Kadmon and Meiji Announce Collaboration to Develop and Commercialize KD025 in Japan

December 26, 2019

NEW YORK, NY and TOKYO, JAPAN / ACCESSWIRE / December 26, 2019 / Kadmon Holdings, Inc. (NYSE:KDMN), a New York-based biopharmaceutical company, and Meiji Seika Pharma Co., Ltd, a Tokyo-based wholly owned subsidiary of Meiji Holdings Co., Ltd. (TYO: 2269), today announced that the companies have entered into a strategic collaboration to form a joint venture to exclusively develop and commercialize KD025 in Japan and certain other Asian countries.

Under the terms of the transaction agreements, Kadmon will receive payments which could exceed $29.0 million, resulting from various potential establishment, development, regulatory and commercial milestones. In addition, Kadmon is eligible to receive double-digit percentage royalty payments on sales of KD025 in the territory.

KD025, Kadmon's ROCK2 inhibitor, is being studied in a pivotal clinical trial in the United States for the treatment of chronic graft-versus-host disease (cGVHD). In October 2018, the U.S. Food and Drug Administration granted Breakthrough Therapy Designation to KD025 for the treatment of cGVHD after two or more lines of systemic therapy.

The joint venture, Romeck Pharma, LLC, is domiciled in Japan with shared oversight between Kadmon and Meiji.

"The KD025 data generated to date provides a clear rationale for our desire to partner with Kadmon to develop KD025 to potentially treat a range of inflammatory and fibrotic diseases for Japanese and other Asian patients," said Daikichiro Kobayashi, President and Representative Director of Meiji. "Kadmon is an exciting company with whom we share the same ethical and innovative vision to develop and deliver important medicines to critically ill patients, and we are highly motivated to seek fast-track regulatory approval of KD025 in our region."

"We are pleased to partner with Meiji, a globally respected organization who has commercialized pharmaceuticals in Japan and Asia for over 70 years," said Harlan W. Waksal, M.D., President and CEO of Kadmon. "KD025 is a unique drug candidate with potential to treat many inflammatory and fibrotic diseases, and we hope that this joint venture will, together with our recently announced collaboration with BioNova in China, accelerate access to this drug for patients across East and Southeast Asia."

"Meiji is an ideal partner for the Japanese region: their drug development experience and commitment to advancing KD025 expeditiously gives us great confidence in this joint venture to bring KD025 to additional patients in need," added Faical Miyara, Ph.D., Senior Vice President, Business Development of Kadmon.

About Kadmon

Kadmon is a biopharmaceutical company developing innovative products for significant unmet medical needs. Our product pipeline is focused on inflammatory and fibrotic diseases as well as immuno-oncology.

About Meiji

In order to protect and improve people's health and lives, Meiji Seika Pharma strives to respond to diversified medical needs and contributes to the well-being of people worldwide.

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President and Representative Director: Daikichiro Kobayashi
https://www.meiji.com/global/about-us/corporate-profile/meiji-seika-pharma/

Forward Looking Statements

This press release contains forward-looking statements. Such statements may be preceded by the words "may," "will," "should," "expects," "plans," "anticipates," "could," "intends," "targets," "projects," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these terms or other similar expressions. Forward-looking statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. We believe that these factors include, but are not limited to, (i) the initiation, timing, progress and results of our preclinical studies and clinical trials, and our research and development programs; (ii) our ability to advance product candidates into, and successfully complete, clinical trials; (iii) our reliance on the success of our product candidates; (iv) the timing or likelihood of regulatory filings and approvals; (v) our ability to expand our sales and marketing capabilities; (vi) the commercialization of our product candidates, if approved; (vii) the pricing and reimbursement of our product candidates, if approved; (viii) the implementation of our business model, strategic plans for our business, product candidates and technology; (ix) the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology; (x) our ability to operate our business without infringing the intellectual property rights and proprietary technology of third parties; (xi) costs associated with defending intellectual property infringement, product liability and other claims; (xii) regulatory developments in the United States, Europe, Japan and other jurisdictions; (xiii) estimates of our expenses, future revenues, capital requirements and our needs for additional financing; (xiv) the potential benefits of strategic collaboration agreements and our ability to enter into strategic arrangements; (xv) our ability to maintain and establish collaborations or obtain additional grant funding; (xvi) the rate and degree of market acceptance of our product candidates; (xvii) developments relating to our competitors and our industry, including competing therapies; (xviii) our ability to effectively manage our anticipated growth; (xix) our ability to attract and retain qualified employees and key personnel; (xx) our ability to achieve cost savings and other benefits from our efforts to streamline our operations and to not harm our business with such efforts; (xxi) the use of proceeds from our recent public offerings; (xxii) the potential benefits of any of our product candidates being granted orphan drug designation; (xxiii) the future trading price of the shares of our common

stock and impact of securities analysts' reports on these prices; (xxiv) the possibility that we will not be able to successfully operate our joint venture with Meiji; and/or (xxv) other risks and uncertainties. More detailed information about Kadmon and the risk factors that may affect the realization of forward-looking statements is set forth in the Company's filings with the U.S. Securities and Exchange Commission (the "SEC"), including the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2018 and subsequent Quarterly Reports on Form 10-Q. Investors and security holders are urged to read these documents free of charge on the SEC's website at www.sec.gov. The Company assumes no obligation to publicly update or revise its forward-looking statements as a result of new information, future events or otherwise.

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