

Press Release

VB Spine Announces FDA Breakthrough Device Designation for New Blood Test Designed to Identify Patients at Risk for Scoliosis Progression

ScolimiR-3D, a novel microRNA-based blood test, is designed to enable earlier intervention and personalized management of adolescent idiopathic scoliosis based on progression risk

NEW YORK, Sept. 29, 2026 – VB Spine LLC (“VB Spine”), the largest privately-held spine company, today announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Device Designation to ScolimiR-3D, an in-vitro diagnostic blood test designed to assess the risk of disease progression in patients diagnosed with adolescent idiopathic scoliosis (AIS). The designation is the first granted to a predictive diagnostic scoliosis risk assessment test.

ScolimiR-3D uses a standard blood draw to measure six circulating microRNAs associated with AIS progression and classify a patient's risk of developing a severe spinal curve. Dr. Alain Moreau and colleagues at the Viscogliosi Laboratory in Molecular Genetics of Musculoskeletal Diseases, part of the Centre de recherche Azrieli du CHU Sainte-Justine and Université de Montréal, developed the underlying science, which was published in Scientific Reports.¹ In that study of 116 AIS patients, the six-microRNA panel that forms the basis of ScolimiR-3D predicted the risk of developing severe scoliosis with 100% sensitivity and 100% specificity in the study's validation testing.

“For decades, physicians have had limited tools to determine which patients with adolescent idiopathic scoliosis are most likely to experience disease progression,” said Dr. Moreau. “The challenge in scoliosis is not simply detecting the curve—it is knowing where that curve is going,” said Dr. Moreau. “ScolimiR-3D was developed to bring that predictive dimension into clinical care: using a simple blood test to identify progression risk earlier, when there is still an opportunity to personalize treatment and potentially change a patient’s trajectory.”

Scoliosis management today is largely reactive, with treatment decisions typically made only after curvature has progressed. ScolimiR-3D gives physicians the opportunity to structure conservative treatments, such as bracing, to align with the patient’s risk assessment. It also serves as an additional resource for counseling families across the continuum of care, from diagnosis through treatment planning by providing a predictive risk assessment that goes beyond the traditional “wait and see” approach.

“Receiving FDA Breakthrough Device Designation is a significant milestone for this technology and for the future of scoliosis care,” said Marc Viscogliosi, co-CEO of VB Spine, speaking on behalf of his brothers and fellow co-CEOs Anthony and John Viscogliosi. “ScolimiR-3D will provide physicians with insights that support earlier, more informed decision-making. We're proud to work alongside Dr. Moreau and his team to advance this work.”

The Breakthrough Devices Program is intended to provide patients and health care providers with timely access to more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. VB Spine's collaboration with Dr. Moreau has also been recognized through a nomination for the Scoliosis Research Society's Hibbs Award. Additional research supporting the technology is expected to be presented at the Scoliosis Research Society (SRS) 2026 Annual Meeting, October 6–10 in Sydney, Australia.

Dr. Moreau is a paid consultant of VB Spine. The opinions expressed by Dr. Moreau are his own and not necessarily those of VB Spine. Individual experiences may vary.

Forward-Looking Statements

Certain statements in this release are forward-looking and are based on current expectations, forecasts, and assumptions. Actual results may differ materially due to regulatory, commercial, and operational risks. VB Spine disclaims any obligation to update forward-looking statements except as required by law.

About VB Spine

VB Spine LLC is the largest privately-held spine company and among the largest family-owned medical technology companies in the world. With a comprehensive portfolio and a large and growing global distribution network, VB Spine delivers specialized solutions that address critical needs in spine surgery and enhance patient outcomes. Focused on people, partnerships, and operational excellence, VB Spine ensures healthcare professionals have access to the tools and resources needed to provide the highest standard of care. VB Spine is owned and led by the Viscoglioni Brothers. For more information on VB Spine, please visit www.vbspineco.com.

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References:

1. Khatami N, Caraus I, Rahaman M, et al. Genome-wide profiling of circulating microRNAs in adolescent idiopathic scoliosis and their relation to spinal deformity severity, and disease pathophysiology. *Sci Rep.* 2025;15(1):5305. Published 2025 Feb 12. doi:10.1038/s41598-025-88985-3

Social Media

ScolimiR-3D has been granted FDA Breakthrough Device Designation, marking a major milestone in advancing scoliosis care. This new microRNA-based blood test is designed to identify patients at risk for scoliosis progression.

The FDA's Breakthrough Devices Program is intended to provide patients and health care providers with timely access to more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions.

Developed through decades of research, conducted by @Dr. Alain Moreau, ScolimiR-3D is the first predictive diagnostic scoliosis risk assessment test to receive this designation.

We are proud and excited to invest in innovative solutions, bringing our mission to the forefront of everything we do: Everything starts with the patient, inspiring us to redefine spine care.

Read the full press release here: <https://www.vbspineco.com/fda-breakthrough-device-designation/>

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