



Trovagene Announces Fourth Quarter and Full-Year 2019 Results

February 27, 2020

SAN DIEGO, Feb. 27, 2020 /PRNewswire/ -- **Trovagene, Inc.** (Nasdaq: TROV), a clinical-stage, Precision Cancer Medicine™ oncology therapeutics company developing drugs that target cell division (mitosis) for the treatment of various cancers including prostate, colorectal and leukemia, today announced company highlights and financial results for the fourth quarter and full-year ended December 31, 2019. The company is issuing this press release in lieu of conducting a conference call.

"We continue to advance the clinical development of onvansertib, our first-in-class, third-generation, oral and highly selective Polo-like Kinase 1 (PLK1) inhibitor, including very encouraging to-date results from our Phase 1b/2 trial in KRAS-mutated metastatic colorectal cancer (mCRC)," said Dr. Thomas Adams, Chief Executive Officer and Chairman of Trovagene. "Regardless of the specific KRAS mutation, we are seeing quantitative decreases in the mutational burden of this once considered 'undruggable' mutation and confirmation of the activity of onvansertib by radiographic scans showing tumor regression in all treated patients. Additionally, in our Phase 2 study in metastatic castration-resistant prostate cancer (mCRPC), onvansertib is demonstrating its ability to overcome resistance in patients treated first-line with androgen-receptor signaling inhibitor, Zytiga®. Data presented earlier this month at ASCO-GU show both efficacy and durability of response to treatment when onvansertib is added to daily Zytiga® therapy. Notably, several patients currently on treatment have had progression-free survival of greater than seven months. Enrollment is also on track in our Phase 2 study of onvansertib in patients with acute myeloid leukemia (AML). We continue to see efficacy in this difficult-to-treat, relapsed/refractory patient population, including in patients who have relapsed following initial treatment with venetoclax, a scenario with limited treatment options and a great need for new targeted therapeutics."

The Company has advanced its business in the fourth quarter of 2019, and to-date in 2020, with the following activities and milestone achievements:

- **Announced presentation of Phase 2 data demonstrating the ability of onvansertib to overcome Zytiga®-resistance and provide clinical benefit for mCRPC patients**

On February 13, 2020, we announced the presentation of positive data from our ongoing Phase 2 trial of onvansertib in combination with Zytiga® for the treatment of patients with Zytiga®-resistant mCRPC. The data demonstrates the efficacy of onvansertib in Zytiga®-resistant mCRPC across known androgen receptor resistance mechanisms. Additionally, onvansertib-induced decreases in circulating tumor cells (CTCs) is a surrogate for efficacy and associated with greater progression-free survival in mCRPC patients.

- **Announced data demonstrating the effectiveness of onvansertib as a pan-KRAS inhibitor with confirmed tumor regression and clinical benefit achieved in KRAS-mutated mCRC patients**

On January 27, 2020, we announced the presentation of data from our ongoing Phase 1b/2 trial of onvansertib in combination with FOLFIRI/Avastin in patients with KRAS-mutated mCRC. All patients treated showed tumor regression by radiographic scan at 8 weeks and confirmation by further tumor shrinkage at 16 weeks, with clinical benefit achieved in 100% of patients. Tumor regression occurred across all major KRAS mutations associated with mCRC, an indication of onvansertib's pan-KRAS inhibitory effect; three patients had greater than 25% tumor shrinkage. One patient is proceeding to curative surgery, which is considered to be unprecedented in this patient population, in which there has been only a 5% response rate to standard-of-care therapy.

- **Announced positive data presented in an oral session at the American Society of Hematology ("ASH") conference demonstrating efficacy, durability of response and safety of onvansertib in completed Phase 1b trial in AML**

On December 9, 2019, we announced the presentation of data demonstrating efficacy, durability of response and safety of onvansertib from the completed Phase 1b segment of the ongoing trial in AML, in an oral session at ASH. Efficacy was observed in patients treated at onvansertib doses ranging from 27 to 90 mg/m², with a complete response (CR) and CR with incomplete count recovery (Cri) rate of 31% (5 out of 16) of patients. Treatment was well tolerated; adverse events related to onvansertib were primarily on-target hematological (based on mechanism of action) and were easily managed and reversible. Biomarker positive patients showed a higher response to treatment; 67% (4 out of 6) of patients had marked decreases in bone marrow blast cells vs only 18% (1 out of 11) biomarker negative patients.

