GRI Bio Reports Full Year 2023 Financial Results and Provides Corporate Update

Ongoing Phase 2a biomarker study evaluating lead program GRI-0621 for the treatment of Idiopathic Pulmonary Fibrosis (IPF) with interim data expected H1 2024 and topline data expected H2 2024

GRI-0803 systemic lupus erythematosus (SLE) program advancing towards completion of Investigational New Drug (IND) Application enabling studies with IND filing on track for H1 2024

The Company closed a public offering with participation from healthcare focused institutional investors for aggregate gross proceeds of $5.5 million, extending its cash runway into Q3 2024

LA JOLLA, CA, April 01, 2024 (GLOBE NEWSWIRE) -- GRI Bio, Inc. (NASDAQ: GRI) ("GRI Bio" or the "Company"), a biotechnology company advancing an innovative pipeline of Natural Killer T (NKT) cell modulators for the treatment of inflammatory, fibrotic and autoimmune diseases, today reported its financial results for the fiscal year ended December 31, 2023 and provided a corporate update.

"Over the past several months we've achieved significant regulatory and clinical milestones while adding $5.5 million to the balance sheet, paving the way for an exciting 2024 marked by key data readouts. Our Phase 2a biomarker study for GRI-0621 in IPF is gaining momentum and with interim and topline data expected this year, we believe we have the potential to unlock substantial value for all stakeholders," commented Marc Hertz, PhD, Chief Executive Officer of GRI Bio.

Recent Highlights

- Received notice of allowance for Canadian patent covering proprietary NKT cell modulators;
- Received authorization of the Company's Clinical Trial Application (CTA) by the United Kingdom (UK) Medicines and Healthcare Products Regulatory Agency to initiate a Phase 2a biomarker study evaluating GRI-0621 for the treatment of IPF in the UK;
- Closed a public offering with participation from healthcare focused institutional investors for aggregate gross proceeds of $5.5 million;
- Commenced screening patients for enrollment in Phase 2a biomarker study evaluating the Company's lead program GRI-0621 for the treatment of IPF;
- Received U.S. Food and Drug Administration clearance for the Company's IND application for GRI-0621 for the treatment of IPF;
- Presented translational data demonstrating connection between NKT cells and the pathogenesis of IPF at the 2023 Pittsburgh-Ireland International Lung Conference and data at the 7th Annual Antifibrotic Drug Development Summit;
- Entered into a key collaboration with the UK Consortia, National Institute for Health and Care Research Respiratory Translational Research Collaboration to advance the translational work in IPF patients and prioritize recruitment for the Phase 2a biomarker study; and
- Announced publication of comprehensive type 1 invariant NKT (iNKT) cell review in Frontiers in Immunology demonstrating a key role of iNKT cells in modulating various fibrotic conditions.

GRI-0621: Type 1 invariant NKT (iNKT) antagonist in development for the treatment of IPF.

IPF is a rare chronic progressive pulmonary disease with abnormal scarring of the lung blocking the movement of oxygen into the bloodstream. Currently available treatments for IPF are limited with only two approved drugs that come with significant side-effects, limited compliance and no impact on survival[1].

GRI Bio's lead program, GRI-0621, is a small molecule RAR-βγ dual agonist that inhibits the activity of human iNKT cells. In preliminary trials to date and previous trials with the oral formulation, GRI-0621 has been shown to improve fibrosis in multiple disease models and improve liver function tests and other markers of inflammation and injury in patients.

The Company plans to leverage the 505(b)(2) regulatory pathway and has launched a Phase 2a biomarker study evaluating GRI-0621 for the treatment of IPF. For more information about the Phase 2a study, please visit clinicaltrials.gov and reference identifier NCT06331624.

Expected GRI-0621 Upcoming Milestones

- H1 2024: Report interim data from Phase 2a biomarker study
- H2 2024: Report topline results from Phase 2a biomarker study

GRI-0803: Novel activator of human type 2 NKT cells in development for the treatment of autoimmune disorders, with an initial focus on SLE.

SLE is an autoimmune disease in which the immune system attacks its own tissue and organs. SLE is the most common form of lupus. Current treatments are limited, consisting primarily of immunosuppressive therapies.

GRI Bio's second asset in development, GRI-0803, is a novel activator of human type 2 NKT cells. Activation of type 2 NKT leads to a dendritic cell-mediated inhibition of iNKT cells. In the Company's preclinical studies, type 2 NKT activating molecules, GRI-0803 and GRI-0124, were observed to inhibit both murine and human iNKT cells. Oral administration of these type 2 NKT activating molecules was observed to inhibit lupus nephritis and to significantly improve overall survival.

Expected GRI-0803 Upcoming Milestones

- H1 2024: Complete IND-enabling studies
- H1 2024: File IND and launch Phase 1a/b
- Q3 2024: Report Phase 1a single ascending dose (SAD) study topline results
- Q4 2024: Report Phase 1b multiple ascending dose (MAD) study topline results

Summary of Financial Results for Fiscal Year 2023

Net loss was $13.0 million for the year ended December 31, 2023.

