

# Arcellx And Kite Announce Strategic Collaboration To Co-Develop And Co-Commercialize Late-Stage Clinical CART-DdBCMA In Multiple Myeloma

12/09/2022

*-- Collaboration leverages expertise across both companies, including Kite's global cell therapy leadership and industry leading reliable manufacturing --*

*-- Arcellx to receive \$225M upfront payment; \$100M equity investment; and up to \$3.9B in total contingent consideration --*

*-- Companies to co-commercialize and split profits in the U.S.; Arcellx to receive low to mid-teen royalties outside the U.S. --*

*-- Arcellx to continue independently progressing its development pipeline and researching new product candidates beyond myeloma --*

*-- Arcellx to host a conference call and webcast today at 5:45 a.m. PT --*

REDWOOD CITY, Calif., and SANTA MONICA, Calif., Dec. 9, 2022 /PRNewswire/ -- Arcellx, Inc. (NASDAQ: ACLX) and Kite, a Gilead Company (NASDAQ: GILD), today announced a global strategic collaboration to co-develop and co-commercialize Arcellx's lead late-stage product candidate, CART-ddBCMA, for the treatment of patients with relapsed or refractory multiple myeloma. Multiple myeloma is an incurable disease for most patients and the need remains for effective, safe, and broadly accessible therapies.

"This collaboration marks a significant achievement for the myeloma field and Arcellx," said [Rami Elghandour, Arcellx's Chairman and Chief Executive Officer](#). "Combining our potentially best-in-class CART-ddBCMA therapy for multiple myeloma with Kite's global leadership in cell therapy provides the foundation for us to commercialize our therapy at scale. Most importantly this collaboration is focused on accelerating access for patients in need. The synergies between the two companies are a natural fit. We both bring complementary expertise to the collaboration allowing each company to contribute to the partnership without duplication or competing interests, which is critical for building long-term value."

Currently in Phase 2 clinical development, CART-ddBCMA is an investigational cell therapy product comprising autologous T cells that have been genetically modified to target multiple myeloma. CART-ddBCMA utilizes Arcellx's novel D-Domain binder. Kite and Arcellx will jointly advance the CART-ddBMCA asset.

"The collaboration with Arcellx enables Kite to expand into a new area of high unmet need and bring a potentially best-in-class cell therapy to help many patients," said Christi Shaw, Chief Executive Officer of Kite. "Cell therapy has proven it can change the way cancer is treated by creating a potentially curative therapy for an individual patient, engineered from their own T cells. To deliver cell therapy globally, and at scale, it requires a highly coordinated, vertically integrated organization from R&D to commercialization to manufacturing, dedicated to the unique needs of this very complex field. The Kite team is excited to engage on this meaningful program in the multiple myeloma field, alongside Arcellx's talented team."

Upon closing, Arcellx will receive an upfront cash payment of \$225 million and \$100 million equity investment. Both companies will share development, clinical trial, and commercialization costs for CART-ddBCMA and will jointly commercialize and split U.S. profits 50/50. Outside the US, Kite will commercialize the product and Arcellx will receive royalties on sales. Kite will be responsible for the development and commercialization costs for any product under the collaboration that is not co-commercialized. After completion of the technical transfer, Kite will be responsible for manufacturing.

### **Terms of the Collaboration**

- **Upfront:** Upon closing, Arcellx will receive an upfront cash payment of \$225 million and \$100 million equity investment from Kite.
- **Manufacturing:** After completion of the technical transfer, Kite will be responsible for manufacturing. Kite will be responsible for all manufacturing expenses associated with commercial readiness.
- **Development:** U.S. and global study costs for the iMMagine-1, iMMagine-2 and future clinical studies for CART-ddBCMA and any other co-commercialized product will be shared 50/50 in the U.S. and 60 to Kite / 40 to Arcellx in the Ex U.S. territory.
- **U.S. Commercialization:** 50/50 profit split for products co-commercialized by Arcellx and Kite; Kite will commercialize all other products and Arcellx will receive low to mid-teen royalties.
- **Ex-U.S. Commercialization:** Kite will commercialize the product and Arcellx will receive low to mid-teen royalties on sales.
- **NextGen, Non-Autologous, and ARC-SparX Programs:** Arcellx and Kite to collaborate on next generation autologous and non-autologous programs incorporating ddBCMA. Arcellx to receive an option to co-develop and co-commercialize next generation autologous programs and Kite to receive an option to selected ARC-SparX programs in myeloma.

