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CUTISPHARMA ANNOUNCES INITIATION OF MANUFACTURING OPERATIONS

Mass. Housing and Economic Development Secretary Jay Ash to Join March 2 Commemoration of Important Milestone in Company History to Bring Production In-House

WILMINGTON, Mass. (March 2, 2016) – CutisPharma, a specialty pharmaceutical company that has historically developed and distributed kits used by pharmacists to safely create compounded medications, today announced the launch of manufacturing operations at its headquarters facility - a key milestone on the company's path to secure new product approvals from the U.S. Food and Drug Administration.

CutisPharma completed a major capital investment to bring the product manufacturing process in-house, including activities necessary to achieve full compliance with the FDA's current Good Manufacturing Practices, or cGMP, a set of rigorous quality and safety requirements considered the gold standard in the pharmaceutical industry. The production line will support CutisPharma's plan to file a New Drug Application (NDA) with the FDA for its lead pipeline drug, RM-01, as well as other drugs in the Company's portfolio currently in development.

"Our entire team is excited to achieve the important goal of validation of our manufacturing equipment, processes and staff training," said Neal Muni, MD, MSPH, Chief Executive Officer of CutisPharma. "The initiation of manufacturing at our state-of-the-art Wilmington facility will allow CutisPharma to build our Company's infrastructure and significantly advance our portfolio of high-quality specialty pharmaceutical products."

CutisPharma celebrated its manufacturing milestone during a special event featuring Jay Ash, the state's Housing and Economic Development Secretary.

"Pharmaceutical manufacturing benefits from Massachusetts' strong innovation ecosystem and significant support for the advanced manufacturing sector," said Ash. "The Baker-Polito administration is committed to investing in the Commonwealth's manufacturing ecosystem by supporting workforce training efforts and manufacturing research and development. I look forward to working with CutisPharma to drive economic growth and job creation in Massachusetts."

Along with its investment and validation process, CutisPharma has ramped up hiring of highly skilled research scientists, chemists, engineers and technicians. The company anticipates hiring more personnel to support a significant scale up in activities over the next few years as additional manufacturing is initiated in-house for future FDA-approved drugs.

"With this manufacturing milestone, we are well on our way to transforming CutisPharma into a full-scale, high-quality specialty pharmaceutical company," Muni said.

CutisPharma has aggressively invested in its research and development pipeline for new products and also enhanced its portfolio of FIRST® Unit-of-Use Prescription Compounding Kits. The kits are designed to improve accuracy and quality for pharmacists who need to compound certain medications for which there is no commercially available alternative.

Among the products made by CutisPharma is an omeprazole compounding kit that enables retail pharmacists to create a liquid solution for children and infants requiring an oral suspension formulation of this drug. The company also makes a vancomycin compounding kit that enables easy preparation of a liquid solution for patients unable to swallow capsules.

About CutisPharma

CutisPharma, Inc., based in Wilmington, Mass., is a privately held, specialty pharmaceutical company focusing on the development and commercialization of value-added proprietary pharmaceutical products and technologies in the prescription compounding sector of the health care industry. The product line and development efforts are focused on providing optimized, more efficient alternatives for the preparation of compounded prescriptions, by offering FIRST® Unit-of-Use Prescription Compounding Kits. Use of these branded compounding kits benefits all key stakeholders, including physicians, pharmacists and patients.

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