Madrigal Pharmaceuticals and Tarveda Therapeutics Announce Exclusive License Agreement for HSP90 Drug Conjugate Oncology Platform

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- PEN-866 positioned to begin clinical trials in 2017 –

- Total potential payments to Madrigal may exceed $249 Million –

CONSHOHOCKEN, Pa. and WATERTOWN, Mass., Sept. 19, 2016 (GLOBE NEWSWIRE) -- Madrigal Pharmaceuticals, Inc. (NASDAQ:MDGL) and Tarveda Therapeutics, Inc. today announced an exclusive worldwide license agreement providing for the discovery, development and commercialization by Tarveda of products based on Madrigal's HSP90 Drug Conjugate program, including the lead clinical candidate, PEN-866. Madrigal is a clinical-stage biopharmaceutical company focused on the development and commercialization of innovative therapeutic candidates for the treatment of cardiovascular, metabolic and liver diseases, and Tarveda Therapeutics, Inc., is a biopharmaceutical company discovering and developing Pentarins™ as a new class of targeted anti-cancer medicines to advance the treatment of patients with solid tumors.

HSP90 drug conjugates are designed to increase cancer cell killing while reducing collateral damage to normal cells and overcome the challenges of current chemotherapies and other payloads, which are commonly limited by insufficient drug exposure in the tumor and/or systemic toxicities. HSP90 drug conjugates are small-molecule conjugates consisting of an HSP90 targeting molecule joined to an anti-cancer payload via a linker that is optimized for controlled release of the payload inside cancer cells. The conjugate's sustained anti-tumor effect comes from selectively accumulating and retaining the conjugate and, importantly, its potent payload in tumors. HSP90 drug conjugates contrast with previous HSP90 inhibitors that were designed to only inhibit HSP90. Madrigal acquired the drug conjugate platform via its recent merger with Synta Pharmaceuticals, Inc.

The lead HSP90 drug conjugate, PEN-866, is a small-molecule drug conjugate that comprises an HSP90 ligand conjugated to SN-38, the highly-potent, active metabolite of the chemotherapeutic agent irinotecan. PEN-866 binds with high affinity to the intracellular HSP90 target. Once bound to its target, PEN-866 delivers the tumor-killing SN-38 payload. PEN-866 has shown an impressive degree of efficacy and durability of response in multiple preclinical tumor models, including patient-derived xenograft models. Studies demonstrate that SN-38 released from PEN-866 accumulated at high levels within the tumors and was associated with increased and widespread cancer cell death when compared with irinotecan alone.

Under the terms of the agreement, Madrigal will receive an upfront payment and is eligible to receive up to an aggregate of $163 million of contingent payments based upon the achievement of specified development, regulatory and sales milestones related to the first HSP90 drug conjugate product developed under the agreement. Madrigal is also eligible to receive a tiered, single-digit royalty based on future worldwide sales of HSP90 drug conjugate products. Potential development, regulatory and sales milestone payments related to a second HSP90 drug conjugate product would be lower. Tarveda will be responsible for all of the development costs for the HSP90 drug conjugate program.

"We are pleased to have completed this important and potentially valuable agreement with Tarveda," said Paul A. Friedman, M.D., Chairman and CEO of Madrigal. "This transaction is a key element of Madrigal's strategy to out-license our novel oncology assets to organizations with the oncology focus and resources to fully exploit the opportunity for product development and commercial success."

The Tarveda team is comprised of seasoned oncology leaders, scientists and drug developers who are taking a novel approach to cancer treatment by creating Pentarins™, which are miniaturized drug conjugates uniquely designed to target, penetrate and eradicate solid tumors. Creating Pentarin drug conjugates that drive efficacy in solid tumors is the core expertise and focus of the team at Tarveda.

"Tarveda is developing therapeutics to overcome the limitations of current cancer treatments through our Pentarin platform. Pentarins leverage their miniature size and improved pharmacokinetics to penetrate into solid tumors and cause cancer cell death with highly selective cell surface and intracellular targeting, tuned linkers and potent payloads," said Drew Fromkin, President and CEO of Tarveda. "The HSP90 drug conjugate platform with its lead drug candidate PEN-866, which is scheduled to be in the clinic during the first half of 2017, is an ideal fit for our growing Pentarin pipeline of novel oncology therapeutics. The Tarveda pipeline also includes PEN-221, our Pentarin conjugate that binds to the somatostatin cell surface receptor, after which the conjugate's potent payload is internalized into the cancer cell. PEN-221 is scheduled to enter Phase I trials this year to treat

patients with neuroendocrine and small-cell lung cancer tumors. We look forward to advancing both of these novel Pentarin drug candidates into clinical studies in the near term and expanding the Pentarin platform pipeline by developing new conjugates linked to other potent payloads, including challenged but promising payloads being developed by potential pharmaceutical partners."

About Madrigal Pharmaceuticals, Inc.

Madrigal Pharmaceuticals, Inc. is a company focused on the development of novel compounds for the treatment of cardiovascular-metabolic diseases and nonalcoholic steatohepatitis (NASH). The Company's lead candidate, MGL-3196, is an orally administered, small-molecule liver-directed ß-selective THR agonist with high liver uptake for the treatment of NASH and dyslipidemia/hypercholesterolemia including in heterozygous and homozygous familial hypercholesterolemia (HeFH, HoFH). For more information, visit: http://www.madrigalpharma.com.

About Tarveda Therapeutics, Inc.

Tarveda Therapeutics, Inc., is a biopharmaceutical company discovering and developing Pentarins™ as a new class of targeted anti-cancer medicines to advance the treatment of patients with solid tumor cancers. Tarveda's lead Pentarin drug candidate, PEN-221, is a miniaturized biologic drug conjugate that targets the somatostatin receptor for treatment of patients with neuroendocrine cancers including small-cell lung cancer. Tarveda is also advancing its HSP90 drug conjugate platform with lead PEN-866, which is a drug conjugate that comprises an HSP90 ligand conjugated to SN-38, the highly-potent, active metabolite of irinotecan. Tarveda's strategy includes developing its own proprietary Pentarins as well as applying the Pentarin platform to enhance the effectiveness of the targeting moieties and novel payloads of pharmaceutical collaborators. Tarveda has attracted top-tier investors including Novo A/S, New Enterprise Associates, Flagship Ventures, NanoDimension, and Eminent Venture Capital.

Forward-Looking Statements

This press release contains forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 that involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this press release regarding our strategy, future operations, and plans may be deemed forward-looking statements. Forward-looking statements reflect management's current knowledge, assumptions, judgment and expectations regarding future performance or events. Although management believes that the expectations reflected in such statements are reasonable, they give no assurance that such expectations will prove to be correct and you should be aware that actual results could differ materially from those contained in the forward-looking statements. Actual results or events could differ materially from the plans, intentions, expectations and projections disclosed in the forward-looking statements. Various risks and uncertainties could cause actual results or events to differ materially from the forward-looking statements that we make, including, but not limited to, our ability to successfully progress, partner or complete further development of our programs, the timing, cost and uncertainty of obtaining regulatory approvals, our ability to protect our intellectual property, changes in the regulatory landscape, and other factors listed under "Risk Factors" in our filings with the Securities and Exchange Commission. We do not plan to update any such forward-looking statements and expressly disclaim any duty to update the information contained in this press release except as required by law.

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