NEW YORK, August 29, 2016 – Kadmon Holdings, Inc. (NYSE: KDMN) today announced that the first patient has been dosed in a Phase 2 clinical trial of tesevatinib, the Company’s oral tyrosine kinase inhibitor, for the treatment of recurrent glioblastoma. The open-label, multicenter study examines tesevatinib monotherapy administered at 300 mg once daily in up to 40 patients in the United States.

Tesevatinib is an oral inhibitor of epidermal growth factor receptor (EGFR), a cell surface receptor whose gene is amplified in more than 50% of gliomas. Unlike other EGFR inhibitors, tesevatinib has been observed in animal models to be highly blood-brain barrier penetrant, reaching equal concentrations in the brain and the blood. Published data have shown that other EGFR inhibitors have poor brain penetration, limiting their ability to reach and effectively treat brain tumors. We believe that tesevatinib may also penetrate the blood-brain barrier in humans, based on initial observations in certain patients exhibiting tumor shrinkage and improvement in neurological symptoms in our ongoing Phase 2 clinical trial in EGFR-mutant non-small cell lung cancer (NSCLC) that has metastasized to the brain. Based on its mechanism of action and brain penetrance, we believe tesevatinib is potentially well suited to treat glioblastoma.

“We are encouraged by tesevatinib’s potential ability to cross the blood-brain barrier in humans, which may lead to meaningful clinical activity against brain tumors,” said Harlan W. Waksal, M.D., President and Chief Executive Officer at Kadmon. “With its potent EGFR inhibition and biodistribution, we believe tesevatinib represents an ideal therapeutic candidate for this difficult-to-treat disease.”

In addition to glioblastoma and the ongoing Phase 2 clinical trial in EGFR-mutant NSCLC that has metastasized to the central nervous system (the brain and leptomeninges), Kadmon is developing tesevatinib for the treatment of polycystic kidney disease, a genetic kidney disorder in which EGFR plays a central role.

About Kadmon Holdings, Inc.
Kadmon Holdings, Inc. is a fully integrated biopharmaceutical company focused on developing innovative products for significant unmet medical needs. We have a diversified product pipeline in autoimmune and fibrotic diseases, oncology and genetic diseases.

Safe Harbor Statement
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 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; and (xix) our ability to attract and retain qualified employees and key personnel. 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 (SEC), including the Company's prospectus filed pursuant to Rule 424(b) under the Securities Act of 1933, as amended, with the SEC on July 27, 2016. Investors and security holders are urged to read these documents free of charge on the SEC's web site 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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