

News Release

Your Contact

Brenda Mulligan +1 (978) 821-5345

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ACR Abstract

Atacicept: 889, 2585, 2586, 2610; **Sprifermin:** 1207, 2183, 1L; **Abituzumab:** 774; **Evobrutinib:** 2565; **Discovery Products:** 25, 1060

Pursuing Novel Pathways in Immunology: Merck KGaA, Darmstadt, Germany Presents New Clinical Data at 2017 ACR/ARHP Annual Meeting

- Company to present 11 abstracts and highlight momentum of its clinical programs in systemic lupus erythematosus (SLE), osteoarthritis (OA), rheumatoid arthritis (RA) and fibrotic diseases
- Late-breaking Phase II data provide insights into potential disease-modifying properties of sprifermin in patients with knee OA
- Oral presentation of atacicept Phase II data analysis provides insights into its possible use for SLE patients with high disease activity

Darmstadt, Germany, October 20, 2017 – Merck KGaA, Darmstadt, Germany, a leading science and technology company which operates its healthcare business in the U.S. and Canada as EMD Serono, today announced 11 abstracts are scheduled for presentation in oral and poster sessions, including one late-breaker, at the 2017 American College of Rheumatology/Association of Rheumatology Health Professionals (ACR/ARHP) Annual Meeting to be held November 3-8, 2017 in San Diego, CA, U.S. This data reflects the company's resolute drive to pursue novel pathways and address areas of high unmet medical need for patients with chronic progressive diseases, particularly those of the immune system.

Noteworthy data includes a late-breaking abstract on FORWARD, a five-year Phase II study of sprifermin in OA of the knee, providing insights into its potential disease-modifying properties.

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Additional data includes an oral presentation on the investigational agent atacicept in a subset of patients with high disease activity based on a post-hoc analysis of ADDRESS II, a 24-week, randomized, placebo-controlled Phase IIb study.

“We are committed to discovering and delivering transformative treatments to significantly improve the lives of people living with chronic progressive diseases,” said Luciano Rossetti, Executive Vice President, Global Head of Research & Development at the biopharma business of Merck KGaA, Darmstadt, Germany. “Our approach has led to the discovery of novel pathways that modulate the immune system in more targeted ways, based on preclinical models. We’re proud to showcase the progress we’ve made as we continue to explore the potential of these compounds that may eventually alter treatment paradigms.”

Other data of note include an updated safety analysis of ADDRESS II and its long-term extension study; an exposure-response and exposure-safety modeling analysis of ADDRESS II and the Phase II APRIL-SLE study; an in-vitro study of abituzumab for potential use in fibrotic diseases (or fibrosis); and a pharmacodynamics (PD) modeling study of evobrutinib, one of the first Bruton’s Tyrosine Kinase Inhibitors to be studied as a potential treatment in autoimmune diseases, with potential for eventual use in RA and SLE. All agents are investigational and have not been proven safe or effective, and are not registered in any market.

Accepted key abstracts at the 2017 ACR/ARHP Annual Meeting include:

Title	Presenting Author	Abstract Number	Presentation Date/Time	Session Type/Title
Sprifermin				
Efficacy and Safety of Intra-Articular Sprifermin in Symptomatic Radiographic Knee Osteoarthritis: Results of the 2-Year Primary Analysis from a 5-Year Randomised, Placebo-Controlled, Phase II Study	M Hochberg	1L	Tuesday, November 7, 4:30 PM - 6:00 PM PT	ACR Late-Breaking Abstract Session
Clinical Relevance of Structural Measures in Knee Osteoarthritis:	C Kwoh	1207	Monday, November 6,	ACR Poster Session B: Osteoarthritis – Clinical Aspects Poster I:

Baseline Values and Change from Baseline Discriminate Patients Subsequently Receiving Knee Replacement			9:00 AM – 11:00 AM PT	Clinical Trials and Interventions
Two-Year Changes in Knee Osteoarthritis Symptoms: Comparing Clinical Relevance of Patient-Reported Outcomes By Anchoring to Knee Replacement	C Kwoh	2183	Tuesday, November 7, 9:00 AM – 11:00 AM PT	ACR Poster Session C: Osteoarthritis – Clinical Aspects Poster II: Observational and Epidemiological Studies
Atacicept				
Attainment of Low Disease Activity By Patients with Systemic Lupus Erythematosus (SLE) Starting with High Disease Activity in a 24-Week, Randomized, Placebo-Controlled, Phase IIb Study of Atacicept (ADDRESS II)	J Merrill	889	Sunday, November 5, 2:30 PM – 4:00 PM PT	ACR Concurrent Abstract Session – Oral Presentation: Systemic Lupus Erythematosus – Clinical Aspects and Treatment I: Novel and Current Therapies
Safety Profile in SLE Patients Treated with Atacicept in a Phase IIb Study (ADDRESS II) and Its Extension Study	J Merrill	2585	Tuesday, November 7, 9:00 AM – 11:00 AM PT	ACR Poster Session C: Systemic Lupus Erythematosus – Clinical Aspects and Treatment Poster III: Therapeutics and Clinical Trial Design
Exposure-Response Modeling and Exposure-Safety Modeling Analyses in Two Phase II Studies of Atacicept in SLE	O Papisoulitis	2586	Tuesday, November 7, 9:00 AM – 11:00 AM PT	ACR Poster Session C: Systemic Lupus Erythematosus – Clinical Aspects and Treatment Poster III: Therapeutics and Clinical Trial Design
QuantiFERON Testing in a Clinical Trial of Systemic Lupus Erythematosus: TB or Not TB	N Goel	2610	Tuesday, November 7, 9:00 AM – 11:00 AM PT	ACR Poster Session C: Systemic Lupus Erythematosus – Clinical Aspects and Treatment Poster III: Therapeutics and Clinical Trial Design
Abituzumab				
The α V Integrin Inhibitor Abituzumab Inhibits Myofibroblast Differentiation	E Samy	774	Sunday, November 5, 9:00 AM – 11:00 AM PT	ACR Poster Session A: Systemic Sclerosis, Fibrosing Syndromes and Raynaud's – Pathogenesis, Animal

