Photocure Provides Update on AssureMDx and Anticipated Medicare Coverage Timeline

Press release – Oslo, Norway, November 9, 2026 – Photocure ASA (OSE: PHO), the Bladder Cancer Company, today provides an update on AssureMDx™ and progress since the acquisition of Vesica Health on June 4, 2026.

Since closing the acquisition, Photocure has continued to advance the commercial and reimbursement strategy for AssureMDx. Discussions with the relevant pricing authorities have been encouraging, with indications of a potential reimbursement level meaningfully above the assumptions included in Photocure's initial acquisition underwriting.

AssureMDx received FDA Breakthrough Device Designation in February 2026, further supporting its clinical and regulatory positioning. Medicare pricing and coverage are separate processes on different timelines. CMS expects to make a final pricing determination before year-end 2026, and the resulting rate would take effect January 1, 2027.

For coverage, Photocure's planning assumption at the June 2026 acquisition was Medicare coverage in 2028, following submission of additional clinical evidence. The proposed Local Coverage Determination ("LCD") from Novitas in May 2026 presented an opportunity for an earlier coverage determination. However, AssureMDx was not yet included in the newly published LCD dated November 6, 2026, for urine-based biomarkers in patients with microhematuria. The determination identifies additional clinical evidence required to support future coverage reconsideration. Accordingly, the anticipated Medicare coverage timeline remains aligned with the Company's original acquisition assumptions.

AssureMDx is already supported by substantial published clinical validation evidence, including prospective studies and microhematuria-specific analyses demonstrating strong diagnostic performance. Novitas acknowledged the favorable diagnostic performance and potential clinical utility of the existing evidence. In the largest prospective study, AssureMDx demonstrated the potential to spare 89% of patients with microhematuria from cystoscopy, while all upper-tract urothelial cancers in the study were detected. This evidence also contributed to the inclusion of AssureMDx in

the 2025 microhematuria guidelines issued by the American Urological Association and the Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (AUA/SUFU), providing important independent recognition of its clinical relevance.

Further clinical evidence generation is already underway. The SeARCH study is an investigator-initiated randomized controlled trial conducted by Erasmus University Medical Center (Erasmus MC) in the Netherlands, with Photocure supporting the study as an industry sponsor and collaborator through its Vesica Health entity. Supported by a grant from the Dutch Cancer Society, the study involves approximately 1,100 patients with microhematuria and was initiated prior to Photocure's acquisition of Vesica Health. SeARCH is evaluating the clinical utility of AssureMDx in guiding diagnostic decisions and reducing unnecessary cystoscopies while maintaining patient safety.

In parallel, Photocure is finalizing the protocol for PATHWAY, a U.S. randomized controlled clinical utility study designed to generate additional evidence in the intended-use microhematuria population. Photocure intends to reengage with the Novitas medical review team to discuss the evidence expectations outlined in the published LCD, share its planned clinical development approach, and seek feedback ahead of study initiation. Together, SeARCH and PATHWAY are designed to generate high-quality randomized clinical utility evidence to support future Medicare coverage reconsideration and potential updates to clinical guidelines.

"The proposed LCD in May 2026 presented an opportunity to accelerate Medicare coverage, while our original development strategy anticipated the potential need for additional randomized clinical utility evidence," said Dan Schneider, President and CEO of Photocure. *"We are encouraged by the recognition of AssureMDx's diagnostic performance in the published clinical literature and AUA/SUFU guidelines, as well as the progress we are making across our pricing and commercial reimbursement strategy. With SeARCH already underway and PATHWAY approaching initiation, we remain focused on generating the additional evidence needed to support future Medicare coverage and advancing AssureMDx as part of our broader uro-oncology precision diagnostics platform."*

The published LCD does not preclude commercialization of AssureMDx through commercial payer and other reimbursement channels, which Photocure will continue to pursue. Consistent with its original acquisition assumptions, the Company continues to expect initial AssureMDx revenue in 2027.

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About Bladder Cancer

Bladder cancer ranks as the 6th most common cancer worldwide – the 4th most common in men – with 1 978 000 prevalent cases (5-year prevalence rate)[1a], 635 000 new cases and more than 227 000 deaths in 2024.[1b]
Approx. 75% of all bladder cancer cases occur in men.[1] It has a high recurrence rate with up to 61% in year one and up to 78% over five years.[2] Bladder cancer has the highest lifetime treatment costs per patient of all cancers.[3]
Bladder cancer is a costly, potentially progressive disease for which patients have to undergo multiple cystoscopies due to the high risk of recurrence. There is an urgent need to improve both the diagnosis and the management of bladder cancer for the benefit of patients and healthcare systems alike.
Bladder cancer is classified into two types, non-muscle invasive bladder cancer (NMIBC) and muscle-invasive bladder cancer (MIBC), depending on the depth of invasion in the bladder wall. NMIBC remains in the inner layer of cells lining the bladder. These cancers are the most common (75%) of all BC cases and include the subtypes Ta, carcinoma in situ (CIS) and T1 lesions. In MIBC the cancer has grown into deeper layers of the bladder wall. These cancers, including subtypes T2, T3 and T4, are more likely to spread and are harder to treat.[4]

[1] Globocan. a) 5-year prevalence / b) incidence/mortality by population. Available at: http://gco.iarc.fr/today, accessed [August 2026].
[2] Babjuk M, et al. Eur Urol. 2019; 76(5): 639-657
[3] Sievert KD et al. World J Urol 2009;27:295–300
[4] Bladder Cancer. American Cancer Society. http://www.cancer.org/cancer/bladder-cancer.html

About AssureMDx™

AssureMDx is a non-invasive, urine-based molecular test designed to aid in the early detection of bladder cancer in patients presenting with hematuria. Offered as a laboratory-developed test (LDT) service, the test analyzes a combination of DNA mutation and methylation biomarkers associated with bladder cancer. The test has been validated in multiple prospective multicenter clinical studies, demonstrating overall sensitivity of 96%, negative predictive value (NPV) of >99% and an area under the curve (AUC) of 0.96 for bladder cancer. The test is included in the AUA/SUFU Microhematuria Guideline and received U.S. FDA Breakthrough Device Designation in February 2026.

About Photocure ASA

Photocure is a commercial diagnostic company with global reach, committed to driving progress in uro-oncology precision diagnostics, delivering meaningful advances for patients with urological cancers. Our unique core technology has led to better health outcomes for patients worldwide. The company aims to provide an array of transformative solutions that

help physicians with timely diagnostic information, to inform more personalized decisions on how best to manage each individual patient. Photocure is headquartered in Oslo, Norway and listed on the Oslo Stock Exchange (OSE: PHO). For more information, please visit www.photocure.com/news.

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