Research and development expenses were $3.2 million and $0.2 million for the years ended December 31, 2023 and 2022, respectively. The $3.0 million increase in research and development expenses was primarily due to increases of $1.9 million in expenses related to the development program of GRI-0621, $0.4 million in personnel expenses, $0.6 million in consulting fees, and $0.1 million in intellectual property expenses.

General and administrative expenses were $8.2 million and $2.0 million for the years ended December 31, 2023 and 2022, respectively. The $6.2 million increase was primarily due to an increase of $4.2 million in legal, accounting and other fees associated with the previously disclosed merger between the Company (formerly known as Vallon Pharmaceuticals, Inc.) and GRI Bio Operations, Inc. (formerly known as GRI Bio, Inc.) as well as fees associated with operating as a public company, an increase of $1.6 million in personnel costs, an increase of $0.3 million in insurance expense, and an increase of $0.2 million in consulting and other general and administrative expenses.

As of December 31, 2023, the Company had cash and cash equivalents of approximately $1.8 million. Subsequent to year end, in February 2024 the Company closed a public offering with participation from healthcare focused institutional investors for aggregate gross proceeds of $5.5 million. Based on the Company's current operating plan, the Company believes that its existing cash and cash equivalents will be sufficient to fund its operating expenses and capital

expenditure requirements into the third quarter of 2024

About GRI Bio, Inc.

GRI Bio is a clinical-stage biopharmaceutical company focused on fundamentally changing the way inflammatory, fibrotic and autoimmune diseases are treated. GRI Bio's therapies are designed to target the activity of NKT cells, which are key regulators earlier in the inflammatory cascade, to interrupt disease progression and restore the immune system to homeostasis. NKT cells are innate-like T cells that share properties of both NK and T cells and are a functional link between the innate and adaptive immune responses. iNKT cells play a critical role in propagating the injury, inflammatory response, and fibrosis observed in inflammatory and fibrotic indications. GRI Bio's lead program, GRI-0621, is an inhibitor of iNKT cell activity and is being developed as a novel oral therapeutic for the treatment of IPF, a serious disease with significant unmet need. The Company is also developing a pipeline of novel type 2 NKT agonists for the treatment of SLE. Additionally, with a library of over 500 proprietary compounds, GRI Bio has the ability to fuel a growing pipeline.

Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements may be identified by the use of words such as "anticipate," "believe," "contemplate," "could," "estimate," "expect," "intend," "seek," "may," "might," "plan," "potential," "predict," "project," "target," "aim," "should," "will," "would," or the negative of these words or other similar expressions. These forward-looking statements are based on the Company's current beliefs and expectations. Forward-looking statements include, but are not limited to, statements regarding: the Company's expectations with respect to development and commercialization of the Company's product candidates, the timing of initiation or completion of clinical trials and availability of resulting data, the potential benefits and impact of the Company's clinical trials and product candidates and any implication that the data or results observed in preclinical trials or earlier studies or trials will be indicative of results of later studies or clinical trials, the Company's beliefs and expectations regarding potential stakeholder value and future financial performance, the Company's beliefs about the timing and outcome of regulatory approvals and potential regulatory approval pathways, the Company's expected milestones for 2024, and the Company's beliefs and expectations regarding the sufficiency of its existing cash and cash equivalents to fund its operating expenses and capital expenditure requirements. Actual results may differ from the forward-looking statements expressed by the Company in this press release and consequently, you should not rely on these forward-looking statements as predictions of future events. These forward-looking statements are subject to inherent uncertainties, risks and assumptions that are difficult to predict, including, without limitation: (1) the inability to maintain the listing of the Company's common stock on Nasdaq and to comply with applicable listing requirements; (2) changes in applicable laws or regulations; (3) the inability of the Company to raise financing in the future; (4) the success, cost and timing of the Company's product development activities; (5) the inability of the Company to obtain and maintain regulatory clearance or approval for its respective products, and any related restrictions and limitations of any cleared or approved product; (6) the inability of the Company to identify, in-license or acquire additional technology; (7) the inability of the Company to compete with other companies currently marketing or engaged in the development of products and services that the Company is currently developing; (8) the size and growth potential of the markets for the Company's products and services, and their respective ability to serve those markets, either alone or in partnership with others; (9) the failure to achieve any milestones or receive any milestone payments under any agreements; (10) inaccuracy in the Company's estimates regarding expenses, future revenue, capital requirements and needs for and the ability to obtain additional financing; (11) the Company's ability to protect and enforce its intellectual property portfolio, including any newly issued patents; and (12) other risks and uncertainties indicated from time to time in the Company's filings with the U.S. Securities and Exchange Commission (the "SEC"), including the risks and uncertainties described in the "Risk Factors" section of the Company's most recent Annual Report on Form 10-K filed with the SEC on March 28, 2024 and subsequently filed reports. Forward-looking statements contained in this announcement are made as of this date, and the Company undertakes no duty to update such information except as required under applicable law.

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[1] T. M. Maher *et al.*, Global incidence and prevalence of idiopathic pulmonary fibrosis. *Respir Res* **22**, 197 (2021)

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