity has been observed, such as PD-L1≥50% NSCLC (ARC-7), castrate-resistant prostate cancer (CRPC; ARC-6), and colorectal cancer (CRC; ARC-9). Patients whose tumors harbor EGFRm+ characteristics are excluded from the ARC-7 and ARC-10 studies.

Anticipated 2022 Milestones:

- Data from the etrumadenant-containing arm of ARC-7 are anticipated to be presented in 2H22, as noted above.
- Data from the randomized cohort of ARC-6 evaluating etrumadenant plus zimberelimab and docetaxel versus docetaxel in second-line (2L) metastatic CRPC are anticipated in 2H22.
- Additional clinical studies for etrumadenant-based combinations, including the “triplet” of etrumadenant plus domvanalimab and zimberelimab, are being planned for 2022.

**Quemliclustat (small molecule CD73 inhibitor)**

Recent Updates:

- Completed enrollment of 90 patients into the randomized portion of ARC-8, a Phase 1 study evaluating quemliclustat plus zimberelimab and gemcitabine/nab-paclitaxel vs quemliclustat plus gemcitabine/nab-paclitaxel in 1L pancreatic cancer.

Anticipated 2022 Milestones:

- Results from the randomized portion of ARC-8, including data on progression-free survival, are expected to be presented in 2H22.
- Enrollment of the cohort in 2L pancreatic cancer, an area of high unmet need, is on track to be completed in 1H22.
- Additional clinical studies for quemliclustat are being planned for 2022.

**AB521 (HIF-2a inhibitor)**

Recent Updates:

- Initiated ARC-14, a study to investigate the safety, tolerability, and pharmacokinetic profile of AB521 in healthy volunteers.

Anticipated 2022 Milestones
- Share pharmacokinetic and safety data from ARC-14 in 1H22, which may demonstrate competitive advantages to other HIF-2a inhibitors.
- Initiate Phase 1/1b study in oncology patients in mid-2022.

**Discovery Programs:**

- Added a research collaboration to the existing agreement with Gilead under which Arcus will lead the discovery and early development of drug candidates against two novel research targets jointly selected by the parties.
- Selected AB598 (CD39 antibody) as a development candidate, which is advancing into IND-enabling studies; several other oncology discovery programs continue to progress.
- In 1H22, expect to select the first development candidate for a non-oncology target. This small molecule may have first-in-class potential in several inflammatory diseases.

**Financial Guidance**

Arcus’s cash position will nearly double to $1.4 billion, upon receiving the option payment totaling $725 million for three programs from Gilead. With this cash position and 50/50 cost sharing with Gilead for the joint development programs, Arcus plans to expand its clinical development programs and anticipates cash utilization of $275-325 million in 2022.

**Arcus Clinical Study Overview**

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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 partners, patients and physicians around the world, Arcus is expediting the development of first- or best-in-class medicines against well characterized biology 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 six investigational medicines into clinical studies, including new combination approaches that target TIGIT, PD-1, the adenosine axis (CD73 and dual A2a/A2b) and most recently, HIF-2alpha. For more information about Arcus Biosciences' clinical and pre-clinical programs, please visit www.arcusbio.com or follow us on Twitter.

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, Dr. Rosen’s quote, upcoming data presentations, trial initiations and other milestones and the associated timing of such activities, including as set forth under the captions “Anticipated 2022 Milestones”, Arcus’s future development plans, and Arcus’s expectations regarding its plans and projected cash utilization, 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 Arcus’s 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: Arcus’s dependence on the collaboration with Gilead for the successful development and commercialization of its optioned molecules; difficulties associated with the management of the collaboration activities or expanded clinical programs; difficulties or delays in initiating or conducting clinical trials due to difficulties or delays in the regulatory process, enrolling subjects or manufacturing or supplying product for such clinical trials, all of which may be exacerbated by the COVID-19 pandemic; the unexpected emergence of adverse events or other undesirable side effects; risks associated with preliminary and interim data; the inherent uncertainty associated with pharmaceutical product development and 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 September 30, 2021, filed on November 8, 2021, 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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