ARTIDIS First Prospective Study, "NANO", Evaluating its Nanotechnology Platform Based on a Novel Nanomechanical Biomarker in Breast Cancer Meets Primary Endpoint

Basel, Switzerland, June 22, 2020 – ARTIDIS AG, a clinical stage health-tech company, announced today that its proprietary nanotechnology platform for cancer diagnosis has met the primary endpoint in the "NANO" clinical study. NANO was designed to demonstrate the power of using a nanomechanical biomarker to evaluate breast biopsies within a routine clinical setting. Secondary analysis indicates that the nanomechanical biomarker can be used independently of histopathology to differentiate and further categorize specific molecular subtypes of breast cancer.

Data from this study will be presented as a late-breaking abstract at the virtual Annual American Association for Cancer Research (AACR) Meeting that takes place from June 22-24, 2020.

The primary endpoint of the study was to achieve a sensitivity (proportion of true positive results divided by the total number of patients with a malignant tumor) for cancer diagnosis of at least 90% (CI 95%). The analysis for the primary endpoint was performed on data obtained from 520 patients. Biopsy tissue was categorized as "normal", "benign" or "malignant" based on a "Nanomechanical Score" as determined by the ARTIDIS nanotechnology platform. After the determination of the "Nanomechanical Score", histological analysis of the same specimens was performed to serve as a gold standard for comparison with the "Nanomechanical Score".

ARTIDIS was able to detect cancer, including lesions with < 5% neoplastic tissue, with a sensitivity of 96% and a specificity of 78% (CI 95%, AUC = 0.94), **meeting the primary study endpoint**.

"We are very pleased with the excellent results from this first prospective study conducted in Switzerland. It demonstrates the clinical utility of the nanomechanical biomarker in a routine clinical setting at the patient bedside. We are convinced that this brings us one step closer to providing patients undergoing a biopsy procedure with a same day diagnosis, opening the path to personalized cancer treatment plans guided by the ARTIDISNet platform." said Marija Plodinec, PhD, CEO of ARTIDIS AG.
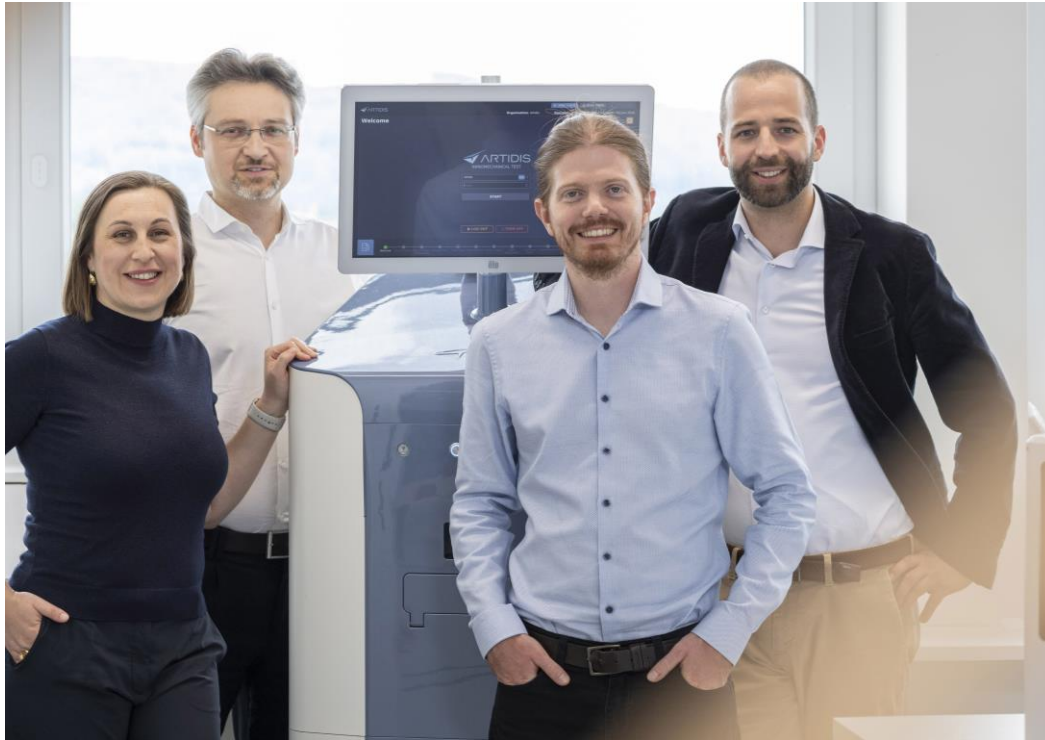
ARTIDIS management team

Secondary endpoints evaluated the ability of the nanomechanical biomarker to distinguish and further categorize molecular subtypes of breast cancer based on their aggressiveness and potentially poor treatment response.

