Press release

Innovative Influenza A vaccine formulation increases stability and provides new options for production and storage

Data presented during the 7th Vaccine & ISV congress in Sitges[1], Spain offers new opportunities for the development and production of more stable vaccines which can be spray dried, terminally sterilized and handled at higher ambient temperatures.

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LEUKOCARE, a German based biotech company, presented data during the 7th Vaccine & ISV Congress on a novel formulation for influenza vaccines. H1N1 antigens stabilized by proprietary formulation technologies of LEUKOCARE elicited an efficacious vaccine effect *in vivo*, after spray drying and sterilization by irradiation. The data were generated in cooperation with Public Health England, UK and the Department of Pharmaceutics and Biopharmaceutics at Kiel University, Germany.

While currently available influenza A vaccines are sensitive to spray drying, irradiation and have to be stored at 4°C the novel formulation demonstrated superior stability. Based on LEUKOCARE's Stabilizing and Protecting Solutions (SPS) technologies the formulation increases the robustness of the vaccine also resulting in an improved stability at 25° C.

In a series of preclinical safety and efficacy studies LEUKOCARE and its partners evaluated different spray dried and irradiated influenza A formulations *in vitro* and *in vivo*. The main goal of the study was to demonstrate an increase in resistance during spray drying, irradiation and better stability during long-term storage.

The original influenza A vaccine formulation exhibited expected levels of seroconversion *in vivo*, while the spray dried and irradiated vaccine did not. In contrast, the SPS-protected spray dried and irradiated vaccine elicited

successful vaccination comparable to control. Ongoing real time storage experiments have revealed a higher stability of SPS-protected vaccine at 4°C and 25°C at 60 % humidity according to WHO requirements.[2]

“These study results represent a promising proof of concept for our SPS technologies in the context of new vaccine formulations. Our SPS-protected vaccine was stable during spray drying, irradiation and at higher temperatures, hence offering options for better cost-effectiveness during production and storage” said Professor Martin Scholz, Chief Scientific Officer (CSO) of LEUKOCARE and speaker at the congress.

Professor Miles Carroll, Head of Research at Public Health England, added that: "LEUKOCARE’s innovative SPS technologies may support the development of new vaccine formulations meeting recommendations continuously discussed by WHO". WHO recommends 'maximising vaccine heat stability to improve effectiveness and enable higher temperature storage', as well as 'licensing of products for higher temperature storage whenever possible'.[3]

Notes for editors:

About LEUKOCARE

LEUKOCARE is a leading provider of technologies for stabilizing proteins to extend shelf-life and to enable terminal sterilization. Based on these technologies, LEUKOCARE can improve biopharmaceutical products and vaccines as well as functionalize a wide variety of surfaces including implant surfaces, wound dressings, stents, catheters and others.

LEUKOCARE developed and successfully brought to clinic a Leukocyte Inhibition Module (LIM) which applies antibodies coupled to the membrane of a filter device to inactivate Leukocytes, thus avoiding inflammation in patient undergoing heart surgery. This anti-inflammatory coating technology has been successfully out-licensed for the use in extracorporeal medical devices.

LEUKOCARE leverages its comprehensive expertise in product-focused industrial partnerships. The company offers its know-how in biofunctional coatings, formulation of biologics and product development to interested parties ranging from service-based collaborations to co-development partnerships. LEUKOCARE was founded in 2003 and is headquartered in Martinsried near Munich, Germany.

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References

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3. Vaccine Presentation and Packaging Advisory Group Generic Preferred Product Profile for Vaccines Version 2.1 Recommendations and Work Programme, Draft 25 August 2009, http://www.who.int/immunization_delivery/systems_policy/VPPAG_Generic_PPP_and_Workplan.pdf