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XSpray Announces Positive Phase I Data for HyNap™ Nilotinib

STOCKHOLM - May 8, 2014. XSpray Microparticles AB today announced that its proprietary HyNap™ formulation of nilotinib demonstrated significantly improved uptake and reduced food interaction in a Phase I clinical trial compared to previously reported data for the commercial available formulation of nilotinib. XSpray is a Karolinska Development portfolio company that creates and develops improved and proprietary versions of already marketed products. Karolinska Development owns 63 percent of XSpray.

Protein kinase inhibitors (PKI) are used in the treatment of cancer and inflammation. Food interaction is a common problem with this class of drugs and to have control of the uptake from the gastrointestinal tract into the blood stream, patients are often restricted to be fasting in connection with administration. According to the drug label for the marketed PKI nilotinib, patients need to refrain from food intake for two hours before and one hour after administration of the drug. Several PKIs also suffers from pH dependent absorption which demand patients not to use acid reducing agents together with the PKI treatment.

In the completed cross-over Phase I clinical trial, XSpray measured the exposure of its proprietary HyNap™ formulation of nilotinib in healthy individuals. When administered in the fasted state, a HyNap™ nilotinib dose of 150 mg produced the same AUC values as those reported for a dose of 400 mg of the marketed product. After a high-fat meal the study showed an increase in drug exposure of 25 percent for HyNap™ nilotinib, measured both as peak concentration (Cmax) and area under the curve (AUC). For the marketed product the corresponding increases after a high-fat meal are reported to be 112 percent and 82 percent, respectively.

In addition to the clinical results obtained for HyNap™ nilotinib, XSpray has in a number of comparative *in vivo* preclinical studies showed improved results, for both exposure and reduced pH dependency for a number of other marketed PKIs.

“There are 24 small molecule PKI anti-cancer products on the market, and more than 250 in clinical development. Our innovative formulation HyNap™ has the potential to improve both present and upcoming product profiles improving safety and enhancing quality of life during this type of therapy”, said Per Andersson, CEO of XSpray.

“This study is the first to show proof of principle in man for a HyNap™ formulated protein kinase inhibitor and validates previous results obtained in animals. These results demonstrate that XSpray’s technology has the potential to be a platform technology, enabling formulation of compounds with superior properties that provide significant benefits for patients“, said Torbjörn Bjerke, CEO of Karolinska Development.

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TO THE EDITORS

About XSpray Microparticles AB
XSpray Microparticles AB is a drug delivery company working to overcome the significant problem of variable bioavailability due to pH dependent absorption, food effect and poor solubility. XSpray focus on creating improved versions of protein kinase inhibitors, which along with many oral targeted anticancer agents, exhibit these traits, and as a result exhibit variable and significant pH dependent bioavailability. This often leads to complicated dosing regimens for patients and even 'black box' warnings.

XSpray formulates compounds as HyNap™ – hybrid nanoparticles that are stable amorphous solid dispersions, which can be formed using a wide range of excipients. The technology is used both to improve and enhance the product profile of currently marketed drugs and to speed up the development of new drugs for the future.

XSpray has its headquarters and development laboratories in Stockholm, Sweden, and offers GMP material from its state-of-the-art facility.

About Karolinska Development AB
Karolinska Development aims to create value for patients, researchers, investors and society by developing innovations from world class science into differentiated products that can be partnered. The business model is to: SELECT the most commercially attractive medical innovations that can potentially satisfy unmet medical needs; DEVELOP innovations to the stage where the greatest return on investment can be achieved; and COMMERCIALIZE the innovations through the sale of companies or out-licensing of products. An exclusive deal flow agreement with Karolinska Institutet Innovations AB, along with other cooperation agreements with leading universities, delivers a continuous flow of innovations. Today, the portfolio consists of 34 projects, of which 17 are in clinical development. For more information, please visit www.karolinskadevelopment.com.

Karolinska Development is listed on NASDAQ OMX. Karolinska Development may be required to disclose the information provided herein pursuant to the Securities Markets Act.