Bank of America is acting as financial advisor to Kite. Wilson Sonsini Goodrich & Rosati is serving as legal counsel to Arcellx.

The transaction is expected to close in the first quarter of 2023. Closing of the transaction is subject to expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act and other customary conditions.

### **Conference Call and Webcast Details**

The live webcast and conference call will be accessible under the [Events & Presentations](#) in the Investors section of the company's website [www.arcellx.com](http://www.arcellx.com). To participate in the conference call, dial 1-888-440-3310 (domestic) or 1-646-960-0513 (international) and reference conference ID# 1012518. The archived audio webcast will be available on Arcellx's website following the call and will be available for 30 days.

### **About Multiple Myeloma**

Multiple Myeloma (MM) is a type of hematological cancer in which diseased plasma cells proliferate and accumulate in the bone marrow, crowding out healthy blood cells and causing bone lesions, loss of bone density, and bone fractures. These abnormal plasma cells also produce excessive quantities of an abnormal immunoglobulin fragment, called a myeloma protein (M protein), causing kidney damage and impairing the patient's immune function. Multiple myeloma is the third most common hematological malignancy in the United States and Europe, representing approximately 10% of all hematological cancer cases and 20% of deaths due to hematological malignancies. The median age of patients at diagnosis is 69 years with one-third of patients diagnosed at an age of at least 75 years. Because MM tends to afflict patients at an advanced stage of life, patients often have multiple co-morbidities and toxicities that can quickly escalate and become life-endangering.

### **About CART-ddBCMA**

CART-ddBCMA is Arcellx's BCMA-specific CAR-modified T-cell therapy utilizing the company's novel binding domain for the treatment of patients with relapsed or refractory multiple myeloma. CART-ddBCMA is currently being investigated in a pivotal Phase 2 study called iMMagine-1. Arcellx's proprietary binding domains are novel synthetic proteins designed to bind specific therapeutic targets. CART-ddBCMA has been granted Fast Track, Orphan Drug, and Regenerative Medicine Advanced Therapy Designations by the U.S. Food and Drug Administration.

### **About Arcellx**

Arcellx, Inc. is a clinical-stage biotechnology company reimagining cell therapy by engineering innovative immunotherapies for patients with cancer and other incurable diseases. Arcellx believes that cell therapies are one of the forward pillars of medicine and Arcellx's mission is to advance humanity by developing cell therapies that are safer, more effective, and more broadly accessible. Arcellx's lead product candidate, CART-ddBCMA, is being developed for the treatment of relapsed or refractory multiple myeloma (r/r MM) in an ongoing Phase 2 study. CART-ddBCMA has been granted Fast

Track, Orphan Drug, and Regenerative Medicine Advanced Therapy designations by the U.S. Food and Drug Administration.

Arcellx is also advancing its dosable and controllable CAR-T therapy, ARC-SparX, through two programs: a Phase 1 study of ACLX-001 for r/r MM, initiated in the second quarter of 2022; and a Phase 1 study of ACLX-002 in relapsed or refractory acute myeloid leukemia and high-risk myelodysplastic syndrome, initiated in the fourth quarter of 2022. For more information on Arcellx, please visit [www.arcellx.com](http://www.arcellx.com).

### **About Kite**

Kite, a Gilead Company, is a global biopharmaceutical company based in Santa Monica, California, focused on cell therapy to treat and potentially cure cancer. As the global cell therapy leader, Kite has treated more patients with CAR T-cell therapy than any other company. Kite has the largest in-house cell therapy manufacturing network in the world, spanning process development, vector manufacturing, clinical trial production and commercial product manufacturing. For more information on Kite, please visit [www.kitepharma.com](http://www.kitepharma.com). Follow Kite on social media on Twitter (@KitePharma) and LinkedIn.

