

## Previse Presents Data From Two Studies At Digestive Disease Week 2023 On New Tests To Detect Risk of Esophageal Cancer

Company behind Esopredict delivers oral and poster presentations sharing clinical data validating use of biomarkers to predict and detect esophageal cancer.

BALTIMORE, MARYLAND, UNITED STATES, May 9, 2023 /EINPresswire.com/ -- Previse, a developer of precision medicine solutions aimed at prevention and earlier detection of cancer, announced details on Monday, May 8, of two studies presented during Digestive Disease Week<sup>®</sup> 2023, held May 6-9 in Chicago. Both analyses clinically validate use of biomarkers to detect and assess risk of esophageal cancer developing in patients with Barrett's esophagus.

Esophageal cancer (EAC) is highly lethal, with a 20% five-year survival rate. According to American Cancer Society (ACS), in 2023, EAC is tied with liver cancer as the second-most lethal cancer in the U.S., only behind pancreatic cancer. ACS estimates about 21,560 new cases will be diagnosed in the U.S., and 16,120 people will die from EAC. To improve survival, it is critical to know which patients with precancerous Barrett's esophagus (BE), will progress to high-grade dysplasia or EAC in the future and to offer effective ways to screen for changes that could indicate EAC or precancer is present.

To address this need, Previse licensed cutting-edge biomarker technology focused on prediction and detection of esophageal cancer from Johns Hopkins University. This technology was made possible by grants from the National Institutes of Health (NIH) and developed after decades of research by Dr. Stephen Meltzer and his GI Early Detection Biomarker Lab at the Johns Hopkins University School of Medicine.

Esopredict<sup>™</sup> allows gastroenterologists to provide a tailored approach to BE treatment. During an oral presentation delivered at DDW 2023, Sarah Laun, Ph.D., VP of Research and Development at Previse presented clinical research validating Esopredict<sup>™</sup>'s ability to assess the risk of EAC developing in patients with BE.

Previse is also conducting research in which esophageal cytology samples are collected using a minimally-invasive swallowable sponge device. DNA from the samples is tested for biomarkers indicating EAC. At DDW 2023, Ke Ma, M.D. delivered a poster presentation sharing how researchers validated this test as a promising method of detecting EAC without endoscopy. This poster was a Poster of Distinction, rated in the top 10 percent of all American

Gastroenterological Association abstracts selected for poster presentation at DDW 2023.

"Our data demonstrates the high performance of our Esopredict<sup>™</sup> prognostic assay, and progress of our non-endoscopic esophageal cancer detection assay," stated Previse CEO, Daniel Lunz. "Together, these technologies will give healthcare providers data to detect, predict progression, and treat esophageal precancers and early cancers, providing the opportunity to save many lives."

Oral presentation details:

Title: Esopredict<sup>™</sup>: A Clinically Applicable Prognostic Assay for Risk Stratification of Patients with Barrett's Esophagus Presenter: Sarah Laun, Ph.D., VP of Research and Development, Previse Presented: May 8, 2023; 5:15 p.m. – 5:30 p.m. CDT

Intro: Management of Barrett's esophagus (BE), a precursor of esophageal adenocarcinoma (EAC), relies on diagnoses of dysplasia i.e., Non-dysplastic (ND), Low-grade Dysplasia (LGD), Indefinite for Dysplasia (IND), or High-grade Dysplasia (HGD). After years of evidence-based, surveillance programs, predicting progression of BE patients is still difficult due to high interobserver variability, inaccuracy, and rarity of dysplasia (absent in 90% of BE cases). In this study, Previse clinically validated the methylation-specific biomarker assay, Esopredict<sup>™</sup>, as a precise clinical assay to stratify BE patients for risk of progression to HGD or EAC.

Methodology: Researchers led a blinded, retrospective study of 335 BE patients across seven clinical sites. All index patient samples had pathology reports with histologic diagnoses (ND, IND, or LGD) and follow-up data with time between index biopsy and outcome biopsy (ND, IND, LGD, HGD, or EAC). Randomized data was split into training (147) and test (77) sets. In the training set, researchers performed uni- and multivariate analyses, variable selection, and Cox proportional hazards method. Data were sorted into four risk groups (Low, Favorable Intermediate, Unfavorable Intermediate, or High), to further inform clinical decisions that it represents for both surveillance frequency and treatment decisions. An additional independent validation set (115) was collected representing a clinical cohort, and predictive performance for this new algorithm was validated.

Results: To evaluate a four-tier classification, test and validation-independent data sets (n=188) were combined. The proportion of progressors to non-progressors increased across the four-risk tier categories. Patients in the high-risk group were 28 times more likely to progress vs. the low-risk group, and 11 times to four times more likely compared to the unfavorable-intermediate-risk to favorable-intermediate-risk groups, respectively. Prevalence-adjusted negative predictive value (NPV) of the low-risk group was 98% overall and 99% for patients who progressed within 10 years. Of patients that progressed within two years, 95% were identified by Esopredict<sup>™</sup> in intermediate or high-risk categories, and 89% of progressors were identified within five years.

Conclusion: Esopredict<sup>™</sup> has value to predict future risk of neoplastic progression in BE patients.

Risk-stratifying BE patients can improve care management by finding high-risk patients who may benefit from increased surveillance or treatment and low-risk patients who may not need as frequent surveillance.

Poster presentation details: Title: Non-Endoscopic Detection of Esophageal Adenocarcinoma Using Novel DNA Methylation Biomarker Panel Presenter: Ke Ma, M.D. Presented: May 8, 2023, 12:30 p.m. – 1:30 p.m. CDT

Synopsis: Researchers conducted genome-wide DNA screening to identify highly methylated regions in samples from patients with esophageal adenocarcinoma (EAC). Top-performing biomarkers were identified and tested on matched EAC and normal esophageal tissues obtained from 22 patients. Each biomarker was further evaluated in a cross-sectional case-control study of 105 patients from whom esophageal cytology samples were collected using a swallowable sponge device.

A multi-marker classification algorithm was created using the most promising biomarkers. The cross-validation study's predictive model demonstrated an AUC of 0.92, demonstrating a promising non-endoscopic method of detecting EAC. Research will continue to develop a comprehensive non-invasive test to detect EAC, precancerous BE, and esophageal squamous cell carcinoma.

## About Previse

Previse is on a mission to save lives through the earlier detection and prevention of cancer, starting with esophageal cancer. Learn more at <u>www.previsedx.com</u>. For press inquiries please contact press@previsedx.com.

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