Leukocare cooperates with the Drug Safety Foundation and the Central Laboratory of German Pharmacists to investigate the stability of monoclonal antibodies during shipment and storage

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Leukocare AG and the Drug Safety Foundation, together with the Central Laboratory of German Pharmacists, today announced their collaboration. The three partners will conduct a study to investigate how shipment affects the stability of diluted ready-to-use preparations of monoclonal antibodies.

The steadily growing outpatient care of cancer patients with ready-to-use drug products based on sensitive active ingredients poses a major challenge on supply logistics. Ready-to-use drug preparations are sometimes transported over long distances to the treatment centers. The study will contribute to a better understanding of the stability of protein-containing medicinal products during shipment in order to lay the foundations of increasing drug safety and patient benefits.

Dr. Franz Stadler, chair of the Foundation and its advisory board, commented, "For the first time globally, this study will determine, under realistic conditions, possible losses of active ingredients e.g. of effect during shipment of ready-to-use infusion bags for the most commonly used monoclonal antibodies. By funding this and future projects, the Drug Safety Foundation would like to contribute to improving drug safety. After all, drug safety concerns us all."

Dr. Andreas Seidl, Chief Operating Officer of Leukocare, added, "We are very pleased to support the Drug Safety Foundation and the Central Laboratory of German Pharmacists in their research projects by applying Leukocare's expertise and technologies. The development of optimized formulations will eventually improve transport and storage conditions and thus increases patient benefits."

Prof. Dr. Mona Tawab, Deputy Scientific Director of the Central Laboratory of German Pharmacists, commented, "We are delighted to collaborate with the Drug Safety Foundation

and Leukocare to answer an important but still unanswered question about the impact of shipment on the pharmaceutical quality of monoclonal antibodies prepared in diluted form in pharmacies. Because of the knowledge gained, it will be possible to derive practice-oriented recommendations and to support pharmacies even better in their daily tasks."

About Leukocare AG

Leukocare AG, located in Martinsried/Munich, Germany and Milford, MA, USA, is a biotechnology company specialized in the field of biopharmaceutical formulation development. Operating at the interface of drug substance and drug product development, Leukocare combines sound knowledge of formulation development with bioinformatics and artificial intelligence.

The formulation development approach consists of two elements: a library of up to 100 different regulatory well-established and employed excipients and a rational development approach which employs statistical software and self-learning algorithms as well as state of the art design of experiment (DoE) matrices. By utilizing the artificial intelligence elements, Leukocare is able to specifically combine excipients leading to stabilizing formulations tailored to the drug product's needs.

Leukocare's superior and innovative drug product formulations can be applied to a broad range of applications: biologics & biosimilars, vaccines & viral vectors and biofunctionalized devices.

www.leukocare.com

About the Drug Safety Foundation

Established in 2020, the Drug Safety Foundation is a non-profit, private foundation that strives to address the core issues of drug safety, particularly focusing on compliance, verification, continuous analysis, and improvement. The foundation's goal is to establish an additional control authority. The activities of the foundation are not subject to official procedures and processes, but address the issue of drug safety without reservations and without political or lobby-interest-driven guidelines. It covers tasks that are hardly focused on officially, or not at all. The foundation sees itself as an aid and supplement to official tasks and procedures.

Further information and the possibility of supporting the work of the Drug Safety Foundation through donations or endowments can be found at www.stiftung-arzneimittelsicherheit.de.

About the Central Laboratory of German Pharmacists

The Central Laboratory of German Pharmacists was founded in 1971 as an independent testing institute of the German Pharmacists. According to its statutes, its core task includes ensuring patient safety through the independent testing of raw materials, packaging materials and finished medicinal products; thereby guaranteeing the quality of medicinal products. For this purpose, the Central Laboratory works closely with the Drug Commission of German Pharmacists with regard to medicinal products monitored because of drug safety and independently conducts comparative studies on finished medicinal products. The Central Laboratory of German Pharmacists was the first one which found in very short time concentrations of NDMA in contaminated valsartan tablets, published these results and thus made a major contribution to patient safety. Furthermore, the Central Laboratory supports pharmacies in external quality assurance by offering round robin tests on formulation quality, hygiene in the formulation workplace, and blood tests performed in the pharmacy. In order to meet national and international quality standards, the testing institute has been equipped with sufficient personnel and lab technology so that it is able to address all important questions of drug quality.

www.zentrallabor.com

Contact:
Leukocare AG
Rebekka Ströver
Specialist Communications & Marketing
rebekka.stroever@leukocare.com
+ 49 (0) 89 7801 665 14

Drug Safety Foundation
Dr. Franz Stadler
Chairman of the Advisory Board
info@stiftung-arzneimittelsicherheit.de
+ 49 (0)89 90143108

Central Laboratory of German Pharmacists
Prof. Dr. Mona Tawab
Deputy Scientific Director of the Central Laboratory of German Pharmacists
m.tawab@zentrallabor.com
+49 6196-937955
+49 1517 4596291