- **Announced data showing the ability of onvansertib to rescue patients previously treated with, and resistant to, venetoclax in AML**

On December 4, 2019, we announced data showing the ability of onvansertib to rescue venetoclax-resistant AML patients. Patients develop resistance to venetoclax in approximately 11 months following the start of treatment with no viable therapeutic options and a median survival of only 1.7 to 2.3 months and a poor prognosis. Onvansertib as a single agent inhibits tumor growth in both venetoclax-resistant in-vitro and in-vivo AML models. The combination of onvansertib and venetoclax is synergistic, which supports the addition of onvansertib to venetoclax in venetoclax-resistant AML patients.

- **Announced positive response to treatment in Phase 2 trial of onvansertib in patients with mCRPC**

On November 14, 2019, we announced data demonstrating positive response to treatment in patients enrolled in our Phase 2 trial of onvansertib in combination with Zytiga® (abiraterone acetate) in patients with mCRPC. 72% of patients had decreases in PSA levels with the addition of onvansertib following 1 cycle of treatment. 60% of patients completing 3 months of treatment and evaluable for efficacy achieved the primary endpoint of disease control.

- **Announced data presented at ESMO providing rationale for a clinical trial of onvansertib in subset of patients with Highly-Aggressive Triple Negative Breast Cancer (TNBC)**

On October 2, 2019, we announced the presentation of data in a poster at ESMO demonstrating significant tumor regression observed with onvansertib in combination with standard-of-care paclitaxel in models of p53-mutated TNBC. Onvansertib's preclinical data provides rationale for conducting a clinical trial targeting the 80% of TNBC that harbors the p53 mutation. The combination has potential to address critical medical needs to

provide targeted treatment options to overcome resistance to paclitaxel as a single agent therapy in TNBC.

Fourth Quarter 2019 Financial Results

Total operating expenses were approximately \$4.4 million for the three months ended December 31, 2019, an increase of \$0.2 million from \$4.2 million for the same period in 2018. The increase in operating expenses is attributed to advancing the onvansertib clinical development programs.

Net cash used in operating activities in the fourth quarter of 2019 was \$3.3 million, compared to \$3.6 million in the fourth quarter of 2018. The quarter-over-quarter decrease of \$0.3 million can be attributed primarily to a favorable change in assets and liabilities offset by increased expenses pertaining to the clinical development of onvansertib.

Research and development expenses increased by approximately \$0.4 million to \$2.9 million for the three months ended December 31, 2019 from \$2.5 million for the same period in 2018. The overall increase in research and development expenses was primarily due to the increased outside service costs for advancing clinical studies related to the development of our drug candidate, onvansertib. We expect increases in research and development costs to continue as we advance the onvansertib clinical development programs in mCRC, mCRPC and AML.

Selling, general and administrative expenses decreased by approximately \$0.2 million to \$1.5 million for the three months ended December 31, 2019 from \$1.7 million for the same period in 2018. The reduction is primarily due to a decrease in outside services and professional fees.

The weighted average basic and diluted shares of common stock outstanding used to calculate per share results for the three months ended December 31, 2019 was 8.3 million.

As of December 31, 2019, Trovogene had approximately \$10.2 million of cash and cash equivalents.

About Trovogene, Inc.

Trovogene is a clinical-stage, oncology therapeutics company, taking a precision medicine approach to develop drugs that target mitosis (cell division) to treat various types of cancer, including leukemias, lymphomas and solid tumors. Trovogene has intellectual property and proprietary technology that enables the Company to analyze circulating tumor DNA (ctDNA) and clinically actionable markers to identify patients most likely to respond to specific cancer therapies. Trovogene plans to continue to vertically integrate its tumor genomics technology with the development of targeted cancer therapeutics. For more information, please visit <https://www.trovogeneoncology.com>.