### **About Gilead Sciences**

Gilead Sciences, Inc. is a biopharmaceutical company that has pursued and achieved breakthroughs in medicine for more than three decades, with the goal of creating a healthier world for all people. The company is committed to advancing innovative medicines to prevent and treat life-threatening diseases, including HIV, viral hepatitis and cancer. Gilead operates in more than 35 countries worldwide, with headquarters in Foster City, California. Gilead Sciences acquired Kite in 2017.

### **Arcellx, Inc. Forward-looking Statements**

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements in this press release that are not purely historical are forward-looking statements, including the potential benefits, synergies and results that may be achieved through the proposed collaboration; the anticipated completion of the proposed transaction including the closing of a proposed concurrent equity investment; the anticipated payments expected to be received by Arcellx in connection with the collaboration, including potential milestones and royalties; expectations regarding the timing and outcomes of clinical trials for its product candidates; the expected capabilities, including in manufacturing and commercialization, of Kite and Arcellx to complete clinical development, obtain regulatory approval, and if approved, commercialize the product candidates; the collaboration's impact on Arcellx's research and development, clinical and commercial activities, expenditures, capabilities and financials; Kite's rights around certain ARC-SparX programs; and Arcellx's research and development pipeline plans in autologous

and allogeneic programs and beyond myeloma. The forward-looking statements contained herein are based upon Arcellx's current expectations and involve assumptions that may never materialize or may prove to be incorrect. These forward-looking statements are neither promises nor guarantees and are subject to a variety of risks and uncertainties, including the ability to complete the proposed transaction, including the concurrent equity investment, in a timely manner or at all, including the possibility that a governmental entity may prohibit, delay or refuse to grant approval for the consummation of the transaction; the possibility that certain closing conditions to the proposed transaction will not be satisfied; uncertainty as to whether the anticipated benefits and opportunities of the proposed collaboration may not be realized or make take longer to realize or may cost more than expected; challenges in technology transfer and cell therapy manufacturing, particularly in scaling up to commercial supply volumes, that can limit the benefits of the collaboration; challenges inherent in new product candidate development, including the uncertainty of clinical success and obtaining regulatory approvals; challenges associated with collaborating with third parties, including intellectual property, operational, financial and other risks; uncertainty of commercial success for new products; the ability of Arcellx and Kite to successfully execute their strategic plans; the risk that the collaboration can be terminated; potential for other unexpected hurdles, costs or delays; and other risks that may be found in the section entitled Part II, Item 1A (Risk Factors) in the Quarterly Report on Form 10-Q for the period ended September 30, 2022, filed with the Securities and Exchange Commission (SEC), and other documents that Arcellx files from time to time with the SEC. These forward-looking statements are made as of the date of this press release, and Arcellx assumes no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

### **Gilead Forward-looking Statements**

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that are subject to risks, uncertainties and other factors, including the ability of the parties to complete the transaction in a timely manner or at all; the possibility that various closing conditions for the transaction may not be satisfied or waived, including the possibility that a governmental entity may prohibit, delay or refuse to grant approval for the consummation of the transaction; difficulties or unanticipated expenses in connection with the collaboration, including with respect to the co-development, co-commercialization, and manufacturing of CART-ddBCMA or other programs subject of the collaboration and associated funding; the risk that Gilead and Kite may not realize the anticipated benefits of the collaboration with Arcellx; the possibility that the parties may make a strategic decision to terminate this collaboration at any time; the risk that Gilead's investment in Arcellx will lose value for any number of reasons; uncertainties relating to regulatory applications and related filing and approval timelines for CART-ddBCMA or other programs subject of the collaboration, including the risk that FDA may not approve any such programs on the currently anticipated timelines or at all, and any marketing approvals, if granted, may have significant limitations on its use; the potential effect of any of the foregoing on

Gilead and Kite's earnings; and any assumptions underlying any of the foregoing. These and other risks, uncertainties and other factors are described in detail in Gilead's Quarterly Report on Form 10-Q for the quarter ended September 30, 2022, as filed with the U.S. Securities and Exchange Commission. These risks, uncertainties and other factors could cause actual results to differ materially from those referred to in the forward-looking statements. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. The reader is cautioned that any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties, and is cautioned not to place undue reliance on these forward-looking statements. All forward-looking statements are based on information currently available to Gilead and Kite, and Gilead and Kite assume no obligation and disclaim any intent to update any such forward-looking statements.

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