Blue Water Biotech Appoints Board-Certified Urologist Jay Newmark, M.D., MBA as Chief Medical Officer

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CINCINNATI, April 26, 2023 (GLOBE NEWSWIRE) -- Blue Water Biotech, Inc. (“Blue Water” or the “Company”), a biotechnology company spanning multiple sectors, today announced the appointment of Jay Newmark, M.D., MBA as the Company’s Chief Medical Officer.

Dr. Newmark is a board-certified urologist with over 30 years of experience managing Men’s Health issues, including benign prostatic hyperplasia (“BPH”). Blue Water currently owns ENTADFI ®, an FDA-approved treatment for BPH that counteracts negative sexual side effects seen in men on alternative BPH therapies. Dr. Newmark’s appointment will support Blue Water’s upcoming launch of ENTADFI ® and he will work closely with Blue Water management to ensure BPH patients are able to receive proper access to treatment.

In addition to his extensive medical training and experience in urology private practice, Dr. Newmark has a strong background in commercial product development in the Men’s Health sector. Previously, Dr. Newmark served as Chief Medical Officer at Clarus Therapeutics, Inc., where he was integral to the launch of JATENZO® and other Men’s Health initiatives. He has also worked on advanced detection technologies for prostate cancer at Genomic Health Inc. and OPKO Health Inc.

“I am thrilled to join the Blue Water team and provide my expertise as we prepare to launch ENTADFI ® to support patients with BPH,” said Dr. Newmark. “Millions of men suffer from BPH symptoms each year and many of those men are faced with frustrating sexual side effects as a result of their BPH medication. We look forward to supporting new BPH patients with ENTADFI® as well as provide current patients a novel option to address BPH symptoms without sacrificing sexual performance as we see with other current therapies.”

“The addition of Dr. Newmark to the Blue Water team is a critical and exciting step in the execution of our commercial strategy for ENTADFI ®,” said Joseph Hernandez, Chairman and Chief Executive Officer of Blue Water. “As we prepare to make this product available to men with BPH across the country, we will rely heavily on his knowledge and experience to support our commercial operation and our patients. We are confident that his expertise both in the medical field as a urologist and in the product development space will be invaluable moving forward through launch and beyond.”

Dr. Newmark received his M.D. from the University of Michigan Medical School and completed his residency in urology at the Johns Hopkins Hospital. He also holds a Master of Business Administration from the University of Chicago.

Dr. Newmark will join Blue Water management at the upcoming American Urological Association Annual Meeting 2023 from April 18th through May 1st in Chicago, Illinois. Blue Water will be available during the conference for one-on-one meetings and can be found at booth 439. Interested parties may request a one-on-one meeting at investors@bwbioinc.com or contact Blue Water at (513) 620-4101.

About ENTADFI®

ENTADFI® is an oral, once daily treatment for benign prostatic hyperplasia ("BPH") that combines finasteride, a 5α-reductase inhibitor, and tadalafil, a phosphodiesterase 5 (PDE5) inhibitor, offering a more effective treatment option compared to other available therapies. Clinical trials have shown that ENTADFI® is more effective in treating BPH symptoms, including urinary frequency, urgency, weak stream, and difficulty initiating or maintaining urination, compared to finasteride monotherapy. Additionally, ENTADFI® has demonstrated a favorable safety profile, with fewer adverse sexual side effects compared to finasteride. ENTADFI® reduces potential for adverse sexual side effects, making it a preferred choice for men seeking relief from BPH symptoms without compromising their sexual health. ENTADFI® has received FDA approval for the indication of initiating treatment of the signs and symptoms of BPH in men with an enlarged prostate for up to 26 weeks. More information about BPH and full ENTADFI® prescribing information can be found on the product website at https://entadfipatient.com/.

About Blue Water Biotech

Blue Water Biotech, Inc. is a biotechnology company focused on developing transformational therapies to address significant health challenges globally. Headquartered in Cincinnati, OH, the Company holds the rights to proprietary technology developed at the University of Oxford, Cincinnati Children’s Hospital Medical Center, St. Jude Children’s Hospital, and The University of Texas Health Science Center at San Antonio. Blue Water is developing a Streptococcus pneumoniae vaccine candidate, designed to specifically prevent highly infectious middle ear infections, known as acute otitis media (AOM), in children, and prevention of pneumonia in the elderly. The Company is also developing a universal flu vaccine that will provide protection from all virulent strains in addition to licensing a novel norovirus (NoV) S&P nanoparticle versatile virus-like particle (VLP) vaccine platform from Cincinnati Children’s to develop vaccines for multiple infectious diseases, including Marburg and monkeypox, among others. Additionally, the Company is developing a Chlamydia vaccine candidate with UT Health Science Center San Antonio to prevent infection and reduce the need for antibiotic treatment associated with contracting Chlamydia disease. Outside of its vaccine franchise, Blue Water owns ENTADFI®, an FDA-approved, once daily pill that combines finasteride and tadalafil for the treatment of benign prostatic hyperplasia. This combination allows men to receive treatment for their symptoms of BPH without the negative sexual side effects typically seen in patients on finasteride alone. For more information about Blue Water, visit www.bwbioinc.com.

Forward-Looking Statements

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. These

statements may be identified by the use of forward-looking words such as “anticipate,” “believe,” “forecast,” “estimate,” “expect,” and “intend,” among others. These forward-looking statements are based on Blue Water’s current expectations and actual results could differ materially. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, risks related to Blue Water’s ability to realize the benefits of its acquisition of ENTADFI ®, risks related to BWV’s ability to expand its business scope and its ability to commercialize ENTADFI®, risks related to the development of Blue Water’s vaccine candidates; the failure to obtain FDA clearances or approvals and noncompliance with FDA regulations; delays and uncertainties caused by the global COVID-19 pandemic; risks related to the timing and progress of clinical development of our product candidates; our need for additional financing; uncertainties of patent protection and litigation; uncertainties of government or third party payor reimbursement; limited research and development efforts and dependence upon third parties; and substantial competition. As with any vaccine under development, there are significant risks in the development, regulatory approval and commercialization of new products. Blue Water does not undertake an obligation to update or revise any forward-looking statement. Investors should read the risk factors set forth in Blue Water’s Annual Report on Form 10-K, filed with the Securities and Exchange Commission (the “SEC”) on March 9, 2023 and periodic reports filed with the SEC on or after the date thereof. All of Blue Water’s forward-looking statements are expressly qualified by all such risk factors and other cautionary statements. The information set forth herein speaks only as of the date thereof.

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