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NEWS RELEASE

Waters Achieves FDA 510(k) Clearance for Ready-to-Use Flow Cytometry Clinical Tests for Leukemia and Lymphoma

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- BD OneFlow™ LST and BD OneFlow™ B-CLPD T1 Tests now FDA 510(k)-cleared in U.S. for identifying B-cell non-Hodgkin lymphoma (NHL)
- Delivers 96.3% sensitivity and 98.2% specificity[1] in identifying chronic lymphocytic leukemia (CLL), one of the most common types of NHL
- All-in-one solution reduces 95% of manual steps,[2] delivering workflow efficiency, fast turnaround times, and a reduction in errors

MILFORD, Mass., Nov. 10, 2026 /PRNewswire/ -- Waters Corporation (NYSE: WAT) today announced that the BD OneFlow LST Test and BD OneFlow B-CLPD T1 Test have received U.S. Food and Drug Administration (FDA) 510(k) clearance. This clearance enables commercialization in the U.S. and provides pathologists and clinicians a standardized, ready-to-use flow cytometry testing solution that aids in identification and diagnosis of B-cell non-Hodgkin lymphoma (NHL), including chronic lymphocytic leukemia (CLL), for faster and reliable diagnostic insights.[2]

The latest in a series of innovations delivered since Waters combined with BD's Biosciences & Diagnostic Solutions Businesses, the BD OneFlow Solution integrates reagents, instruments, defined staining protocols, pre-defined assay templates, and supporting consumables into a consistent, recurring workflow for immunophenotyping normal and abnormal cell populations. The solution significantly reduces hands-on time compared to liquid reagent cocktails, helping labs increase workflow efficiency, speed turnaround time, and lower the risk of human error.

"Clinical flow cytometry in the U.S. has traditionally been laboratory-developed and institution-specific," said Alexandra Kovach, M.D., Hematopathologist, Boston Children's Hospital. "Standardization of gating, analysis, and

interpretation of flow cytometry data across sample types and diseases provide reproducibility, reliability, and confidence in the results for patients and their providers in our increasingly fragmented health care system. For these reasons, flow cytometry-based IVD diagnostics are well positioned to bring significant value to patient care."

In 2026, an estimated 79,320 people in the U.S. will be diagnosed with NHL, including 22,760 cases of CLL, which is expected to cause approximately 4,350 deaths.[3] CLL is the most common form of leukemia in adults, accounting for approximately one-third of new leukemia cases in the U.S.[3] Expanding access to accurate, standardized diagnostic testing can help pathologists and clinicians identify disease and determine the appropriate path for further evaluation, monitoring, and treatment.

"Marking the first FDA clearance from the broader BD OneFlow portfolio, the BD OneFlow LST Test and BD OneFlow B-CLPD T1 Test represent an important step toward making reliable, high-quality flow cytometry diagnostics for blood cancers more accessible to U.S. laboratories and the patients they serve," said Steve Conly, Senior Vice President, Waters Biosciences, Waters Corporation. "We want to reduce the complexity and variability that labs face in diagnosing disease, and this clearance establishes a foundation for bringing additional standardized tests to other blood cancers in the future."

The broader BD OneFlow portfolio is comprised of tests built on the research and validation work of the EuroFlow™ Consortium, a collaborative research effort to develop fast, highly sensitive flow cytometry tests for diagnosis, classification, and monitoring of hematological malignancies. Within this portfolio, tests supporting the evaluation of other blood cancers including multiple myeloma (MM), acute lymphoblastic leukemia (ALL), and acute myeloid leukemia (AML) have been available as CE-IVD reagents.

The BD OneFlow LST and BD OneFlow B-CLPD T1 Tests are available for preorder and will be commercially available in the U.S. in spring 2027 through online ordering and local representatives.

For more information, please visit **www.bdbiosciences.com/oneflow-us**.

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Additional Resources:

- Product Page: **www.bdbiosciences.com/oneflow-us**

About Waters Corporation:

Waters Corporation (NYSE: WAT) is a global leader in life sciences and diagnostics, dedicated to accelerating the

benefits of pioneering science through analytical technologies, informatics, and service. With a focus on regulated, high-volume testing environments, our innovative portfolio harnesses deep scientific expertise across chemistry, physics, and biology. We collaborate with customers around the world to advance the release of effective, high-quality medicines, ensure the safety of food and water, and drive better patient outcomes by detecting diseases earlier, managing routine infections, and combating antibiotic resistance. Through a shared culture of relentless innovation, our passionate team of ~15,000 colleagues turn scientific challenges into breakthroughs that improve lives worldwide. For more information, please visit **www.waters.com/about**.

Disclaimer:

The BD Biosciences and BD Diagnostic Solutions businesses have been acquired by Waters Corporation ("Waters"). Becton, Dickinson and Company or one of its affiliates or subsidiaries ("BD") remains the legal manufacturer of Biosciences and Diagnostic Solutions products until all required regulatory transfers are completed. During this interim period, BD maintains full responsibility for all regulatory obligations of the legal manufacturer. Product information provided here is supplied under BD's regulatory authority. To learn more about the relationship between Waters and BD during this transition period, please see our detailed summary: **www.waters.com/bdtransaction**.

References:

Internal clinical study.
Internal Waters Data from internal study comparing OneFlow assay tubes with liquid antibodies.
NIH Cancer Stat Facts: Leukemia - Chronic Lymphocytic Leukemia (CLL), Non-Hodgkin Lymphoma.

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