GeneDx Announces First U.S. National Genomic Newborn Screening Initiative Launched with $14.4 Million NIH Award

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‘BEACONS,’ a multi-state collaboration led by Mass General Brigham and Ariadne Labs, will enroll up to 30,000 newborns to explore adding genomic sequencing in U.S. newborn screening

GAITHERSBURG, Md., October 01, 2025--(BUSINESS WIRE)--GeneDx (Nasdaq: WGS), a leader in delivering improved health outcomes through genomic insights, alongside Mass General Brigham, Ariadne Labs, Boston Children’s Hospital, Albert Einstein College of Medicine, the Association of Public Health Laboratories (APHL), Case Western Reserve University, Baylor College of Medicine, and Illumina, today announced the launch of BEACONS (Building Evidence and Collaboration for GenOmics in Nationwide Newborn Screening), the nation’s first multi-state genomic newborn screening initiative.

Funded by a $14.4 million award from the National Institutes of Health (NIH) Common Fund Venture Program, BEACONS will pilot the integration of whole genome sequencing into existing state newborn screening systems. The study will recruit, consent, and enroll up to 30,000 newborns in as many as 10 states over the next three years. If successful, BEACONS will provide the first national evidence that genome sequencing can be implemented responsibly, fairly, and sustainably through public health newborn screening programs. The project is intended as the beginning of a broader national initiative, with the potential to scale beyond the initial 30,000 newborns.

APHL’s Newborn Screening and Genetics program directors Jelili Ojodu, MPH and Sikha Singh, MHS, PMP, co-investigators, will provide critical leadership to align the study with state public health laboratories and programs. By working collaboratively with existing newborn screening

programs, the initiative aims to build a sustainable roadmap for incorporating genome sequencing into U.S. public health practice.

"For more than 50 years, newborn screening has been a beacon of trust, saving children's lives by analyzing a few drops of blood after birth," said Robert Green, MD, MPH, contact and co-lead investigator at Mass General Brigham and Ariadne Labs. "BEACONS brings the next generation of hope, giving families the option of genomic screening for hundreds of additional conditions that can be treated from birth, in an era when gene and cell therapies are rapidly expanding treatment possibilities. Together, families who volunteer in participating state programs will be collaborating in a national effort to give every child the brightest start to life."

GeneDx will perform genomic sequencing and interpretation for the study. Partners bring expertise to the technical aspects of testing, while the overall governance, data protections, and decision-making will remain firmly anchored in the public health and academic sectors which will be guided by parental consent preferences. With advanced genomic technology, the world's largest rare disease dataset, and unmatched clinical expertise, GeneDx has diagnosed more children with rare diseases – and screened more newborns with genomic sequencing – in the U.S.
"By bringing the power of genomics to the very start of life, we have the potential to shorten, and one day eliminate, the diagnostic odyssey that so many families endure," said Britt Johnson, PhD, FACMG, Senior Vice President of Medical Affairs at GeneDx. "This collaboration marks an exciting and transformative step toward a future where every child has the opportunity to live a healthier, fuller life."

BEACONS is led by a multidisciplinary leadership team, combining scientific, clinical and ethical expertise to guide every aspect of the project. "Knowledge is power. Identifying early that a child has a treatable or preventable condition gives the child the best chance for a healthy life. It also means parents won't have to go through the long diagnostic odyssey that is so common in children with rare diseases, sometimes delaying a diagnosis until it is too late to provide treatment that could change the course of their medical outcome," said Ingrid Holm, MD, MPH, co-lead investigator at Boston Children's Hospital.

Early in the study, the team will select which genetic conditions to include in screening with input from rare disease advocates, state public health laboratories, and evidence from prior research studies. "We will be developing a list of conditions which, when identified early, can meaningfully improve the health of a child," said Nina Gold, MD, MS, co-lead investigator at Mass General Brigham.

Parental and community perspectives are integral to BEACONS and will be incorporated throughout the project. Newborns will be enrolled only after parental education and consent, and parents will be invited to participate in a series of surveys and interviews about their experiences to ensure that their voices are heard. A Community Advisory Board will contribute critical insight to help address the complex ethical, legal, privacy, and social considerations of newborn sequencing.

"We will rely on the input of parents and community leaders to make sure that newborn screening expansion is done in a thoughtful and transparent way," said Melissa Wasserstein, MD, co-lead investigator from Albert Einstein College of Medicine and Children's Hospital at Montefiore Einstein. "This is about building trust as much as building science."

