Verve Therapeutics Highlights Recent Company Progress and Reports Third Quarter 2023 Financial Results

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U.S. Food and Drug Administration (FDA) Clears Investigational New Drug Application for VERVE-101 in Patients with Heterozygous Familial Hypercholesterolemia (HeFH)

Collaboration with Eli Lilly and Company (Lilly) Expands Through Lilly's Acquisition of Product Rights to Verve's PCSK9 and ANGPTL3 Programs from Beam Therapeutics

Interim Data from the heart-1 Phase 1b Clinical Trial of VERVE-101 in Patients with HeFH to be Presented at the American Heart Association (AHA) Scientific Sessions 2023 on November 12 at 3:30 p.m. ET; Company to Host Investor Event and Webcast on November 12 at 6:30 p.m. ET

Cash, Cash Equivalents and Marketable Securities of $485.2 Million with Cash Runway into 2026

BOSTON, Nov. 07, 2023 (GLOBE NEWSWIRE) -- Verve Therapeutics, Inc., a clinical-stage biotechnology company pioneering a new approach to the care of cardiovascular disease with single-course gene editing medicines, today reported recent company progress and financial results for the third quarter of 2023.

"Verve was founded in 2018 with a vision to develop single-course gene editing medicines for cardiovascular disease and throughout this year, we have made tremendous strides towards realizing that vision," said Sekar Kathiresan, M.D., co-founder and chief executive officer of Verve. "We continue to progress the heart-1 Phase 1b trial of VERVE-101 in patients in the United Kingdom and New Zealand, and we are looking forward to presenting interim data from this trial at the upcoming AHA meeting. We have obtained clearance of our first IND application from the FDA, which now enables us to add U.S. sites to the heart-1 trial and begins the regulatory path in the U.S. for VERVE-101. Beyond VERVE-101, we remain focused on advancing our pipeline and are on-track to initiate Phase 1 clinical trials for VERVE-102 in the first half of 2024 and VERVE-201 in the second half of 2024. Finally, we are thrilled to gain Lilly as a collaborator for our *PCSK9* and *ANGPTL3* programs. Lilly brings development expertise as well as a track record of successful commercialization of cardiometabolic medicines. We believe all of this progress in 2023 moves us closer to being able to deliver a new class of medicines to patients living with atherosclerotic cardiovascular disease (ASCVD)."

VERVE-101 heart-1 Phase 1b Interim Data to be Presented at the American Heart Association's Scientific Sessions 2023

- VERVE-101, an *in vivo* base editing medicine delivered as a one-time intravenous infusion, is designed to inactivate the *PCSK9* gene in liver cells, turning off liver production of PCSK9 protein and thereby durably reducing low-density lipoprotein cholesterol (LDL-C). VERVE-101 is being developed initially for the treatment of patients living with HeFH.
- VERVE-101 is being evaluated in the Phase 1b heart-1 clinical trial with trial endpoints of safety and tolerability as well as blood PCSK9 protein and LDL-C levels. In September, the company announced that it will present interim data from the heart-1 trial in a late-breaking science presentation at the AHA Scientific Sessions 2023 on Sunday, November 12 from 3:30 – 3:40 p.m. ET. At AHA, Verve expects to report initial safety, tolerability and pharmacodynamic data, as well as changes in blood PCSK9 protein and LDL-C levels, from patients across four single-ascending dose cohorts.
- Verve is hosting an investor event on Sunday, November 12 from 6:30 – 8:30 p.m. ET in Philadelphia. The event will be accessible virtually and in-person. The webcast will be available under the "Events" section of the company's website at https://ir.vervetx.com/events. Following the live event, an archived replay of the webcast will be made available on the company website.
- In October, Verve announced that the U.S. FDA cleared its Investigational New Drug Application for VERVE-101 in patients living with HeFH. Verve plans to activate U.S. sites to supplement the already active sites in the United Kingdom and New Zealand.

