Allogene Therapeutics Reports First Quarter 2022 Financial Results

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- Pivotal Phase 2 ALPHA2 Trial of ALLO-501A in R/R Large B Cell Lymphoma Planned to Commence Mid 2022 Using Product from Cell Forge 1 (CF1)
    - CF1 is Projected to Support the Manufacture of ~20,000 Doses of AlloCAR T™ Products Annually at Scale
- Clinical Updates from the CD19 and BCMA Programs Planned for 2H 2022
    - Received FDA Orphan Drug Designation (ODD) for ALLO-605, the First TurboCAR™ Product Candidate for the Treatment of Multiple Myeloma
- Phase 1 TRAVERSE Trial of ALLO-316 Targeting CD70 for the Treatment of Renal Cell Carcinoma Continues to Enroll Patients
    - FDA Granted Fast Track Designation for ALLO-316 for the Treatment of Renal Cell Carcinoma
    - Preclinical Data on ALLO-316 Presented at AACR's Annual Meeting
- Ended First Quarter with $733 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., May 04, 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 March 31, 2022.

"This month marks the fourth anniversary of Allogene. I am immensely proud of all that we have accomplished in such a short period of time, including our ability to treat more patients with our pipeline of AlloCAR T candidates than anyone else in the field," said David Chang, M.D., Ph.D., President, Chief Executive Officer and Co-Founder of Allogene. "Every advance we make in manufacturing, clinical development, and research brings us one step closer to achieving our vision of making CAR T therapy accessible to all eligible patients."

Corporate Highlights
Cell Forge 1 (CF1), Allogene's commercial scale manufacturing facility located in Newark, California is now 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.

In March, the Company published its inaugural ESG report. The report details Allogene's commitment to corporate integrity and sustainable business operations and highlights its priorities: employees, the environment, and patients, including increasing their access to potential life-saving products.

Pipeline Updates

Hematologic Malignancies
Enrollment in the Phase 1 ALLO-501A ALPHA2 trial in relapsed/refractory (r/r) Large B Cell Lymphoma (LBCL) has re-opened with the goal of offering AlloCAR T to patients while the Company prepares to launch the pivotal Phase 2 ALPHA2 trial. The single-arm pivotal ALPHA2 trial of ALLO-501A in r/r LBCL is on track to begin mid-year 2022 with FDA discussions directed at finalizing clinical trial design and Chemistry Manufacturing and Controls (CMC) requirements.

The EXPAND trial, planned to support registration of the lymphodepleting agent ALLO-647, is intended to demonstrate the contribution of ALLO-647 to the lymphodepletion regimen.

Enrollment has also resumed in trials targeting BCMA for the treatment of patients with r/r multiple myeloma (MM), including the UNIVERSAL trial with ALLO-715 and the IGNITE trial with TurboCAR™ candidate, ALLO-605. In April, preclinical data was published demonstrating the superior long-term in vitro myeloma-killing activity of allogeneic anti-BCMA CAR T cells from healthy donors compared with anti-BCMA CAR T cells from patients with MM. The findings were published in *Cancer Research Communications*, a journal of the American Association for Cancer Research (AACR).

In May 2022, the Company was granted U.S. Food and Drug Administration (FDA) Orphan Drug Designation (ODD) for ALLO-605 for the treatment of MM. The Company intends to provide an update on its CD19 and BCMA programs by the end of the year.

Solid Tumors
ALLO-316 is the Company's first AlloCAR T candidate for solid tumors. The 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 trial, now in its second dose level cohort, continues to accrue patients.

In April, the Company presented preclinical data at the 2022 AACR Annual Meeting which support the ongoing clinical evaluation of ALLO-316 for the treatment of patients with RCC and other CD70 expressing cancers. The findings were simultaneously published in AACR's *Cancer Research*.

In March, the FDA 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 RCC 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.

First Quarter Financial Results

- Research and development expenses were $60.2 million for the first quarter of 2022, which includes $11.1 million of non-cash stock-based compensation expense.
- General and administrative expenses were $19.9 million for the first quarter of 2022, which includes $11.2 million of non-cash stock-based compensation expense.
- Net loss for the first quarter of 2022 was $79.9 million, or $0.56 per share, including non-cash stock-based compensation expense of $22.3 million.
- The Company had $733.1 million in cash, cash equivalents, and investments as of March 31, 2022.

2022 Financial Guidance

- Allogene continues to expect full year GAAP Operating Expenses to be between $360 million and $390 million including estimated non-cash stock-based compensation expense of $90 million to $100 million and excluding any impact from potential business development activities.

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 (866) 940-5062 (U.S.) or 1 (409) 216-0618 (International). The conference ID number for the live call is 6579454. 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 March 31, 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.

AlloCAR T™ and TurboCAR™ are trademarks of Allogene Therapeutics, Inc.
TALEN® is a registered trademark of Cellectis, S.A.

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 March 31,	
	2022	**2021**
Collaboration revenue - related party	$ 61	$ 38,345
Operating expenses:		
Research and development	$ 60,156	$ 55,183
General and administrative	19,897	16,363
Total operating expenses	80,053	71,546
Loss from operations	(79,992)	(33,201)
Other income (expense), net:		

Interest and other income, net	492	511
Other expenses	(350)	(325)
Total other income (expense), net	142	186
Net loss	(79,850)	(33,015)
Net loss per share, basic and diluted	$ (0.56)	$ (0.25)
Weighted-average number of shares used in computing net loss per share, basic and diluted	141,356,306	132,165,014

SELECTED BALANCE SHEET DATA

	As of March 31, 2022	As of December 31, 2021
Cash, cash equivalents and investments	$ 733,143	$ 809,481
Total assets	964,632	1,038,634
Total liabilities	109,402	122,228
Total stockholders' equity	855,230	916,406

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Source: Allogene Therapeutics, Inc.