MIMEDX Engages Nordic Bioscience Clinical Development A/S to Propel Registrational Trials of Placental Biologic Injectable for Knee Osteoarthritis

June 15, 2022

Image Analysis Group to Provide Imaging Strategy and Advanced Imaging Analytics in Support of MIMEDX's Knee Osteoarthritis Clinical Trial Program

MARIETTA, Ga., June 15, 2022 (GLOBE NEWSWIRE) -- MiMedx Group, Inc. (Nasdaq: MDXG) ("MIMEDX" or the "Company"), a transformational placental biologics company, today announced a collaboration agreement with Nordic Bioscience Clinical Development A/S (NBCD), a world-class Contract Research Organization (CRO) specializing in Osteoarthritis (OA) clinical trials. Image Analysis Group, an expert imaging company, will also provide advanced tools to detect the potential for the Company's placental biologic injectable, micronized dehydrated Human Amnion Chorion Membrane (mdHACM), to act as a Disease Modifying Osteoarthritis Drug (DMOAD) and potentially moderate the progression of OA. The Company plans to initiate its registrational Knee Osteoarthritis (KOA) clinical trial program later this year, using Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) Pain and WOMAC Function as co-primary endpoints.

Robert B. Stein, M.D., Ph.D., MIMEDX President, Regenerative Medicine & Biologics Innovation, said, "We have significant evidence that mdHACM injected into the knees of people with OA provides lasting pain relief and improves function, and we believe it has potential as a DMOAD. MIMEDX has discovered how to preserve the remarkable healing properties of placental membranes when we produce mdHACM, and we have demonstrated that it contains many proteins that influence the biology of cartilage-forming cells and reduce inflammation. We believe these active proteins contribute to the striking, long-lasting benefits we have seen in patients receiving a single injection of mdHACM into their osteoarthritic knee. Following an extensive review and selection process, we are very excited to have world-class partners who are at the forefront of advancing meaningful medicines; working in collaboration accelerates our ability to gather quality data for our future Biologics License Application (BLA), and our potential to bring tremendous benefit for people living with OA."

David Mason, M.D., MIMEDX Chief Medical Officer, added, "NBCD has well-established expertise in the field of OA and a proven track record of conducting clinical studies of the highest quality to help advance drug development. They have worked with numerous biopharmaceutical companies to support clinical studies of treatments for KOA in various stages of clinical development, and their approach to operationalizing clinical trials can greatly streamline patient recruitment and accelerate study initiation and enrollment in our upcoming registrational studies."

Jeppe Ragnar Andersen, NBCD Chief Executive Officer, said, "We are excited to be working with MIMEDX's mdHACM technology and very glad to be engaged with them to drive their registrational studies forward."

As MIMEDX's selected CRO, NBCD will provide full operational support for the upcoming KOA clinical trial program, helping identify and select clinical trial sites and manage patient recruitment and enrollment. In addition, they will oversee clinical trial site monitoring, data management, and statistical analysis and reporting activities. Image Analysis Group will partner with MIMEDX and NBCD to incorporate state-of-the-art imaging techniques and analytic approaches the Company plans to utilize in its KOA clinical trial program.

Olga Kubassova, Ph.D., Chief Executive Officer, Image Analysis Group (IAG), commented, "IAG offers robust regulatory-required state-of-the-art and exploratory imaging techniques to assess joint health in OA, both qualitatively and quantitatively, enabling early detection and evaluation of the potential for various interventions to modify the course of the disease. By deploying robust patient-centric strategies to understand the variability in those afflicted with OA, we can help reduce irregularities in clinical trials and better assess OA progression and possible DMOAD activity. IAG has a long-standing history of working with leading global sponsors in OA clinical trials, and we are looking forward to working with MIMEDX to assess the potential of mdHACM to modify the progression, course, and patient impact of knee OA."

The Company's Phase 2B KOA clinical study results reported last year demonstrated a statistically significant and clinically meaningful improvement in WOMAC Pain at three and six months, respectively (p=0.032 and p=0.009), WOMAC Function (p=0.046 and p=0.009), and WOMAC Total (p=0.038 and p=0.008) for the Pre-Interim Analysis Cohort of 190 patients. These results were observable compared to a substantial placebo response noted in the patient cohort injected with saline. Root-cause analysis determined that the potency of the investigational product faded as it aged, and an intense examination of study results identified this factor as the primary difference in clinical responses observed between the Pre-Interim Analysis Cohort of 190 patients, dosed with newer investigational product, and the Post-Interim Analysis Cohort of 256 patients, dosed with older investigational product. MIMEDX believes it has taken appropriate steps to address these issues and ensure our investigational product can deliver the robust efficacy noted in the first portion of the Phase 2B KOA clinical trial.

