

VetStem Secures Strategic Funding to Advance FDA Conditional Approval of StemStat™ Orthofor Canine Osteoarthritis

VetStem, Inc. has secured funding for final development work on StemStatTM
Ortho for conditional approval submission to the FDA CVM.

POWAY, CA, UNITED STATES, March 18, 2025 /EINPresswire.com/ -- VetStem, Inc., a pioneer in

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Dr. Robert Harman, VetStem
CFO

regenerative veterinary medicine, has secured additional funding to accelerate the final steps toward FDA conditional approval of StemStat™ Ortho, an allogeneic, off-the-shelf stem cell therapy for the treatment of canine osteoarthritis (OA). This milestone positions VetStem to become the first company to bring an FDA-approved allogeneic stem cell product to the veterinary market - a groundbreaking achievement in the field of regenerative medicine.

The funding announcement follows new market research presented at the Western Veterinary Conference's State of the Industry Address by Mike McGinley of Brakke

Consulting, which valued the market opportunity for an allogeneic stem cell product for canine osteoarthritis at over \$1 billion. This reinforces the urgent need for innovative and effective treatment solutions like StemStat™ Ortho, and highlights the significant commercial potential of VetStem's product pipeline.

"This additional funding allows us to finalize the regulatory submission data and bring StemStat Ortho to market, providing a much-needed, FDA-regulated treatment for dogs suffering from osteoarthritis," said Robert Harman, DVM, MPVM, CEO of VetStem, Inc. "With a \$1 billion market opportunity and over two decades of leadership in veterinary regenerative medicine, VetStem remains at the forefront of innovation in veterinary care."

Pioneering the Future of Veterinary Biologics

VetStem has over 22 years of research, development, and clinical experience in stem cell therapy. The company has demonstrated a unique capability to advance regenerative veterinary products

through the complex FDA regulatory pathway, including the successful risk review and market introduction of <u>PrecisePRP™</u> for canine and equine use.

VetStem was the first company to bring an allogeneic, off-the-shelf, plateletrich plasma (PRP) product to market. Its success with PrecisePRP™, now commercialized in partnership with PetVivo Animal Health, validates VetStem's ability to create and deliver FDA-compliant biologic therapies to the veterinary market.

The company's ongoing engagement with the FDA Center for Veterinary Medicine (CVM) reflects its



commitment to compliance and regulatory excellence. VetStem's expertise in navigating the regulatory landscape sets it apart in the growing field of veterinary regenerative medicine.

A \$1 Billion Market Opportunity

- 22 million dogs in the U.S. suffer from osteoarthritis, creating a large, underserved market.
- Existing treatments (NSAIDs, joint supplements) are often inadequate or carry side effects.
- StemStat™ Ortho provides a potentially disease-modifying solution—targeting the underlying pathology of osteoarthritis rather than just managing symptoms.
- The allogeneic, off-the-shelf nature of StemStat™ Ortho ensures consistent product quality, ease of use, and scalability, making it an attractive commercial opportunity.

Strategic Partnerships and Future Growth

VetStem is actively engaged in discussions with strategic partners, including PetVivo Animal Health, for commercialization and distribution of StemStat™ Ortho, with a clear pathway for expanding into other orthopedic and inflammatory conditions in companion animals. The success of PrecisePRP™ with PetVivo provides a strong commercialization blueprint, and early-stage discussions are already underway for similar distribution agreements for StemStat™ Ortho and future pipeline products.

About VetStem, Inc.

VetStem, Inc., founded in 2002 and based near San Diego, California, is a leader in regenerative veterinary medicine. VetStem was the first company to introduce stem cell therapy to veterinary medicine and has facilitated over 40,000 treatments across more than 60 species. The company offers both autologous and allogeneic regenerative therapies, including the proprietary

PrecisePRP™ and autologous adipose stem cell platforms. VetStem holds an extensive portfolio of patents in regenerative medicine and maintains exclusive global veterinary licenses for key stem cell technologies.

About PetVivo Animal Health, Inc.

PetVivo Animal Health, Inc., a wholly owned subsidiary of PetVivo Holdings, Inc. (OTCQB: PETV; OTCPINK: PETVW), is a biomedical device company focused on the manufacturing and commercialization of innovative medical devices and therapeutics for companion animals. The company's flagship product, Spryng™ with OsteoCushion™ Technology, is a veterinarian-administered injectable designed to manage joint-related afflictions in cats, dogs, and horses. PetVivo holds a robust pipeline of products and a portfolio of 21 patents.

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