

Diese Meldung kann unter <http://www.presseportal.de/pm/53037/1539346/eans-news-intercell-starts-an-additional-efficacy-trial-for-its-patch-based-investigational> abgerufen werden.

Intercell AG

EANS-News: Intercell starts an additional efficacy trial for its patch-based investigational Travelers' Diarrhea Vaccine System in Asia

04.01.2010 - 17:33 Uhr, Intercell AG

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----- Research & Development

Wien (euro adhoc) - _ » Phase II pilot efficacy trial - placebo controlled field study to evaluate efficacy and enterotoxigenic E. coli (ETEC) incidence of vaccinated European travelers to India » Study designed to complement ongoing Phase III pivotal efficacy trial of European travelers to Latin America - data expected to further support licensure for prevention of enterotoxigenic E. coli (ETEC) disease in travelers to multiple risk regions » Results expected for end 2010

Vienna (Austria) / Gaithersburg (USA), January 4, 2010 - Intercell AG (VSE:ICLL) announced today the start of a Phase II study in India as part of its clinical development program for the investigational Travelers' Diarrhea (TD) Vaccine system. This placebo controlled field study with vaccinated travelers from the EU to India will test the efficacy of the Intercell TD vaccine. The primary objective of this clinical trial is prevention of all moderate/severe diarrheal cases in which LT, LT/ST or ST toxins (ETEC) are detected. The trial will enroll approximately 800 travelers from the UK and Germany.

"The start of our next important TD trial underlines our dynamic route to licensure and earliest possible commercialization with our marketing partner GSK. Positive results from this study can greatly support our expected product target profile" stated Thomas Lingelbach, COO of Intercell AG and CEO of Intercell USA.

About the Travelers' Diarrhea Vaccine System

The TD vaccine system is a combination of a patch containing the dry-formulated LT (heat-labile toxin from E. coli, the vaccine antigen) with a skin preparation system (SPS). The skin preparation system (SPS) disrupts the stratum corneum of the skin and prepares the skin for the antigen delivery. The antigen is dissolved from the patch by transepidermal water loss and diffuses into the skin. Activated Langerhans cells take the vaccine antigen to the draining lymph nodes where the immune response is initiated. Currently, this product candidate is undergoing pivotal Phase III testing in about 1,800 European travelers to Latin America. First results are expected end 2010 / early 2011.

About Travelers' Diarrhea

Diarrhea caused by enterotoxigenic E. coli (ETEC) is a disease associated with significant morbidity in travelers to areas of the world where fecal contamination of food and water is common. Travelers' diarrhea is generally a 4-5 day illness with frequent loose stools, usually associated with nausea, vomiting, abdominal cramps, prostration, and dehydration. ETEC is also implicated in new onsets of post-infectious irritable bowel syndrome (IBS), which affects 10 to 20% of travelers who develop Travelers' Diarrhea.

end of announcement

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----- Further inquiry note:

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