				Models and Genetics Poster I
Evobrutinib				
Pharmacodynamic Modeling of BTK Occupancy Versus Efficacy in RA and SLE Models Using the Novel Specific BTK Inhibitor Evobrutinib	P Haselmayer	2565	Tuesday, November 7, 9:00 AM – 11:00 AM PT	ACR Poster Session C: Systemic Lupus Erythematosus – Animal Models Poster
Discovery Products				
A novel role for galectin-3 binding protein in B cell biology and antibody secretion	S Okitsu	25	Sunday, November 5, 9:00 AM – 11:00 AM PT	ACR Poster Session A: B Cell Biology and Targets in Autoimmune Disease Poster
Assessing interferon regulatory factor 5 (IRF5) function in human primary immune cells with cell- penetrating peptides	G Chen	1060	Monday, November 6, 9:00 AM – 11:00 AM PT	ACR Poster Session B: Innate Immunity and Rheumatic Disease Poster II

For more information about the data to be presented, please visit the ACR/ARHP [website](#). Also, visit the EMD Serono booth at this year's Annual Meeting to learn more about the company's commitment to advancing innovation in immunological diseases.

About Atacept

Atacept is in clinical development to investigate its potential as a treatment for systemic lupus erythematosus (SLE). It is a recombinant fusion protein which targets the cytokines APRIL and BlyS, two members of the tumor necrosis factor family that regulates B-cell maturation, function and survival and autoantibody production associated with certain autoimmune diseases such as SLE. Atacept has been shown in animal models to affect several stages of B-cell development and may inhibit the survival of cells responsible for making antibodies. It is currently in Phase II studies.

About Sprifermin

Sprifermin is in clinical development to investigate its potential as a treatment for osteoarthritis (OA) in the knee. It is a truncated recombinant human FGF-18 protein thought to induce chondrocyte proliferation and increased extra-cellular matrix (ECM) production, with the potential of promoting cartilage growth and repair. Sprifermin is currently in Phase II studies.

About Abituzumab

Abituzumab is in clinical development to investigate its potential as a treatment for fibrotic diseases (or fibrosis). It is a recombinant de-immunized humanized IgG2 monoclonal antibody (mAb) that inhibits all subtypes of α v integrins. Abituzumab is designed to block integrin-mediated activation of latent TGF- β and prevent fibroblast-to-myofibroblast transition, a key event in fibrosis. It is currently in Phase II studies.

About Evobrutinib

Evobrutinib (M2951) is in clinical development to investigate its potential as a treatment for multiple sclerosis (MS), rheumatoid arthritis (RA) and systemic lupus erythematosus (SLE). It is an oral, highly selective inhibitor of Bruton's Tyrosine Kinase (BTK) which is important in the development and

functioning of various immune cells including B lymphocytes and macrophages. Evobrutinib is designed to inhibit primary B cell responses such as proliferation and antibody and cytokine release, without directly affecting T cells. BTK inhibition is thought to suppress autoantibody-producing cells, which preclinical research suggests may be therapeutically useful in certain autoimmune diseases. Evobrutinib is currently in Phase II studies.

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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.

About EMD Serono, Inc.

EMD Serono is the biopharma business of Merck KGaA, Darmstadt, Germany, in the U.S. and Canada - a leading science and technology company - focused exclusively on specialty care. For more than 40 years, the business has integrated cutting-edge science, innovative products and industry-leading patient support and access programs. EMD Serono has deep expertise in neurology, fertility and endocrinology, as well as a robust pipeline of potential therapies in oncology, immuno-oncology and immunology as R&D focus areas. Today, the business has more than 1,100 employees around the country with commercial, clinical and research operations based in the company's home state of Massachusetts.

<http://www.emdserono.com>