

#### For Immediate Release

**15 November 2012** 

ImmuPharma presents Lupuzor's<sup>™</sup> Phase IIb data at leading medical congress, the 2012 American College of Rheumatology Meeting, Washington, D.C.

London Analyst Meeting: Friday 16 November @ 10am

ImmuPharma PLC (LSE:IMM), ("ImmuPharma" or the "Company"), the specialist drug discovery and development company, is pleased to today outline the key abstract information presented on Wednesday 14 November at the 2012 Annual American College of Rheumatology ("ACR") Meeting which was held this week. The ACR Annual Scientific Meeting is the premier worldwide scientific meeting devoted to rheumatic diseases and is attended by key opinion leaders and medical practicioners as well as scientific staff and pharmaceutical companies. The title of the session was called "Systemic Lupus Erythematosus - Clinical Aspects and Treatment".

The presentation was given by the authors of the abstract: ImmuPharma's President and Chief Science Officer Dr. Robert Zimmer, together with Daniel J. Wallace, Associate Director, Rheumatology Fellowship Program, Cedars-Sinai Medical Center, Los Angeles, a leading practicioner within the field of Lupus and Sylviane Muller, Research Director at CNRS, Strasbourg, France, who was the key inventor of Lupuzor. (Full biographies can be found in 'Notes to Editors').

Lupus is an autoimmune disease which involves the immune system of the patient targeting multiple organs, with recurrent flares causing a progressive level of damage and disability the disease is clinically heterogeneous (or of varying nature) in its basis which makes diagnosis difficult. The condition is often misdiagnosed in the beginning as rheumatoid arthritis. According to the US Lupus Foundation, it affects up to 1.5m individuals in the US alone.

The multicenter, randomized, placebo-controlled phase IIb study of Lupuzor<sup>TM</sup> (P140 with Mannitol as stabilizer) run by ImmuPharma in patients with Lupus (a dose of  $200\mu g$  / month in addition to "standard of care" vs "standard of care" alone), including patients with clinical SLEDAI-2K scores above 6 and no Bilag A score. Efficacy was evaluated using the SRI score.

**Results:** Clinical studies results:

|                       | P140     | P140      | Benlysta* |
|-----------------------|----------|-----------|-----------|
|                       |          |           | (BLISS-   |
|                       | mannitol | trehalose | 76)       |
|                       | 3        |           | 12        |
| Duration of treatment | months   | 6 months  | months    |
| Number of patients x  |          |           |           |
| arms                  | 50 x 3   | 92 x 2    | 273 x 3   |
| SAE active/placebo    | 6%/6%    | 10%/14%   | 19%/20%   |
|                       |          |           |           |
| Drop-out rate active  | 5%       | 22%       | 23%       |
| Drop-out rate placebo | 16%      | 23%       | 25%       |
| ,                     |          |           |           |
| Responder rate active | 62%      | 34%       | 43%       |
| Responder rate        | 37%      | 40%       | 33%       |
| •                     |          |           |           |

#### placebo

\*Shown for comparison from third party clinical data sources

Lupuzor<sup>™</sup> showed to be safe and met its primary efficacy end point in lupus patients. Data suggest that Lupuzor<sup>™</sup> may restore tolerance by acting as an altered peptide ligand of the T cell receptor. Lupuzor<sup>™</sup> also reduces autophagic (cell degradation) process, which has been shown recently to be abnormally enhanced in T lymphocytes from lupus mice and patients. The potential reduction by Lupuzor<sup>™</sup> of the enhanced autophagy process led to a very short onset of action, which is supported by the efficacy data. These data also formed the basis of the review and approval by the FDA of Lupuzor's phase III programme and grant of a Special Protocol Assessment and Fast Track designation.

ImmuPharma also presented the data from the additional, non-pivotal phase II study that ImmuPharma's former licensee, Cephalon, had performed, using a different stabilizer (trehalose). ImmuPharma had previously stated that due to the mechanism of action of trehalose and Lupuzor™, (trehalose is a known inducer of autophagy), the trial was not expected to produce meaningful results. As anticipated, trehalose was shown to interfere with the beneficial effect of Lupuzor™. Its use together with the P140 peptide is therefore inappropriate in the treatment of lupus patients.

ImmuPharma is in ongoing discussions with potential partners to conclude a commercialisation deal and commence Phase III trials.

Commenting on the abstract highlights, Dr Robert Zimmer, Chief Science Officer said: "We were indeed delighted to have been selected to present at the ACR meeting this week. I am also honoured to have two highly prestigious experts in the field of Lupus, Professor Daniel J. Wallace and Dr. Sylviane Muller, as co-authors. Based on the data presented, there should now be no doubt with regards to the superior safety and efficacy profile of Lupuzor™, as validated by the FDA and EMA's green light for late-stage Phase III trials to commence."

