



Bionano Announces Publication Showing Utility of Optical Genome Mapping in Clinical Research of Infant & Toddler T-ALL

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SAN DIEGO, Aug. 07, 2025 (GLOBE NEWSWIRE) -- Bionano Genomics, Inc. (Nasdaq: BNGO) today announced a peer-reviewed publication from a team led by Manon Delafoy from the Institut Necker Enfants Malades (INEM) and colleagues from multiple French pediatric hematology centers showing how optical genome mapping (OGM) can be used to detect oncogenic structural variants (SVs) in clinical research of infant and toddler T-cell acute lymphoblastic leukemia (T-ALL). The publication shows that OGM can reveal distinct genetic drivers and prognostic subgroups that conventional cytogenetics failed to identify in a retrospective, national cohort of 27 T-ALL cases of infants and toddlers (<3 years) as part of a combined workflow of targeted sequencing, OGM, and RNA sequencing. Infants and toddlers can be a difficult segment of the population to analyze because their cancers are rare. The study conclusions support using OGM as a complementary tool to conventional assays to help accurately stratify samples from infants and toddlers according to prognostic risk.

Key OGM Findings based on Retrospective Analysis

- **NKX2 rearrangements in one-third of cases:** In the French cohort, 33% of cases (9 of 27) infant/toddler T-ALL cases carried *NKX2* family gene rearrangements. These events had not been previously characterized in this age group and frequently co-occurred with *MYB* alterations (5/9) or complex chromothripsis-like events (3/9)
- **Distinct genomic profile versus older pediatric subjects:** Compared with a larger cohort of 245 cases aged 3-18 years, infant/toddler cases lacked *TLX1/3* dysregulation but showed rates of *TAL1*-like anomalies (30%), *STAG2::LMO2* fusions (15%), *ETS* rearrangements (15%), and rarely, *KMT2A* rearrangements (7%)
- **Comparable survival despite aggressive presentation:** Despite higher rates of hyperleukocytosis and slower treatment response, these youngest subjects (infants and toddlers) achieved a 5-year overall survival (OS) of 75.4% (95% confidence interval [CI]: 60.0%–94.8%), closely matching the 75.2% (95% CI: 69.8%–81.1%) seen in the older pediatric subjects ($p = 0.86$) in the retrospective cohort
- **Prognostic subgroups defined by structural variants in the retrospective analysis:** Alterations in *NKX2*, *KMT2A*, and *STAG2::LMO2* identified a subgroup with 100% overall survival (OS), whereas subjects with *TAL1* or *ETS* dysregulation had less favorable outcomes. Findings were further supported by analysis of an independent cohort from the COG AALL0434 trial.
- **Single-workflow capability of OGM:** OGM enabled detection and precise sizing of cryptic or complex rearrangements in a single assay, streamlining genomic profiling, compared to conventional or standard screening methods that may miss key variants or require multiple tests

"This study represents a significant collaborative effort across leading centers in France and offers a substantial leap forward for the pediatric leukemia community. Studying T-ALL in infants and young children is difficult because data are scarce and the genomic landscape is complex. Furthermore, standard approaches can often miss critical variants. OGM can provide a more complete view of the genome, revealing structural alterations that would otherwise remain hidden, uncovering drivers that can guide how we classify these cases, which may one day lead to better disease management and treatment," said Erik Holmlin, Bionano's President and CEO.

The full research publication is available at: <https://onlinelibrary.wiley.com/doi/epdf/10.1002/hem3.70154>

About Bionano

Bionano is a provider of genome analysis solutions that can enable researchers and clinicians to reveal answers to challenging questions in biology and medicine. The Company's mission is to transform the way the world sees the genome through optical genome mapping (OGM) solutions, diagnostic services and software. The Company offers OGM solutions for applications across basic, translational and clinical research. The Company also offers an industry-leading, platform-agnostic genome analysis software solution, and nucleic acid extraction and purification solutions using proprietary isotachopheresis (ITP) technology. Through its Lineagen, Inc. d/b/a Bionano Laboratories business, the Company also offers OGM-based diagnostic testing services.

For more information, visit www.bionano.com or www.bionanolaboratories.com.

Bionano's products are for research use only and not for use in diagnostic procedures.

Forward-Looking Statements of Bionano Genomics

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "can," "may," "expect," "will" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) convey uncertainty of future events or outcomes and are intended to identify these forward-looking statements. Forward-looking statements describe future expectations, plans, results, or strategies, among other things, and in this release include, but are not limited to, the ability of OGM to reveal distinct genetic drivers and prognostic subgroups that conventional cytogenetics failed to identify in a national cohort of 27 T-ALL cases of infants and toddlers (<3 years) as part of a combined workflow of targeted sequencing, OGM, and RNA sequencing; the ability of OGM to provide a more complete view of the genome, revealing structural alterations that would otherwise remain hidden, uncovering drivers that can guide classification of

cases; the ability of OGM to lead to better disease management and treatment; and any other statements that are not historical fact. Such statements are subject to a multitude of risks and uncertainties that could cause future circumstances, events, or results to differ materially from those projected in the forward-looking statements. Each of these forward-looking statements involves risks and uncertainties. Actual results or developments may differ materially from those projected or implied in these forward-looking statements. Factors that may cause such a difference include the risks and uncertainties associated with: the failure of OGM to reveal distinct genetic drivers and prognostic subgroups that conventional cytogenetics failed to identify in a national cohort of 27 T-ALL cases of infants and toddlers (<3 years) as part of a combined workflow of targeted sequencing, OGM, and RNA sequencing; the failure of OGM to provide a more complete view of the genome, revealing structural alterations that would otherwise remain hidden, uncovering drivers that can guide classification of cases; the failure of OGM to lead to better disease management and treatment; study results that differ or contradict the results mentioned in this press release; our ability to obtain sufficient financing to fund our strategic plans and commercialization efforts and our ability to continue as a "going concern," which requires us to manage costs and obtain significant additional financing to fund our strategic plans and commercialization efforts; the risk that if we fail to obtain additional financing we may seek relief under applicable insolvency laws; the impact of adverse geopolitical and macroeconomic events, such as the ongoing conflicts between Ukraine and Russia and Israel and Gaza and uncertain market conditions, including inflation, tariffs, and supply chain disruptions, on our business and the global economy; general market conditions; changes in the competitive landscape and the introduction of competitive technologies or improvements to existing technologies; changes in our strategic and commercial plans; the ability of medical and research institutions to obtain funding to support adoption or continued use of our technologies; and the risks and uncertainties associated with our business and financial condition in general, including the risks and uncertainties described in our filings with the Securities and Exchange Commission ("SEC"), including, without limitation, our Annual Report on Form 10-K for the year ended December 31, 2024 and in other filings subsequently made by us with the SEC. All forward-looking statements contained in this report speak only as of the date on which they were made and are based on management's assumptions and estimates as of such date. We are under no duty to update any of these forward-looking statements after the date they are made to conform these statements to actual results or revised expectations, except as required by law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date the statements are made. Moreover, except as required by law, neither we nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements contained in this press release.

CONTACTS

Company Contact:

Erik Holmlin, CEO
Bionano Genomics, Inc.
+1 (858) 888-7610
eholmlin@bionano.com

Investor Relations:

Kelly Gura
Gilmartin Group
+1 (212) 229-6163
IR@bionano.com



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