

Prof Cazzola Presented new positive immunological study at Monaco's International Workshop on Lung Health

March 17, 2014- Massagno, Switzerland — Lallemand Pharma is pleased to announce that the Ancillary results of the on-going AIACE(1) clinical study were presented by Prof. M. Cazzola, at the International Workshop on Lung Health dedicated to Chronic Obstructive Pulmonary Disease (COPD), which took place in Monaco in December 2013. These results, which represented a further proof of concept of the **immunostimulating** effect of PMBL in patients, were well received by an audience of lung and immunology experts. COPD is ranked by the World Health Organization (WHO) among the top-10 causes of mortality worldwide, projected to become the fourth one by 2030, and its economic burden has been estimated to €48.4 billion in Europe (2).

Prof. Cazzola's presentation was titled **"Polyvalent Mechanical Bacterial Lysate as a Potentially Effective Approach In Preventing Acute Exacerbations of COPD"**. He exposed PMBL activity on both innate and adaptive immune response, linked to a proven clinical efficacy in reducing acute exacerbations in COPD patients. This has been confirmed by a meta-analysis of all randomized clinical trials, indicating that PMBL induced a significant reduction in AECOPDs (RR, 0.83; 95% CI, 0.77–0.89). In the ancillary clinical study (3), it was shown for example that during the study, 25% of patients experienced a single acute episode in the PMBL group, while 72% of patients in the placebo group experienced at least one acute episode (27% of these patients experienced multiple episodes) ($p < 0.05$). The aim of this ancillary study was to get a better insight of PMBL modes of action *in vivo*: many immunological parameters were monitored. Interestingly, it was shown that the clinical benefits observed were correlated with serological signs of an **efficient specific (memory) and non specific immune response** against bacteria as well as viruses. Moreover, the study also showed that PMBL™ had a stimulating effect against vaccinal antigens, which can be described a real **"vaccine boosting" effect**. These results complement previous findings and further indicate that PMBL™ is **able to stimulate both innate and adaptive immune response**, even in elderly COPD patients.

PMBL™ is a bacterial lysate obtained mechanically for optimal preservation of the antigens structures. PMBL™ contains a blend of 13 inactivated bacterial strains of the most common pathogens involved in infections of the upper and lower respiratory tract. It is formulated in sublingual tablets, described as an optimal route of administration to stimulate a strong and long-lasting immune response and enhance anti-microbial defences. A recent meta-analysis encompassing the data of 15 randomized clinical studies using PMBL™ in both upper and lower respiratory tract infections concluded that it is effective in both children and adults in preventing respiratory tract infections.

(1) Advanced Immunological Approach Against COPD Exacerbations, a Phase IV clinical trial in COPD patients

(2) <http://www.erswhitebook.org/>

(3) Ricci R, Palmero C, Bazurro G, Riccio AM, Garelli V, Di Marco E, Cirillo C, Braido F, Canonica GW, Melioli G. *The administration of a polyvalent mechanical bacterial lysate in elderly patients with COPD results in serological signs of an efficient immune response associated with a reduced number of acute episodes.* Pulm Pharmacol Ther. 2013 Jun 21. pii: S1094-5539(13)00124-7. doi: 10.1016/j.pupt.2013.05.006. [Epub ahead of print]

About Lallemand Pharma

Based in Zug (Switzerland), Lallemand Pharma International (LPI) is a pharmaceutical subsidiary of the Lallemand group. LPI is in charge of the business and possesses the intellectual property rights of an oral vaccine indicated in the prevention of respiratory infections: PMBL™, a polyvalent bacterial lysate obtained by mechanical lysis.

Lallemand Pharma AG, subsidiary of LPI, based in Massagno (Switzerland) is dedicated exclusively to the clinical studies, registrations, marketing and sales of PMBL™ drug.

Thanks to its important distributor's network consisting of leading international pharmaceutical companies, the core business of Lallemand Pharma is to develop and market all around the world drugs containing PMBL™ tablets under different brands : Ismigen®, Immubron®, Respibron®, PIR-05®, Pulmigen® and Provax.

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