

Trovagene and Nerviano Announce License Agreement for therapeutic candidate PCM-075

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SAN DIEGO and NERVIANO, Italy, March 15, 2017 /[PRNewswire](#)/ -- Trovagene, Inc. (NASDAQ: TROV), a precision medicine biotechnology company, and Nerviano Medical Sciences, S.r.l., a leading oncology discovery organization, today announced that they have signed a license agreement that grants Trovagene exclusive global development and commercialization rights to NMS-1286937, which Trovagene refers to as PCM-075. PCM-075 is an oral, investigative drug and a highly-selective adenosine triphosphate (ATP) competitive inhibitor of the serine/threonine polo-like-kinase 1 (PLK 1).

"We are excited to license PCM-075 and look forward to beginning a development program in patients with acute myeloid leukemia (AML)," said Bill Welch, CEO of Trovagene. "This transaction allows Trovagene to execute on our strategy to vertically integrate our ctDNA Precision Cancer Monitoring[®] (PCM) technology with precision cancer therapeutics by developing drugs where our deep understanding of tumor genomics may allow for effective targeting of appropriate cancer patients."

"We are very pleased to start a collaboration with Trovagene, a world leader in precision medicine," said Andrea Agazzi, President of the NMS Group. "Both Nerviano and Trovagene share the common goal of developing innovative new drugs for cancer patients. We're proud of this new important agreement as a further confirmation of our commitment to develop high level innovation through partnering. Our continuously increasing track record involves, in fact, companies at a worldwide level like Trovagene."

Under the terms of the license agreement, Trovagene will assume sole responsibility for global development and commercialization of PCM-075. Nerviano will receive an upfront payment of \$2.0 million, as well as development and regulatory-based milestone payments and royalty payments on future net sales of PCM-075. Nerviano is the current manufacturer for bulk and finished drug for PCM-075 and Trovagene has all rights to manufacture bulk and finished goods.

PLK1 is over-expressed in several different tumor types, including breast, prostate, ovarian, lung, gastric and colon cancers, as well as hematological malignancies. A phase 1 safety study of PCM-075 was successfully completed in patients with advanced metastatic disease. Trovagene plans to develop PCM-075 initially in AML, where both Trovagene and Nerviano believe PCM-075's target selectivity for PLK1, along with its oral availability, and shorter half-life as compared to other polo-like-kinase inhibitors, may be advantageous features of the drug.

Trovagene has significant experience and expertise with biomarkers and technology in cancer, including AML. Trovagene is the patent holder of NPM1 for diagnosis and monitoring of patients. NPM1-mutated AML is a founder genetic marker in leukemia and accounts for approximately one-third of all AML patients.



Trovagene will use its PCM technology to profile other dominant AML markers, such as FLT3, DNMT3A, NRAS, and KIT, to identify and measure patient therapy response.

About Nerviano Medical Sciences

Nerviano Medical Sciences is the largest Oncology-focused R&D company in Italy, and among the most important in Europe. Nerviano has already accomplished several important cooperation or licensing agreements with pharmaceutical companies, including Genentech (Roche), Pfizer, Array Pharmaceuticals and Servier, as well as with biotechnology companies and the world of academia. On 31 December 2011, the Lombardy Region became the major shareholder of NMS, through the FRRB (Regional Foundation for Biomedical Research). For further information on Nerviano Medical Sciences: www.nervianoms.com.

About Trovagene, Inc.

Trovagene is a biotechnology company that leverages its proprietary Precision Cancer Monitoring[®] (PCM) technology in tumor genomics to effectively develop oncology therapeutics to target appropriate cancer patient populations. Trovagene has broad intellectual property and proprietary technology to measure circulating tumor DNA (ctDNA) in urine and blood to identify and quantify clinically actionable markers for predicting response to cancer therapies. Trovagene offers its PCM technology at its CLIA/CAP – accredited laboratory. Trovagene plans to continue to vertically integrate its PCM technology with precision cancer therapeutics by developing drugs. For more information, please visit www.trovagene.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 Trovagene's expectations, strategy, plans or intentions. These forward-looking statements are based on Trovagene'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, or that Trovagene's strategy to design its liquid biopsy tests to report on clinically actionable cancer genes will ultimately be successful or result in better reimbursement outcomes. 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 Trovagene's Form 10-K for the year ended December 31, 2016 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 Trovagene does not undertake any obligation to update publicly such statements to reflect subsequent events or circumstances.

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