About Knee Osteoarthritis

Osteoarthritis (OA) is by far the most common joint disease – millions of adults experience pain and decreased quality of life every day because of joint destruction characteristic of OA. More than 300 million people worldwide currently suffer from symptomatic OA of the knee and hip; 45% of all people have a lifetime risk of developing OA of the knee; and OA is responsible for approximately $71 billion in lost earnings annually in the United States. There are currently over 17.5 million people in the United States with KOA, and this number is growing. The early onset of the disease is growing as age, obesity, and sports injuries make their contribution. Many of these people will face progressive disability or require total knee replacement surgery. Although knee replacement is an option for those with advanced OA, it carries significant risks, and the current non-surgical treatment algorithm for these patients, including oral anti-inflammatory medications, cortisone injections, and hyaluronic acid injections, are limited in the amount of relief they can provide.

About MIMEDX

MIMEDX is a transformational placental biologics company, developing and distributing placental tissue allografts with patent-protected, proprietary processes for multiple sectors of healthcare. As a pioneer in placental tissue engineering, we have both a commercial business, focused on addressing the needs of patients with acute and chronic non-healing wounds, and a promising late-stage pipeline targeted at decreasing pain and improving function for patients with degenerative musculoskeletal conditions. We derive our products from human placental tissues and process these tissues using our proprietary methods, including the PURION® process. We employ Current Good Tissue Practices, Current Good Manufacturing Practices, and terminal sterilization to produce our allografts. MIMEDX has supplied over two million allografts, through both direct and consignment shipments. For additional information, please visit www.mimedx.com.

About NBCD A/S

NBCD is a Contract Research Organization (CRO) dedicated to clinical drug development and research in osteoarthritis. NBCD specializes in design and execution of clinical trials within both pain and Disease-Modifying Osteoarthritis Drugs (DMOAD) compounds for osteoarthritis. NBCD are experts in placebo response mitigation and osteoarthritis study design. NBCD support their biotech and pharmaceutical clients in advancing osteoarthritis compounds through all clinical development phases. NBCD has more than 25 years of experience in osteoarthritis biomarkers and clinical trials. Combining the background in preclinical research and clinical research enables NBCD to help provide a faster and smarter evaluation the potential clinical viability of drug candidates. For further details about NBCD, please visit: www.nbcd.com.

About Image Analysis Group

Image Analysis Group, an imaging expert company, helps to accelerate novel drug development by using the right analytical tools and modern trial infrastructure. This includes bringing Artificial Intelligence, machine learning and smart image analysis methods to ensure speed and cost-effectiveness, while delivering true insights about your mechanism of action and patients' response, in real-time. Please visit www.ia-grp.com for more details.

Important Cautionary Statement

This press release includes forward-looking statements, such as statements regarding: (i) our expectations regarding the timing of clinical programs and trials; (ii) the effectiveness of amniotic tissue and mdHACM as a therapy for any particular indication or condition, including its potential as a disease modifying osteoarthritis drug; (iii) our belief that active proteins in mdHACM contribute to the benefits we have seen in patients receiving a single injection of mdHACM into their osteoarthritic knee; and (iv) our belief that we have taken appropriate steps to address issues to ensure our investigational product can deliver the robust efficacy noted in the first portion of our Phase 2B mdHACM KOA clinical trial. Additional forward-looking statements may be identified by words such as "believe," "expect," "may," "plan," “goal,” “outlook,” "potential," "will," "preliminary," and similar expressions, and are based on management's current beliefs and expectations.

Forward-looking statements are subject to risks and uncertainties, and the Company cautions investors against placing undue reliance on such statements. Actual results may differ materially from those set forth in the forward-looking statements. Factors that could cause actual results to differ from expectations include: (i) future sales are uncertain and are affected by competition, access to customers, patient access to healthcare providers, and many other factors; (ii) the status, timing, results, and expected results of the Company's clinical trials, planned regulatory submissions and regulatory approvals, and our expectations regarding our ability to potentially accelerate the timing of any trial or regulatory submission, depend on a number of factors including favorable trial results, patient access, and our ability to manufacture in accordance with Current Good Manufacturing Practices (CGMP) and appropriate chemistry and manufacturing controls; (iii) the Company may change its plans due to unforeseen circumstances, or delays in analyzing and auditing results, and may delay or alter the timeline for future trials, analyses, or public announcements; (iv) our access to hospitals and health care provider facilities could be restricted as a result of the ongoing COVID-19 pandemic or other factors; (v) the results of scientific research are uncertain and may have little or no value; (vi) our ability to sell our products in other countries depends on a number of factors including adequate levels of reimbursement, regulatory approvals, market acceptance of novel therapies, and our ability to build and manage a direct sales force or third party distribution relationship; (vii) the effectiveness of amniotic tissue as a therapy for particular indications or conditions is the subject of further scientific and clinical studies; and (viii) we may alter the timing and amount of planned expenditures for research and development based on the results of clinical trials and other regulatory developments. The Company describes additional risks and uncertainties in the Risk Factors section of its most recent annual report and quarterly reports filed with the Securities and Exchange Commission. Any forward-looking statements speak only as of the date of this press release and the Company assumes no obligation to update any forward-looking statement.

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