Forward-Looking Statements

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of words such as "anticipate," "believe," "forecast," "estimated" and "intend" or other similar terms or expressions that concern Trovogene's expectations, strategy, plans or intentions. These forward-looking statements are based on Trovogene's current expectations and actual results could differ materially. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, our need for additional financing; our ability to continue as a going concern; clinical trials involve a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results; our clinical trials may be suspended or discontinued due to unexpected side effects or other safety risks that could preclude approval of our product candidates; uncertainties of government or third party payer reimbursement; dependence on key personnel; limited experience in marketing and sales; substantial competition; uncertainties of patent protection and litigation; dependence upon third parties; our ability to develop tests, kits and systems and the success of those products; regulatory, financial and business risks related to our international expansion and risks related to failure to obtain FDA clearances or approvals and noncompliance with FDA regulations. There are no guarantees that any of our technology or products will be utilized or prove to be commercially successful. Additionally, there are no guarantees that future clinical trials will be completed or successful or that any precision medicine therapeutics will receive regulatory approval for any indication or prove to be commercially successful. Investors should read the risk factors set forth in Trovogene's Form 10-K for the year ended December 31, 2019, and other periodic reports filed with the Securities and Exchange Commission. While the list of factors presented here is considered representative, no such list should be considered to be a complete statement of all potential risks and uncertainties. Unlisted factors may present significant additional obstacles to the realization of forward-looking statements. Forward-looking statements included herein are made as of the date hereof, and Trovogene does not undertake any obligation to update publicly such statements to reflect subsequent events or circumstances.

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Trovogene, Inc.

Condensed Statements of Operations

(in thousands, except for per share amounts)

	Three Months Ended		Year Ended	
	December 31,	December 31,	December 31,	December 31,
	2019	2018	2019	2018
	(unaudited)			
Revenues:				
Royalties	\$93	\$76	\$243	\$250
Services	—	2	2	128
Total revenues	93	78	245	378
Costs and expenses:				
Cost of revenues	—	—	—	597
Research and development	2,865	2,497	11,162	8,164
Selling, general and administrative	1,517	1,685	5,761	8,006
Restructuring charges	—	—	—	664
Total operating expenses	4,382	4,182	16,923	17,431
Loss from operations	(4,289)	(4,104)	(16,678)	(17,053)
Net interest income	46	75	234	194

Gain from change in fair value of derivative financial instruments warrants	1	38	28	617
Gain on extinguishment of debt	—	—	—	18
Other (loss) income, net	—	(168)	2	(237)
Net loss	(4,242)	(4,159)	(16,414)	(16,461)
Preferred Stock Dividend	(6)	(6)	(293)	(2,794)
Net loss attributable to common stockholders	\$(4,248)	\$(4,165)	\$(16,707)	\$(19,255)
Net loss per common share - basic and diluted	\$(0.51)	\$(1.09)	\$(2.80)	\$(8.26)
Weighted-average shares outstanding - basic and diluted	8,329	3,832	5,974	2,330

Trovagene, Inc.
Condensed Balance Sheets
(in thousands)

	December 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 10,195	\$ 11,453
Accounts receivable and unbilled receivable	204	168
Prepaid expenses	955	1,144
Total current assets	11,354	12,765
Property and equipment, net	878	1,304
Operating lease right-of-use assets	697	—
Other assets	158	103
Total Assets	\$ 13,087	\$ 14,172
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	\$ 656	\$ 665
Accrued expenses	3,260	1,772
Operating lease liabilities	866	—
Deferred rent, current portion	—	486
Total current liabilities	4,782	2,923
Derivative financial instruments warrants	4	32
Operating lease liabilities, net of current portion	861	—
Deferred rent, net of current portion	—	1,091
Other liabilities	129	42
Total Liabilities	5,776	4,088
Stockholders equity	7,311	10,084
Total liabilities and stockholders equity	\$ 13,087	\$ 14,172

Trovagene, Inc.
Condensed Statements of Cash Flows
(in thousands)

	Year Ended December 31, 2019 2018	
Operating activities		
Net loss	\$(16,414)	\$(16,461)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	494	859
Stock based compensation expense	885	2,175
Change in fair value of derivative financial instruments - warrants	(28)	(617)
Release of clinical trial funding commitment	703	—
Gain on extinguishment of debt	—	(18)
Other non-cash items	—	610
Changes in operating assets and liabilities	1,092	253
Net cash used in operating activities	(13,268)	(13,199)
Investing activities:		
Net proceeds from disposal (purchase) of capital equipment	(68)	23
Net cash provided (used) in investing activities	(68)	23
Financing activities:		
Proceeds from sales of common stock and warrants, net of expenses	8,818	11,779
Proceeds from sales of Series B Convertible Preferred Stock, net of expenses	—	4,387
Costs related to the clinical trial funding commitment	(40)	—
Proceeds from exercise of warrants	3,300	1,613
Repayment of debt	—	(1,376)
Net cash provided by financing activities	12,078	16,403
Net change in cash and cash equivalents	(1,258)	3,227
Cash and cash equivalents Beginning of period	11,453	8,226
Cash and cash equivalents End of period	\$10,195	\$11,453

SOURCE Trovogene, Inc.