Kadmon Doses First Patient in Open-Label Phase 2 Clinical Trial of Belumosudil in Systemic Sclerosis

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NEW YORK, NY / ACCESSWIRE / April 1, 2021 / Kadmon Holdings, Inc. (NASDAQ:KDMN) today announced that the first patient has been dosed in an open-label Phase 2 clinical trial of belumosudil, the Company's ROCK2 inhibitor, in patients with diffuse cutaneous systemic sclerosis (dcSSc), a chronic immune disorder characterized by fibrosis of the skin and internal organs.

The Phase 2 study (KD025-215) will enroll up to 15 adults with dcSSc who will receive orally administered belumosudil 200 mg twice daily (BID). The primary endpoint is the Combined Response Index for Systemic Sclerosis (CRISS) score. The Company plans to present initial data from this study by year-end 2021.

In addition to the KD025-215 trial, an ongoing, double-blind, placebo-controlled Phase 2 clinical trial of belumosudil (KD025-209) is currently enrolling 60 adults with dcSSc. Patients are randomized to receive belumosudil 200 mg once daily (QD), belumosudil 200 mg BID or placebo.

"As we await the results of our placebo-controlled study, we are pleased to concurrently initiate the open-label trial of belumosudil in systemic sclerosis, as its mechanism represents a promising therapeutic approach for this difficult-to-treat disease," said Harlan W. Waksal, M.D., President and CEO of Kadmon. "We are encouraged by the robust responses achieved across all organ systems in clinical trials of belumosudil in cGVHD, which shares mechanistic and pathophysiologic similarities to systemic sclerosis. We look forward to receiving initial data from this trial later this year."

The U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation to belumosudil for the treatment of systemic sclerosis.

About Belumosudil

Belumosudil (KD025) is a selective oral inhibitor of Rho-associated coiled-coil kinase 2 (ROCK2), a signaling pathway that modulates inflammatory response and pro-fibrotic processes. The FDA granted Priority Review for the New Drug Application (NDA) for belumosudil for the treatment of chronic graft-versus-host disease (cGVHD) and assigned a Prescription Drug User Fee Act (PDUFA) target action date of August 30, 2021. The NDA is being reviewed under the FDA's Real-Time Oncology Review (RTOR) and Project Orbis pilot programs. The FDA has granted Breakthrough Therapy Designation to belumosudil for the treatment of patients with cGVHD after failure of two or more lines of systemic therapy as well as Orphan Drug Designation to belumosudil for the treatment of cGVHD.

About Kadmon

Kadmon is a clinical-stage biopharmaceutical company that discovers, develops and delivers transformative therapies for unmet medical needs. Kadmon's clinical pipeline includes treatments for immune and fibrotic diseases as well as immuno-oncology therapies.

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. Among those risks and uncertainties are risks related to market conditions, including market interest rates, and the trading price and volatility of Kadmon's common stock. 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) the impact of the COVID-19 pandemic on our business, workforce, patients, collaborators and suppliers, including delays in anticipated timelines and milestones of our clinical trials and on various government agencies who we interact with and/or are governed by; (iv) our reliance on the success of our product candidates; (v) the timing or likelihood of regulatory filings and approvals, especially in light of the COVID-19 pandemic; (vi) our ability to expand our sales and marketing capabilities; (vii) the commercialization, 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, 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; (xvi) the rate and degree of market acceptance of our product candidates, if approved; (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 expected use of cash and cash equivalents and other sources of liquidity; (xxi) our expected use for the proceeds from the offering of our convertible senior notes; (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) our ability to apply unused federal and state net operating loss carryforwards against future taxable income and/or (xv) other risks and uncertainties. More detailed information about the Company 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 Kadmon's Annual Report on Form 10-K for the fiscal year ended December 31, 2020. 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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