Allogene Therapeutics Reports Second Quarter 2022 Financial Results

August 9, 2022

- U.S. FDA Clearance on Potential Pivotal Phase 2 Trial of ALLO-501A Anticipated in Coming Weeks
  - Expected to be the Industry's First Allogeneic CAR T Phase 2 Pivotal Trial
  - Clearance to Cover ALPHA2 Protocol and Chemistry Manufacturing and Controls (CMC) for Use of ALLO-501A Manufactured from Cell Forge 1 (CF1)
  - CF1 is Projected to Support the Manufacture of ~20,000 Doses of AlloCAR T™ Products Annually at Scale
- CF1 Earned a LEED® Interior Design and Construction Gold Designation from the U.S Green Building Council
- Company Plans to Evaluate Potential Phase 2 Pivotal Study Approach and Timing for BCMA Program for Multiple Myeloma by Year End
- Clinical Updates Focused on Longer-Term Follow-Up in the ALPHA, ALPHA2 and UNIVERSAL Trials Planned for YE 2022
- Ended Second Quarter with $686 Million in Cash, Cash Equivalents and Investments
- Quarterly Conference Call and Webcast Scheduled for Today at 2:00 PM PT/5:00 PM ET

SOUTH SAN FRANCISCO, Calif., Aug. 09, 2022 (GLOBE NEWSWIRE) -- Allogene Therapeutics, Inc. (Nasdaq: ALLO), a clinical-stage biotechnology company pioneering the development of allogeneic CAR T (AlloCAR T™) products for cancer, today provided a corporate update and reported financial results for the quarter ended June 30, 2022.

"We feel confident that we could soon initiate the industry's first Phase 2 pivotal trial for an allogeneic CAR T product, thereby paving the road not just for ALLO-501A, but our entire portfolio," said David Chang, M.D., Ph.D., President, Chief Executive Officer and Co-Founder of Allogene. "As the use of autologous CAR T therapy increases, we are seeing a greater need for an off-the-shelf, allogeneic CAR T option. We are keenly aware of the devastating consequences patients face when only a minority are able to access the curative potential of CAR T therapy. Clinicians have been forced into the unfathomable position of needing to choose which of their patients will receive this potentially life-saving therapy. As patients face access bottlenecks, we are determined to transform CAR T therapy from a complex individualized procedure to an off-the-shelf, on demand pharmaceutical product."

Pipeline Updates

CD19 Program

In the coming weeks, the Company expects to receive clearance from the U.S. Food and Drug Administration (FDA) to initiate a potential Phase 2 pivotal clinical trial for ALLO-501A in relapsed/refractory (r/r) large B cell lymphoma (LBCL). This includes meeting Chemistry Manufacturing and Controls (CMC) requirements to use ALLO-501A from its manufacturing facility, Cell Forge 1.

In June, the FDA granted Regenerative Medicine Advanced Therapy (RMAT) designation to ALLO-501A in r/r LBCL. RMAT designation was based on data demonstrating the potential of ALLO-501A to address the unmet need for patients who have failed other therapies. Previously presented data support the potential of ALLO-501A to provide a safe and durable alternative to approved autologous CAR T therapies in CAR T naïve patients, including manageable safety with no dose limiting toxicities (DLTs) or graft-vs-host disease (GvHD) and minimal Grade 3 Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS), or Grade 3 cytokine release syndrome (CRS). In the Phase 1 ALPHA2 study, nearly all enrolled patients were able to receive therapy with the median time from enrollment to initiation of treatment of two days.

Allogene anticipates providing an update on the Phase 1 portion of the ALPHA and ALPHA2 trials toward the end of 2022. This update will include a few additional patients enrolled in ALPHA2 and will focus on longer-term follow up of patients previously treated in the ALPHA and ALPHA2 trials.

The EXPAND trial is expected to begin in 2022 and is planned to support registration of the lymphodepleting agent ALLO-647. This trial is intended to demonstrate the contribution of ALLO-647 to the lymphodepletion regimen.

BCMA Program

Allogene plans to explore its pivotal study approach and timing for its BCMA program by year end. In parallel, the Company intends to work within the framework afforded by its RMAT designation for ALLO-715 to facilitate FDA interactions and determine the best course forward.

Enrollment continues in the Phase 1 UNIVERSAL trial on ALLO-715 in r/r multiple myeloma (MM). Toward the end of 2022, Allogene intends to provide a clinical update that will focus on the longer-term follow up of patients in UNIVERSAL treated with a single dose of ALLO-715. Allogene has made the decision not to advance ALLO-715 in combination with nirogacestat from SpringWorks Therapeutics into dose expansion cohorts. There was no clear indication that the combination would meaningfully improve the benefit-risk profile of ALLO-715 as a monotherapy. Allogene's Clinical Trial Collaboration Agreement with SpringWorks is expected to remain in effect until the data from the combination study are fully analyzed.

The IGNITE trial on TurboCAR™ candidate ALLO-605 continues to enroll patients in the dose escalation portion of this Phase 1 study.

Solid Tumor Programs

ALLO-316, which targets CD70, is the Company's first AlloCAR T candidate for solid tumors. The ongoing Phase 1 TRAVERSE trial is designed to evaluate the safety, tolerability, anti-tumor efficacy, pharmacokinetics, and pharmacodynamics of ALLO-316 in patients with advanced or metastatic clear cell renal cell carcinoma (RCC).

The FDA previously granted ALLO-316 Fast Track Designation (FTD) based on its potential to address the unmet need for patients with difficult to treat RCC who have failed standard therapies. Metastatic solid tumors have historically been a challenge regardless of treatment modality, and the five-year survival rate for patients with advanced kidney cancer is less than 15%, highlighting the need for innovation.