While exploratory, secondary analysis indicates that the nanomechanical biomarker can be used independently of histopathology to differentiate and further categorize specific molecular subtypes of breast cancer (sensitivity 83%, specificity 82%, CI 95%, AUC = 0.86). The study includes a long-term follow-up of the same patients after two, five, and ten years.

"Secondary analyses indicate that this novel technology will be able to subclassify the breast cancer subtypes into more or less aggressive subgroups, which could define the patients' treatment plan and thus reduce over- and undertreatment." commented Dr. Rosemarie Burian, gynecologist at the Breast Center, University Hospital Basel and lead investigator of the study.

About the "NANO" study

To demonstrate clinical utility of the nanomechanical biomarker as measured by the ARTIDIS nanotechnology platform, a blinded prospective clinical study led by Dr. Rosemarie Burian, was conducted at the Breast Center, University Hospital Basel and at the Biozentrum, University of Basel from 2016 until 2019.

All patients undergoing a core needle or vacuum biopsy of the breast qualified for the study. Within 3 hours, fresh biopsies were analyzed in a physiological solution to maintain their viability for consecutive histological and genetic analysis within the routine clinical workflow. In total, 588 biopsies from N=545 patients were analyzed with a drop-out rate of 4.5%. 61.8% were B1-B4 (normal, benign, of uncertain malignant potential, or suspicious) and 38.2 % were B5a – B5d (malignant). The majority of the B5b lesions were Luminal B, followed by Luminal A, Luminal B-like, Her2 and triple negative breast cancers.

The nanomechanical biomarker measurements of the same patients were comprehensively analyzed in relation to more than 180 structured clinical parameters per patient within the digital ARTIDISNet platform to further categorize molecular subtypes of breast cancer based on their aggressiveness and potential for poor treatment response.

"I am delighted that the "NANO" study met its primary endpoint", said Dr. Burian. "I would like to thank my radiology colleagues Dr. Sophie Dellas and her team who were essential to the success of the study, Prof. Markus Tolnay's wonderful team of pathologists, in particular Prof. Ellen Obermann, Sabine Schädelin from the Clinical Trial Unit of the University Hospital, as well as the Biozentrum team led by Prof. Roderick Lim for their continuous collaboration. And, of course, I thank each of the patients who consented to participate in our study and thus supported us in their very personal way".

The Lead of the clinical study Dr. Rosemarie Burian

About ARTIDIS nanotechnology platform

ARTIDIS introduces a game-changing improvement in the field of cancer diagnostics and treatment by shortening the workflow of bedside biopsy analysis to less than three hours. The ARTIDISNet data platform integrates the mechanical biomarker data with other clinical parameters enabling personalized disease prognosis and aiding with treatment optimization, thereby significantly improving individual patient experience. Its sophisticated AI-powered algorithm allows healthcare professionals to gather insights into rich clinical data sets and supports them in tailoring the treatment of their patients securing better outcomes.

These aspects will be further examined in a multicenter study at centers in Switzerland, Germany, and the US. This will ensure that the current data is evaluated in an international setting and confirm its clinical validity across a wider cohort of patients.

"We are also expanding our clinical program to include the diagnosis of lung and pancreatic cancers and to identify its potential for treatment optimization in collaboration with centers in Barcelona, Spain, and the Texas Medical Center in Houston, US", commented Dr. Marija Plodinec.

About breast cancer

Breast cancer is the number one cancer among women worldwide. Each year, 7.5 million women rely on accurate and fast diagnosis and personalized advice when undergoing routine biopsy. Existing diagnostic procedures are complex and can take up to a week or longer resulting in high anxiety and negative patient experience. Out of all biopsies analyzed, approximately 25% will render a cancer diagnosis. These patients will benefit from a reliable biomarker supporting much faster, accurate disease prognosis and treatment optimization.

About ARTIDIS AG

ARTIDIS AG is a clinical stage health-tech company located in Basel, Switzerland, that has developed the first nanomechanical biomarker for cancer diagnosis and treatment optimization. The ARTIDIS nanotechnology platform integrates different types of clinical data into the ARTIDISNet digital platform, allowing physicians to significantly shorten the current diagnostic process bringing benefit to both the patient and the healthcare system. ARTIDIS applications are not limited to oncology, and its nanotechnology platform can be used to analyze any kind of living tissue. For more information please visit www.artidis.com

E-Poster Details:
Abstract #9677: First clinical validation of the physical biomarker based on the nanomechanical tissue profiling for rapid breast cancer diagnosis, prognosis and prediction of treatment outcome
Poster Session Title: Late-Breaking Research: Clinical Research 2
Poster Number: LB-273
Additional information on the meeting can be found on the AACR website:
https://www.aacr.org/meeting/aacr-annual-meeting-2020/aacr-virtual-annual-meeting-ii/

For further information please contact:
ARTIDIS AG
Dr. Marija Plodinec, CEO
Phone: +41 61 633 29 95
marija.plodinec@artidis.com