

News Release

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November 1, 2017

Merck KGaA, Darmstadt, Germany, and Lupus Foundation of America Launch Initiative to Improve Future of Lupus Care

- **The ALPHA Project aims to identify critical gaps and solutions for people with lupus, a disease affecting 1.5 million Americans**
- **Insights-driven collaboration paves path for timely and accurate diagnosis, greater access to care and improved treatment options**

Darmstadt, Germany, October 19, 2017 – Merck KGaA, Darmstadt, Germany, a leading science and technology company, and the Lupus Foundation of America (Foundation) today announced collaboration on The ALPHA Project: **Addressing Lupus Pillars for Health Advancement**, a global initiative to drive advancement in lupus research and care. This multi-phase initiative will seek to achieve better and timelier diagnosis, expand access to expert care, and improve treatment options for those living with this complex and unpredictable disease.

Lupus is a chronic autoimmune disease in which the body's immune system can attack and damage skin, joints, and internal organs. The Foundation estimates that 1.5 million Americans¹ have a form of lupus and as many as 16,000 new cases are reported each year.² In addition, lupus impacts at least 5 million people worldwide.

"The road to diagnosis and treatment is often fraught with obstacles and frustration for people living with this devastating condition," said Luciano Rossetti, MD, Executive Vice President, Global Head of R&D for the biopharma business of Merck KGaA, Darmstadt, Germany. "We are proud to partner with the Lupus Foundation of America and support their unyielding resolution to advance lupus research and treatment. At Merck KGaA, Darmstadt, Germany, we are committed to identifying



innovative solutions to help people with chronic, under-served conditions like lupus and are resolute in our search for ways to improve patient care.”

Many unknowns remain about how to best care for people affected. The impact of lupus varies by individual, making it difficult to diagnose, treat and manage. Simple tests that allow clinicians to reliably identify lupus, as well as track and predict disease progression and related organ damage, are lacking.³ The patient journey is often characterized by multiple visits, tests, and referrals over months – even years – prior to diagnosis.⁴ On average, it takes nearly six years for people with lupus to be diagnosed from the time they first notice their lupus symptom.⁵ Many others likely remain undiagnosed. Late diagnosis, poor access to care, less effective treatments, and poor adherence to therapeutic regimens may increase the damaging effects of lupus, causing more complications, and an increased risk of death.⁶

The ALPHA Project’s goal is to enhance care for people with this difficult-to-treat disease. The initiative will consist of two parts: building a comprehensive picture of the challenges faced by individuals with lupus and developing actionable solutions to address these needs. This includes building a steering committee of leaders in the field of lupus, conducting qualitative research on the lupus patient journey to identify knowledge gaps in diagnosis and treatment, issuing a public report of the findings, and developing a roadmap to address these gaps.

The ALPHA Project will also build upon the National Public Health Agenda for Lupus, a first of its kind approach guiding lupus policy, planning, advocacy, and action initiatives. The National Public Health Agenda for Lupus was published in 2015 by the Lupus Foundation of America in partnership with the National Association of Chronic Disease Directors (NACDD) and the Centers for Disease Control and Prevention (CDC).

“Lupus is a highly complex and debilitating disease that has no cures. It is our hope that this project will lead to consensus positions and research directions agreed to by the international experts in lupus,” said Sandra C. Raymond, CEO of the Lupus Foundation of America. “We are pleased to collaborate with Merck KGaA, Darmstadt, Germany, on this important work that will translate science into new treatments and

better tools to manage lupus with an eye directly on helping the patient as soon as possible.”

About Lupus

Lupus is a chronic inflammatory disease that occurs when the body's immune system attacks its own tissues and organs. Inflammation caused by lupus can affect many different body systems — including the joints, skin, kidneys, blood cells, brain, heart and lungs.⁷ Systemic lupus erythematosus (SLE) is the most common form of lupus and accounts for approximately 70% of all cases.⁸ SLE can be mild or severe, and can cause serious complications involving major organ systems, including kidney failure, memory problems, stroke, seizures, behavioral changes, and heart attack.⁹ Lupus impacts an estimated 1.5 million Americans and at least 5 million people worldwide.¹⁰

About the Lupus Foundation of America

The Lupus Foundation of America is the only national force devoted to solving the mystery of lupus, one of the world's cruelest, most unpredictable and devastating diseases, while giving caring support to those who suffer from its brutal impact. Through a comprehensive program of research, education, and advocacy, we lead the fight to improve the quality of life for all people affected by lupus. Learn more about the Lupus Foundation of America at lupus.org.

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About Merck KGaA, Darmstadt, Germany

Merck KGaA, Darmstadt, Germany, is a leading science and technology company in healthcare, life science and performance materials. Around 50,000 employees work to further develop technologies that improve and enhance life – from biopharmaceutical therapies to treat cancer or multiple sclerosis, cutting-edge systems for scientific research and production, to liquid crystals for smartphones and LCD televisions. In 2016, Merck KGaA, Darmstadt, Germany, generated sales of € 15.0 billion in 66 countries. Founded in 1668, Merck KGaA, Darmstadt, Germany, is the world's oldest pharmaceutical and chemical company. The founding family remains the majority owner of the publicly listed corporate group. Merck KGaA, Darmstadt, Germany, holds the global rights to the „Merck“ name and brand. The only exceptions are the United States and Canada, where the company operates as EMD Serono, MilliporeSigma and EMD Performance Materials.

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- ¹ Lupus facts and statistics. The Lupus Foundation of America. <http://resources.lupus.org/entry/facts-and-statistics>. Accessed September 6, 2017.
- ² Lupus facts and statistics. The Lupus Foundation of America. <http://resources.lupus.org/entry/facts-and-statistics>. Accessed September 6, 2017.
- ³ How lupus is diagnosed. The Lupus Foundation of America. <http://resources.lupus.org/entry/how-lupus-is-diagnosed>. Accessed September 6, 2017.
- ⁴ Reducing time to diagnosis. The Lupus Foundation of America. <http://resources.lupus.org/entry/diagnose-sooner>. Accessed September 6, 2017.
- ⁵ Al Sawah S, Daly R, Foster S, et al. SAT0423 Understanding Delay in Diagnosis, Access to Care and Satisfaction with Care in Lupus: Findings from a Cross-Sectional Online Survey in the United States *Annals of the Rheumatic Diseases*. 2015;74:812.
- ⁶ Dall'Era M. Systemic lupus erythematosus. In: Imboden JB, Hellman DB, Stone JH. (Eds). *Current Rheumatology Diagnosis and Treatment*. 3rd ed. New York, NY:McGraw-Hill; 2013.
- ⁷ Lupus definition. Mayo Clinic. <http://www.mayoclinic.org/diseases-conditions/lupus/basics/definition/con-20019676>. Accessed September 6, 2017.
- ⁸ Lupus facts and statistics. The Lupus Foundation of America. <http://resources.lupus.org/entry/facts-and-statistics>. Accessed September 6, 2017.
- ⁹ Different types of lupus. The Lupus Foundation of America. <http://resources.lupus.org/entry/types-of-lupus>. Accessed September 6, 2017.
- ¹⁰ Lupus facts and statistics. The Lupus Foundation of America. <http://resources.lupus.org/entry/facts-and-statistics>. Accessed September 6, 2017.