VERVE-102 On-Track for Clinical Trial Initiation in First Half of 2024

- VERVE-102 is an *in vivo* base editing medicine that aims to inactivate the *PCSK9* gene in a

similar way to VERVE-101. VERVE-101 and VERVE-102 share an identical guide RNA targeting *PCSK9* as well as similar messenger RNA expressing an adenine base editor; however, VERVE-102 is delivered using the company's proprietary GalNAc-LNP delivery technology. Preclinical studies with VERVE-102 in mice and non-human primates demonstrated effective *in vivo* liver gene editing and significant reduction of blood PCSK9 protein.
- Preclinical development to support a regulatory submission for VERVE-102 began in early 2022, and, following regulatory clearance, Verve expects to initiate a Phase 1b clinical trial with VERVE-102 for patients with HeFH in the first half of 2024.

VERVE-201 On-Track for Clinical Trial Initiation in Second Half of 2024

- VERVE-201, an *in vivo* base editing medicine delivered as a one-time intravenous infusion, is designed to inactivate the *ANGPTL3* gene in liver cells, turning off liver production of blood ANGPTL3 and thereby durably reducing blood LDL-C and triglyceride-rich lipoproteins. VERVE-201 is being developed initially for the treatment of patients living with homozygous familial hypercholesterolemia (HoFH), a rare and often fatal genetic subtype of premature ASCVD characterized by extremely high blood LDL-C. VERVE-201 aims to reduce the heavy treatment burden associated with available therapies for HoFH including the requirement for multiple oral, injectable, and intravenous infusions, often administered over decades.
- Preclinical studies to support a regulatory submission for clinical development of VERVE-201 are ongoing, and, following regulatory clearance, Verve expects to initiate a Phase 1b clinical trial with VERVE-201 in the second half of 2024.

Corporate Update

- In October 2023, Verve announced the expansion of its relationship with Lilly which has acquired from Beam Therapeutics certain product rights to Verve's cardiovascular *in vivo* gene editing programs targeting *PCSK9* and *ANGPTL3*, as well as a third undisclosed cardiovascular disease target. In June 2023, Verve and Lilly entered into an exclusive research collaboration focused on advancing Verve's preclinical stage *in vivo* gene editing program targeting lipoprotein(a) (Lp(a)).
- In September 2023, Verve announced the appointment of Frederick "Fred" T. Fiedorek, M.D., as chief medical officer.
- In addition, Jason Politi, B.S., M.B.A., who has served as Verve's senior vice president, technical operations since 2021, has been promoted to the role of chief technical operations officer.

Other Upcoming Investor Events
Verve plans to participate in fireside chats during the following upcoming investor events:

- Stifel Healthcare Conference, November 14, New York City
- Jefferies London Healthcare Conference, November 16, London, UK

Third Quarter 2023 Financial Results

- **Cash Position:** Verve ended the third quarter of 2023 with $485.2 million in cash, cash equivalents, and marketable securities. Verve expects its existing cash, cash equivalents, and marketable securities to be sufficient to fund its operations into 2026.
- **Collaboration Revenue:** Collaboration revenue was $3.1 million for the third quarter of 2023, which was related to research services performed under the collaboration agreement with Vertex Pharmaceuticals Incorporated (Vertex) and the Lp(a) collaboration with Lilly.

Collaboration revenue in the third quarter of 2022 was $0.9 million which was related to research services performed under the collaboration agreement with Vertex.

- **Research & Development (R&D) Expenses:** R&D expenses were $43.8 million for the third quarter of 2023, compared to $35.2 million for the third quarter of 2022.
- **General & Administrative (G&A) Expenses:** G&A expenses were $11.7 million for the third quarter of 2023, compared to $9.6 million for the third quarter of 2022.
- **Net Loss:** Net loss was $45.8 million, or $0.72 basic and diluted net loss per share, for the third quarter of 2023, compared to $45.2 million, or $0.79 basic and diluted net loss per share, for the third quarter of 2022.

About Verve Therapeutics
Verve Therapeutics, Inc. (Nasdaq: VERV) is a clinical-stage genetic medicines company pioneering a new approach to the care of cardiovascular disease, potentially transforming treatment from chronic management to single-course gene editing medicines. The company's initial three programs – VERVE-101, VERVE-102, and VERVE-201 – target genes that have been extensively validated as targets for lowering low-density lipoprotein cholesterol (LDL-C), a root cause of cardiovascular disease, in order to durably reduce blood LDL-C levels. VERVE-101 and VERVE-102 are designed to permanently turn off the *PCSK9* gene in the liver and are being developed initially for heterozygous familial hypercholesterolemia (HeFH) and ultimately to treat atherosclerotic cardiovascular disease (ASCVD) patients not at goal on oral therapy. VERVE-201 is designed to permanently turn off the *ANGPTL3* gene in the liver and is initially being developed for homozygous familial hypercholesterolemia (HoFH) and ultimately to treat patients with refractory hypercholesterolemia. For more information, please visit www.VerveTx.com.