Corporate Highlights
CF1, Allogene's commercial scale manufacturing facility located in Newark, California is fully operational and producing GMP material with the intent of supplying ALLO-501A for the planned pivotal study as well as other clinical trials. CF1 is projected to have the ability to manufacture approximately 20,000 ALLO-501A AlloCAR T doses annually at scale. CF1 recently earned a LEED® Interior Design and Construction Gold designation from the U.S. Green Building Council (USGBS), a non-profit dedicated to sustainable building design and construction.

In July, Allogene announced the appointment of Stephen L. Mayo, Ph.D., a world-renowned expert in computational protein design, to the company's Board of Directors. Dr. Mayo is the Bren Professor of Biology and Chemistry and Merkin Institute Professor at the California Institute of Technology in Pasadena, California. Dr. Mayo also serves on the Board of Directors of Merck & Co. and Sarepta Therapeutics, Inc.

Second Quarter Financial Results

- Research and development expenses were $57.2 million for the second quarter of 2022, which includes $13.0 million of non-cash stock-based compensation expense.
- General and administrative expenses were $19.5 million for the second quarter of 2022, which includes $9.9 million of non-cash stock-based compensation expense.
- Net loss for the second quarter of 2022 was $74.8 million, or $0.52 per share, including non-cash stock-based compensation expense of $22.9 million.
- The Company had $686 million in cash, cash equivalents, and investments as of June 30, 2022.

Updated 2022 Financial Guidance
While the Company anticipates spending to increase in the second half relative to the first half of 2022, it now expects full year GAAP Operating Expenses to be at the low end of the previous range of $360 million and $390 million. This includes estimated non-cash stock-based compensation expense of $90 million to $100 million and excluding any impact from potential business development activities. Cash burn for 2022 is now expected to be approximately $250 million.

Conference Call and Webcast Details
Allogene will host a live conference call and webcast today at 2:00 p.m. Pacific Time / 5:00 p.m. Eastern Time to discuss financial results and provide a business update. To access the live conference call by telephone, please dial 1 (800) 715-9871 (U.S.) or 1 (646) 307-1963 (International). The conference ID number for the live call is 7832993. The webcast will be made available on the Company's website at www.allogene.com under the Investors tab in the News and Events section. Following the live audio webcast, a replay will be available on the Company's website for approximately 30 days.

About Allogene Therapeutics
Allogene Therapeutics, with headquarters in South San Francisco, is a clinical-stage biotechnology company pioneering the development of allogeneic chimeric antigen receptor T cell (AlloCAR T™) products for cancer. Led by a management team with significant experience in cell therapy, Allogene is developing a pipeline of "off-the-shelf" CAR T cell candidates with the goal of delivering readily available cell therapy on-demand, more reliably, and at greater scale to more patients. For more information, please visit www.allogene.com and follow @AllogeneTx on Twitter and LinkedIn.

Cautionary Note on Forward-Looking Statements
This press release contains forward-looking statements for purposes of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. The press release may, in some cases, use terms such as "predicts," "believes," "potential," "proposed," "continue," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Forward-looking statements include statements regarding intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things: the timing and ability to progress the ALPHA2, UNIVERSAL, IGNITE and TRAVERSE trials, including advancing to the Phase 2 portion of the ALPHA2 trial; the timing and ability to initiate the EXPAND trial for ALLO-647; clinical outcomes, which may materially change as more patient data become available; the ability to manufacture AlloCAR T™ products, including obtaining FDA agreement to use ALLO-501A manufactured at the Company's manufacturing facility for use in the ALPHA2 trial; the projection related to the number of AlloCAR T doses that can be produced at Cell Forge 1 at scale on an annual basis; the potential benefits of AlloCAR T products; and 2022 financial guidance. Various factors may cause differences between Allogene's expectations and actual results as discussed in greater detail in Allogene's filings with the SEC, including without limitation in its Form 10-Q for the quarter ended June 30, 2022. Any forward-looking statements that are made in this press release speak only as of the date of this press release. Allogene assumes no obligation to update the forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

Allogene's AlloCAR T™ programs utilize Cellectis technologies. ALLO-501 and ALLO-501A are anti-CD19 products being jointly developed under a collaboration agreement between Servier and Allogene based on an exclusive license granted by Cellectis to Servier. Servier grants to Allogene exclusive rights to ALLO-501 and ALLO-501A in the U.S. while Servier retains exclusive rights for all other countries. The anti-BCMA and anti-CD70 AlloCAR T programs are licensed exclusively from Cellectis by Allogene and Allogene holds global development and commercial rights to these AlloCAR T programs.

ALLOGENE THERAPEUTICS, INC.

SELECTED FINANCIAL DATA
(unaudited; in thousands, except share and per share data)

STATEMENTS OF OPERATIONS

	Three Months Ended June 30,	
	2022	**2021**
Collaboration revenue - related party	$ 86	$ 44
Operating expenses:		
Research and development	$ 57,171	$ 52,290
General and administrative	19,509	18,783
Total operating expenses	76,680	71,073
Loss from operations	(76,594)	(71,029)
Other income (expense), net:		
Interest and other income, net	315	624
Other expenses	1,492	(531)
Total other income (expense), net	1,807	93
Net loss	(74,787)	(70,936)
Net loss per share, basic and diluted	$ (0.52)	$ (0.53)
Weighted-average number of shares used in computing net loss per share, basic and diluted	143,385,045	134,826,805

SELECTED BALANCE SHEET DATA

	As of June 30, 2022	**As of December 31, 2021**
Cash, cash equivalents and investments	$ 686,129	$ 809,481
Total assets	947,644	1,038,634
Total liabilities	145,695	122,228
Total stockholders' equity	801,949	916,406

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Source: Allogene Therapeutics, Inc.