For more information about BEACONS, see www.BEACONSnbs.org.

Read the NIH's announcement: https://commonfund.nih.gov/venture/nbsxwgs/news/nih-venture-program-announces-first-award-beacons-initiative

BEACONS is supported by the following award from the National Institutes of Health: 1OT2OD040029-01

To connect with BEACONS investigators, please email info@BEACONSnbs.org

QUOTE SHEET

Leading experts in the ethical, legal, and social dimensions of genomics, including Aaron Goldenberg PhD, MPH, co-investigator at Case Western Reserve University School of Medicine and Stacey Pereira, PhD, co-investigator at Baylor College of Medicine, will oversee outcomes research and guide the Community Advisory Board composed of parents, advocates, community leaders, clinicians, genetic counselors, bioethicists, and data privacy experts.

"Evaluating the feasibility of genomic newborn screening requires careful attention to ethical, legal, and social concerns," said Aaron Goldenberg, PhD, MPH, co-investigator at Case Western Reserve University School. "Our study will explore ways programs can reflect parental and public values, protect a newborn's privacy, preserve universal access, and enhance the benefits of newborn screening for all families."

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"APHL is proud to join this partnership in bringing whole genome sequencing to newborn screening in a way that will provide more information to families and save even more babies' lives. We welcome the opportunity to bring innovation to the public health laboratory community and the newborn screening system," said Jelili Ojodu, MPH, senior director, Newborn Screening and Genetics, APHL.

"Integrating genomics into healthcare starting at birth to reduce the burden of genetic diseases has been an important concept since the Human Genome Project," said Swaroop Aradhya, PhD, Global Head of Medical & Scientific Affairs at Illumina. "Research conducted by this group will produce critical insights that inform proper use of whole genome sequencing for newborn screening in the US public healthcare setting."

About GeneDx

GeneDx (Nasdaq: WGS) is the global leader in rare disease diagnosis, transforming the way medicine is practiced by making genomics the starting point for health, not the last resort. We bring together unmatched clinical expertise, advanced technology, and the power of GeneDx Infinity™ – the largest rare disease dataset – built over 25 years from millions of genomic tests and deep clinical insights. This unparalleled foundation powers our ExomeDx and GenomeDx tests, giving clinicians the highest likelihood of delivering a timely, accurate diagnosis. GeneDx is shaping the future of healthcare by moving the standard of care from sick care to proactive healthcare. While our roots are in rare disease diagnosis, our commitment extends beyond – growing with the families we serve – as a trusted partner at every stage of life. For more information, visit genedx.com and connect with us on LinkedIn, Facebook, and Instagram.

Forward Looking Statements

This press release may contain "forward-looking statements" within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and the U.S. Private Securities Litigation Reform Act of 1995. These forward-looking statements generally are identified by the words "believe," "project," "expect," "anticipate," "estimate," "intend," "strategy," "future," "opportunity," "plan," "may," "should," "will," "would," "will be," "will continue," "will likely result," and similar expressions. Forward-looking statements are predictions, projections and other statements about future events that are based on current expectations and assumptions and, as a result, are subject to risks and uncertainties. Many factors could cause actual future events to differ materially from the forward-looking statements in this press release, including but not limited to: (i) our ability to implement plans to accelerate and unlock the full potential of precision medicine, (ii) the risk of downturns and a changing regulatory landscape in the highly competitive healthcare industry, (iii) the size and growth of the market in which we operate, (iv) our ability to pursue our new strategic direction. The foregoing list of factors is not exhaustive. A further list and description of risks, uncertainties and other matters can be found in the "Risk Factors" section of our Annual Report on Form 10-K for the fiscal year ended December 31, 2024 and our Quarterly Reports on Form 10-Q for the fiscal quarters ended March 31, 2025 and June 30, 2025, and other documents filed by us from time to time with the SEC. These filings identify and address other important risks and uncertainties that could cause actual events and results to differ materially from those contained in the forward-looking statements. Forward-looking statements speak only as of the date they are made. Readers are cautioned not to put undue reliance on forward-looking statements, and we assume no obligation and do not intend to update or revise these forward-looking statements, whether as a result of new information, future events, or otherwise. We do not give any assurance that we will achieve our expectations.

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