Intercell announces Phase I results on its Vaccine Enhancement Patch (VEP) with Pandemic Influenza antigens

- The co-administration of an A/H5N1 antigen via intramuscular administration (IM) with VEP met two of three CHMP criteria for Pandemic Influenza Vaccines, but the intended level of increased immune response was not achieved
- Intercell will focus its future patch strategy on partnering and out-licensing based on an updated target product profile

Vienna (Austria), September 18, 2012 – Today Intercell AG (VSE: ICLL) announced the results from a Phase I study investigating Intercell's adjuvant patch (Vaccine Enhancement Patch - VEP) containing LT (a heat-labile toxin from E. coli) in combination with an IM administration of an A/H5N1 antigen supplied by GSK.

This trial follows earlier Phase I and Phase II clinical investigations in combination with a pandemic Influenza antigen (manufactured by Solvay Biologicals, B.V.) carried out by Iomai Corp./ Intercell USA Inc. under a contract with the U.S. Department of Health and Human Services (HHS) to develop a dose-sparing Pandemic Influenza approach with the potential for a single application immunization.

The recent trial was performed to confirm the mode of action of transcutaneous applied adjuvants when co-administered with an Influenza A/H5N1 antigen, following different and inconsistent results from the previous Phase I and Phase II clinical studies.

The study involved 300 healthy adults and investigated two combinations of A/H5N1antigen doses with or without patch in one and two injection regimes. GSK's adjuvanted and licensed H5N1 vaccine was used to provide a positive control arm.

The combination of A/H5N1 with VEP met two of three CHMP criteria for Pandemic Influenza Vaccines (GMT fold rise from day 0 and Seroconversion). However, the study endpoint of a 2 or more fold rise in HI titers was not achieved since the immunogenicity was only moderately increased by VEP.

Further analysis revealed that the VEP effect was more pronounced and statistically significant on titer, seroconversion and seroprotection in subjects with existing HI titer (of > 1:10 at day 21) compared to A/H5N1 alone which indicates the potential for use of the VEP for booster vaccinations.

The overall adverse event rate was similar across all treatment groups and the local safety profile for the VEP was as expected from previous observations in various clinical studies where LT was administered transcutaneously.

"We are glad that we have been able to achieve a valid and decisive study outcome that allows us to finally assess the potential of the Vaccines Enhance Patch – our remaining Patch based program under clinical investigation". "Although the external adjuvantation effect in combination with A/H5N1 is not sufficient to proceed in a priming Pandemic Influenza indication, the results do indicate opportunities for transcutaneous booster vaccinations" states Thomas Lingelbach, Chief Executive Officer of Intercell AG.

Based on this study outcome and other pre-clinical results achieved with different antigens, Intercell will focus its future patch strategy on partnering and out-licensing – with a strong emphasis on antigen delivery as well as booster vaccination target product profiles.

About Intercell AG

Intercell AG is a vaccine-biotechnology company with the clear vision to develop and commercialize novel immunomodulatory biologicals to prevent disease and reduce suffering across the world.

Intercell's vaccine to prevent Japanese Encephalitis (JE) is the Company's first product on the market. This is a next generation vaccine against the most common vaccine-preventable cause of encephalitis in Asia licensed in more than thirty countries.

The Company's technology base includes novel platforms, such as the patch-based delivery system and the proprietary human monoclonal antibody discovery system eMAB®, in addition to well-established technologies upon which Intercell has entered into strategic partnerships with a number of leading pharmaceutical companies, including GSK, Novartis, Merck & Co., Inc., and Sanofi.

The Company's pipeline of investigational products includes a development program for the pediatric use of Intercell's JE-Vaccine IXIARO®/JESPECT® in non-endemic markets and the development for endemic markets in collaboration with Biological E. of a comparable vaccine based on Intercell's technology. Furthermore, the portfolio comprises different product candidates in clinical trials: a Pseudomonas aeruginosa vaccine candidate (Phase II/III) partnered with Novartis, a vaccine candidate against infections with C. difficile (Phase I) as well as numerous investigative vaccine programs using the Company's IC31® adjuvant, e.g. in a Tuberculosis vaccine candidate (Phase II).

Intercell has in-house cGMP capability to manufacture both clinical and commercial biologicals at its fully owned site in Livingston, Scotland. The manufacturing site is currently dedicated to the production of the Company's novel Japanese Encephalitis vaccine. It is licensed and operates under a Manufacturing Authorisation granted by the Medicines and Healthcare products Regulatory Agency (MHRA) and it is also registered by the FDA. As such, the facility is subject to routine inspection by the MHRA, FDA and other Competent Authorities in connection with the manufacture, sale and supply of Japanese Encephalitis vaccine (trade name IXIARO®/JESPECT®).

Intercell is listed on the Vienna Stock Exchange under the symbol "ICLL" (U.S. level one ADR symbol "INRLY").

For more information, please visit: www.intercell.com

Contact

Intercell AG
Corporate Communications
Campus Vienna Biocenter 3, A-1030 Vienna
P: +43-1-20620-1222/-1116
Mail to: communications@intercell.com

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