

VetStem, Inc. Launches First FDA-Reviewed Allogeneic Off-the-Shelf Cell Medicine Product in the U.S.

VetStem, Inc. announces PrecisePRP™ Canine has cleared the FDA review process and is launching in May 2024 in the U.S.

POWAY, CALIFORNIA, UNITED STATES, April 29, 2024 /EINPresswire.com/ -- Leading regenerative veterinary medicine company, [VetStem, Inc.](#), is changing the way platelet-rich plasma (PRP) is delivered to patients with the launch of their new off-the-shelf PRP products. The first product to clear the FDA review process is PrecisePRP™ Canine. This is a leucoreduced, allogeneic, pooled, freeze-dried PRP intended to provide a canine-specific source of concentrated platelets in plasma for intra-articular administration in dogs. The equine version is expected to clear the FDA review process in early May and launch later that month.



PrecisePRP™ is unlike any PRP mechanical kit currently on the market. PrecisePRP™ does not require a blood draw or centrifugation, nor refrigeration, making it a truly off-the-shelf product that is easy and convenient. Perhaps more important is the uniformity and consistency that PrecisePRP™ provides with its unique patent pending manufacturing process. Each vial of PrecisePRP™ contains a consistent dose of 4 billion platelets per vial at a concentration of 500,000 platelets per microliter and is leucoreduced with less than 1500 white blood cells per microliter. Each lot is quality tested before release.

To significantly minimize safety risks, all dog donors are screened according to the FDA CVM Guidance 254 for infectious diseases. Along with infectious disease screening, donors are tested for blood type and plasma antibody to red blood cells, providing a lower risk of transfusion reaction. At the request of the FDA, randomized placebo-controlled [safety studies](#) were conducted in both dogs and horses. There were no treatment-related adverse events reported in



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dogs or horses after treatment with PrecisePRP™.

PrecisePRP™ Canine was reviewed under the FDA animal cells, tissues, and cell- and tissue-based products (ACTPs) program. The FDA review process involved a rigorous evaluation by the Center for Veterinary Medicine that resulted in a formal Risk Review and that allows VetStem to enter the U.S. market with this product. VetStem founder and CEO, Dr. Bob Harman, stated, "We are proud to have collaborated with the FDA under this new review program

and applaud their requirements for the review process." The FDA risk assessment is available for review by [request to VetStem](#).

As stated in a press release from the FDA, "PrecisePRP Canine is the first animal cell, tissue, and cell- and tissue-based product (ACTP) intended for intra-articular use to undergo FDA review and receive this determination." Additionally, the FDA stated, "Prior to the FDA's determination for PrecisePRP Canine, there were no FDA-reviewed animal platelet-rich plasma products available to veterinarians." (https://www.fda.gov/animal-veterinary/cvm-updates/fda-announces-decision-tissue-based-product-use-dogs?utm_medium=email&utm_source=govdelivery)

This revolutionary new product was developed by VetStem in response to requests by veterinarians and academic leaders for a product that improves the consistency and ease of use of PRP. PrecisePRP™ delivers on the VetStem promise to provide the best-in-class products to veterinary specialists and general practitioners alike. Kristi Hauta, Director of Commercial Operations, stated, "We have provided PRP mechanical and gravity separation devices to the industry for over a decade. I am excited to bring this innovative easy to use and consistent product to the field, one that every veterinarian can use in their practice. PrecisePRP is game-changing for the general practitioner because it makes PRP more accessible than ever before. It takes the guess work out of PRP therapy so that veterinarians know that the PRP they are injecting has been quality tested for sterility, platelet count, and potency. This means providing a more consistent product every time."

As the first company to provide adipose-derived stem cell services to veterinarians in the United States and Canada, VetStem is a leader in the field of regenerative veterinary medicine. The company has spent over two decades educating veterinarians and working to bring the latest innovations in regenerative medicine to veterinarians and their patients. Dr. Harman stated, "After listening to our customers, it was clear that an off-the-shelf source of platelet-rich plasma was needed by equine and small animal veterinarians. PrecisePRP will provide veterinarians with a convenient and consistent dose that avoids the high variability, labor, and sterility risk of using the centrifuge-based tube systems on the market today. We are proud to continue our history of innovations and firsts in the veterinary field."

Platelet-rich plasma has been used in veterinary medicine for over 20 years. It is commonly used to treat musculoskeletal diseases and injuries such as osteoarthritis and injured tendons and ligaments. It has also been used topically for wounds and corneal ulcers as well as several other indications. The principle of PRP therapy is to accelerate lagging internal healing processes by amplifying the biological signals that would naturally occur when platelets aggregate at a site of injury. By concentrating platelets and releasing more of those growth factors than would naturally occur, the intended effect is to attract stem cells and other healing cells to stimulate local tissue repair processes.

PrecisePRP™ is a trademark of VetStem, Inc. and is currently patent pending. Please see the prescribing instructions for current label claims, dosing, safety information, and precautions on www.VetStem.com.

About VetStem, Inc.

VetStem is a veterinarian-led Company that was formed in 2002 to bring regenerative medicine to the profession. This privately held biopharmaceutical enterprise, based near San Diego, California, currently offers veterinarians an autologous stem cell processing service (from patients' own fat tissue) among other regenerative modalities. With a unique expertise acquired over the past 20 years and thousands of treatments by veterinarians for joint, tendon and ligament issues, VetStem has made regenerative medicine applications a therapeutic reality. The VetStem team is focused on developing new clinically practical and affordable veterinary solutions that leverage the natural restorative abilities present in all living creatures. In addition to its own portfolio of patents, VetStem holds exclusive global veterinary licenses to a large portfolio of issued patents in the field of regenerative medicine.

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