

VetStem, Inc. Completes FDA-Review for Second Allogeneic Off-the-Shelf Cell Medicine Product in the U.S.

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

POWAY, CALIFORNIA, U.S., May 8, 2024 /EINPresswire.com/ -- Last month, leading regenerative



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VetStem CEO and Founder, Dr. Bob Harman

veterinary medicine company, [VetStem, Inc.](#), announced the launch of PrecisePRP™ Canine, 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 company has just completed the FDA-review process on their second product, PrecisePRP™ Equine, which is intended to provide an equine-specific source of concentrated platelets in plasma for intra-articular administration in horses. VetStem has entered into negotiations with prospective partners for U.S. and global distribution of the PrecisePRP™ products.

With the launch of these off-the-shelf cell medicine products, VetStem is changing the way platelet-rich plasma (PRP) is delivered to patients. 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 and horse 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 dogs or horses after treatment with PrecisePRP™.

Both PrecisePRP™ Equine and PrecisePRP™ Canine were 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 both products. The FDA risk assessments are available for review by [request to VetStem](#).

As stated in a press release from the FDA, "PrecisePRP Equine is the second animal cell, tissue, and cell- and tissue-based product (ACTP) intended for

intra-articular use to undergo FDA review and receive this determination and it is the first such product for use in horses." Additionally, the FDA stated, "This is the first FDA-reviewed, platelet-rich plasma for horses available to veterinarians." (<https://www.fda.gov/animal-veterinary/cvm-updates/fda-announces-decision-tissue-based-product-use-horses>)

VetStem has been a leader in the field of regenerative veterinary medicine since 2004 and has consistently delivered on the promise to provide the best-in-class products to veterinary specialists and general practitioners alike. PrecisePRP™ was developed by VetStem with that promise in mind. VetStem CEO and founder, Dr. Bob Harman, stated, "Veterinarians and academics in the field have long called for PRP products that are more consistent and easier to use. PrecisePRP was our answer to those requests. After over a decade of providing PRP mechanical and gravity separation devices to the industry, we are excited to bring this innovative and consistent product to the field. PrecisePRP makes PRP more accessible than ever before and allows veterinarians to know that the PRP they are injecting has been quality tested for sterility, platelet count, and potency."

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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