Ends

#### **Notes to Editors**

For more information on ImmuPharma, please visit www.immupharma.com

# **Biographies**

## Dr Robert Zimmer, President and Chief Science Officer, ImmuPharma

Dr. Robert Zimmer was the founder and chief executive officer of both ImmuPharma Switzerland and ImmuPharma France. He is an expert in clinical pharmacology and life cycle management. He was instrumental in developing a substantial number of products for clients including Roche, GlaxoSmithKline, Abbott, Searle, Sanofi-Aventis and Lilly. He began his career in Roche's headquarters in Basle as coordinator of clinical pharmacology and international clinical leader. He subsequently joined Jago Pharma, the drug delivery company, and became a director and head of research and development at SkyePharma after it acquired JAGO. He obtained his MD at Strasbourg Medical School and his PHD at the University of Aix-Marseille.

## Dr Sylviane Muller, Research Director at CNRS & Co-founder of ImmuPharma France

Dr Muller is Distinguished class Research Director at the CNRS and head of the 'Immunologie et chimie thérapeutiques' unit of the Centre National de la Recherche Scientifique, the largest scientific research institution in France. Her field of expertise covers autoimmunity, immuno-peptides and synthetic vaccines. She has made 23 patented discoveries and is widely published. She was also a founder of Neosystem, now Polypeptide-France, a leading peptide development and manufacturing company. She is the key inventor of ImmuPharma's Lupus lead drug candidate Lupuzor and has been working in this field for more than ten years.

# Dr Daniel J Wallace, Associate Director, Rheumatology Fellowship Program, Cedars-Sinai Medical Center, Los Angeles

Dr Wallace received his undergraduate and medical education at the <u>University of Southern California</u>, graduating with an MD in 1974. His graduate medical training included an internship at <u>Brown University</u> in Providence, Rhode Island, medical residency at <u>Cedars-Sinai Medical Center</u> in Los Angeles and a fellowship in rheumatology at <u>UCLA</u>. He is Board Certified in both Internal Medicine and Rheumatology.

While a fellow at UCLA, he conducted pioneering arthritis research that landed his picture in Time magazine and developed a close relationship with his mentor, Edmund Dubois. Dr Dubois had the largest lupus practice in the United States at the time and was the principal editor of the only lupus textbook. He is the author of 6 medical textbooks (including the last 4 editions of <a href="Dubois">Dubois</a>' Lupus Erythematosus, All About Fibromyalgia, The Lupus Book, All About Osteoarthritis, The New Sjogren's Syndrome Handbook, and Fibromyalgia & Other Central Pain Syndromes), 19 book chapters, and over 250 medical publications. The latter have appeared in the New England Journal of Medicine, Annals of Internal Medicine, the Lancet,

Journal of Clinical Investigation, Journal of Immunology, and Journal of the American Medical Association. Wallace's academic efforts include having served as Chief of Rheumatology at Cedars-Sinai Medical Center, Century City Hospital, and the City of Hope Medical Center in Duarte, CA. He is currently a Clinical Professor of Medicine at the David Geffen School of Medicine at UCLA. His clinical practice is based at Cedars-Sinai, where he is involved in the care of 2,000 lupus patients, the largest practice of its kind in the United States. The Wallace Rheumatic Disease Research Center currently runs over 30 clinical trials for patients with rheumatoid arthritis, lupus, ankylosing spondylitis, psoriatic arthritis and fibromyalgia. The center has been the recipient of 3 National Institute of Health grants. 20% of his time is spent in teaching and research, providing free medical care.

## About The American College of Rheumatology "ACR"

The American College of Rheumatology's <u>mission</u> is advancing rheumatology. The organization is for physicians, health professionals, and scientists that meets the mission through programs of <u>education</u>, <u>research</u>, <u>advocacy</u> and <u>practice support</u>.

The ACR provides professional education for its members through several venues. The <u>Annual Scientific Meeting</u> is the premier scientific meeting devoted to the rheumatic diseases. This meeting draws thousands of rheumatologists and arthritis health professionals from around the world. A winter rheumatology symposium, spring clinical meetings, and other topical conferences round out the ACR's <u>educational offerings</u>.

The ACR publishes <u>Arthritis & Rheumatism</u>, the premier scientific journal for research in the rheumatic diseases. <u>Arthritis Care & Research</u> is published by the Association of Rheumatology Health Professionals, a division of the ACR. This journal focuses on the health services and clinical aspects of rheumatology.

The Association of Rheumatology Health Professionals, a division of the American College of Rheumatology, is a professional membership society composed of non-physician health care professionals specializing in rheumatology, such as advanced practice nurses, nurses, occupational therapists, physical therapists, psychologists, social workers, epidemiologists, physician assistants, educators, clinicians, researchers, research coordinators and office staff.

#### The ACR Annual Meeting - The Premier Meeting in Rheumatology

The ACR Annual Meeting is the must-attend event for anyone involved in research or delivery of rheumatologic care or services. Innovative sessions, ground breaking scientific abstracts, education developed based on practice gaps, the return of popular session formats, as well as hands-on skill training sessions are just some of the highlights.