

PROLIGHT ANNOUNCES POSITIVE PRE-CLINICAL DATA

Prolight Diagnostics today announces positive results from the company's pre-clinical validation study using plasma biobank samples. The results demonstrate that Prolight is on track to deliver its high-sensitivity troponin assay on the Psyros™ single-molecule-counting system.

"The study results are highly encouraging and affirm the performance underlying the Psyros technology. Our system demonstrated very good clinical sensitivity and specificity with chest-pain samples, provided an initial estimate of the healthy normal reference range and showed equivalence of commercial prototypes with lab prototypes. All in all, this gives us added confidence as we progress towards the full clinical performance study, which is planned to start later this year," said Ulf Bladin, CEO at Prolight.

"This is the first time that we have tested significant numbers of patient samples on the Psyros platform. To obtain such good data on the first attempt has reassured us that the Psyros single-molecule-counting POC system will deliver as promised," said Aileen McGettrick, Chief Scientific Officer at Prolight.

A primary estimation of the reference range for healthy individuals was carried using duplicate measurements on 294 samples from the ADLM (Association for Diagnostics and Laboratory Medicine) Universal Sample Bank. The measurement distribution and pooled precision were consistent with the definition of a high-sensitivity troponin assay.

Clinical sensitivity and specificity were estimated from 94 chest-pain samples (46 with confirmed myocardial infarction) measured on in-house prototype instruments and also measured on Psyros™ commercial prototypes. The areas under the ROC curve (AUC) were 0.97 and 0.98 respectively, demonstrating good clinical performance. The correlation between in-house prototypes and commercial prototypes (R^2) of 0.97 confirms that our low-cost optical module can deliver the performance required for launch.

"Going forward, these positive results enable us to focus on the final optimisation of the Psyros POC system and to continue our planning for the full clinical performance study. In parallel, we continue to explore opportunities with potential industrial partners," said Ulf Bladin CEO at Prolight Diagnostics.

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About Us

Prolight Diagnostics AB develops innovative Point-of-Care (POC) systems. These are small, portable instruments and disposable cartridges for performing in-vitro diagnostic (IVD) tests from a drop of blood.

We want to offer the foremost POC systems on the market for quick, reliable diagnosis of acute events. Our launch product will be for the measurement of troponin, to aid in the rule-in and rule-out of myocardial infarction.

The company's share is traded on the NGM Nordic SME marketplace, under the ticker PRLD.

This information is information that Prolight Diagnostics is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2025-03-31 08:00 CEST.

Attachments

Prolight announces positive pre-clinical data