Cautionary Note Regarding Forward Looking Statements
This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 that involve substantial risks and uncertainties, including statements regarding the company's ability to enroll patients in its ongoing heart-1 trial and activate clinical trial sites in the United States; the timing and availability of clinical data from its heart-1 trial; the expected timing of initiating clinical trials of VERVE-102 and VERVE-201; its research and development plans; the potential advantages and therapeutic potential of the company's programs, including VERVE-101, VERVE-102, and VERVE-201; and the period over which the company believes that its existing cash, cash equivalents and marketable securities will be sufficient to fund its operating expenses. All statements, other than statements of historical facts, contained in this press release, including statements regarding the company's strategy, future operations, future financial position, prospects, plans and objectives of management, are forward-looking statements. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in, or implied by, such forward-looking statements. These risks and uncertainties include, but are not limited to, risks associated with the company's limited operating history; the company's ability to timely submit and receive approvals of regulatory applications for its product candidates; advance its product candidates in clinical trials; initiate, enroll and complete its ongoing and future clinical trials on the timeline expected or at all; correctly estimate the potential patient population and/or market for the company's product candidates; replicate in clinical trials positive results found in preclinical studies and/or earlier-stage clinical trials of VERVE-101, VERVE-102, and VERVE-201; advance the development of its product candidates under the timelines it anticipates in current and future clinical trials; obtain, maintain or protect intellectual property rights related to its product candidates; manage expenses; and raise the substantial additional capital needed to achieve its business objectives. For a discussion of other risks and uncertainties, and other important factors, any of which could cause the company's actual results to differ from those contained in the forward-looking statements, see the "Risk Factors" section, as well as discussions of potential risks, uncertainties and other important factors, in the company's most recent filings with the Securities and Exchange Commission and in other filings that the company makes with the Securities and Exchange Commission in the future. In addition, the forward-looking statements included in this press release represent the company's views as of the date hereof and should not be relied upon as representing the company's views as of any date subsequent to the date hereof. The company anticipates that subsequent events and developments will cause the company's views to change. However, while the company may elect to update these forward-looking statements at some point in the future, the company specifically disclaims any obligation to do so.

Investor Contact
Jen Robinson
Verve Therapeutics, Inc.
jrobinson@vervetx.com

Media Contact
Ashlea Kosikowski
1AB
ashlea@1abmedia.com

Verve Therapeutics, Inc.
Selected Condensed Financial Information
(in thousands, except share and per share amounts)
(unaudited)

	Three months ended September 30,		Nine months ended September 30,	
Condensed consolidated statements of operations	**2023**	**2022**	**2023**	**2022**
Collaboration revenue	$ 3,117	$ 929	$ 6,614	$ 929
Operating expenses:				
Research and development	43,765	35,197	138,135	92,811
General and administrative	11,686	9,592	37,655	26,095
Total operating expenses	55,451	44,789	175,790	118,906

Loss from operations	(52,334)	(43,860)	(169,176)	(117,977)
Other income (expense):				
Change in fair value of success payment liability	802	(3,306)	878	(691)
Interest and other income, net	5,841	1,976	16,825	2,366
Total other income (expense), net	6,643	(1,330)	17,703	1,675
Loss before provision for income taxes	(45,691)	(45,190)	(151,473)	(116,302)
Provision for income taxes	(67)	-	(243)	-
Net loss	$ (45,758)	$ (45,190)	$ (151,716)	$ (116,302)
Net loss per common share, basic and diluted	$ (0.72)	$ (0.79)	$ (2.43)	$ (2.26)
Weighted-average common shares used in net loss per share, basic and diluted	63,211,849	57,207,125	62,322,965	51,516,037

Condensed consolidated balance sheet data	**September 30, 2023**	**December 31, 2022**
Cash, cash equivalents and marketable securities	$ 485,226	$ 554,808
Total assets	$ 612,407	$ 679,223
Total liabilities	$ 152,038	$ 128,291
Total stockholders' equity	$ 460,369	$ 550,932