Preclinical, Clinical, and Field Evidence of Viroplazin

1. Overview of Preclinical and Clinical Evaluation

Experimental and clinical testing of **Viroplazin** has been ongoing for **over six years** across multiple animal species, including companion animals and livestock. The safety and efficacy profile has been extensively investigated through a combination of:

- **Preclinical toxicology studies**
- **Controlled efficacy trials**
- **Field-based clinical case reports**

These investigations were conducted in collaboration with an **independent research group** at the **University of Veterinary Medicine**. Full **study documentation, protocols, and statistical evaluations** are available for regulatory review.

2. Safety and Toxicity Assessment

2.1. Laboratory Toxicology Studies

Viroplazin has undergone **acute and chronic toxicity testing** in:

- **Rodents** (mice)
- **Healthy dogs**
- **Healthy cats**

Key findings:

- Even at doses **1,000 times higher than the maximum therapeutic dose**, **no morbidity or mortality** was observed in mice.
  Note: This extreme dosing study was performed out of scientific curiosity and significantly exceeds the requirements for regulatory acute toxicity testing.
- Across all species tested, **orders-of-magnitude overdosing** relative to clinically effective doses produced **no detectable adverse effects**.

These findings establish a **wide therapeutic index** and confirm the **excellent systemic tolerance** of Viroplazin.

3. Controlled Efficacy Studies

3.1. Study Design

Controlled clinical trials were performed on three high-mortality viral diseases in companion animals:

- **Canine parvoviral enteritis**
- **Feline panleukopenia**
- **Feline herpesvirus rhinotracheitis**

3.2. Methodology

- Diagnosis confirmed by **real-time PCR (rt-PCR)** for the respective pathogens.

- Infected animals were **randomized into two groups**:
    1. **Standard symptomatic treatment only**
    2. **Standard treatment + Viroplazin**

3.3. Results

- **Survival rate: 100% survival** in Viroplazin-treated groups vs. significantly lower survival in controls.
- **Time to clinical recovery:** Markedly shorter in Viroplazin-treated animals, supported by **statistically significant differences**.
- **Viral shedding:** In Viroplazin-treated animals, **post-recovery viral shedding ceased in 80% of tested cats with Calici viral infection, while all untreated cats continued shedding virus 3 weeks after treatment start.**
- Whereas untreated and treated animals continued to shed herpes virus but, the Viroplazin-treated group was Clinically symptoms fee unlike the untreated group.

Epidemiological relevance: Reduced shedding significantly lowers environmental contamination and transmission risk in Canine Parvo, Feline Panleukopenia, and Feline Calicivirus infections.

4. Real-World Clinical Evidence

Beyond controlled studies, extensive **field experience** demonstrates Viroplazin's broad-spectrum antiviral efficacy and safety. Documented positive clinical outcomes have been observed across a wide range of species and viral pathogens, as well as Mycoplasma and some bacterial infections:

4.1. Dogs

- Parvoviral enteritis
- Distemper (*Canine morbillivirus*, closely related to human measles virus)
- Parainfluenza infection
- Canine herpesvirus infection
- Hemotropic mycoplasma-associated infections

4.2. Cats

- Feline parvoviral panleukopenia
- Feline herpesvirus rhinotracheitis
- Feline calicivirus-associated rhinotracheitis

4.3. Horses

- **Rhodococcus equi** septicemia (2-month-old foal). Viroplazin experimental injectable treatment resulted in full recovery.

4.4. Rabbits

Pasteurellosis-associated pneumonia: 5 treatment and 10 control rabbits were experimentally infected with Acute septicemic form/virulent strains of Pasteurella multocida. The Viroplazin treatment group received 15mg/kg dose starting 2 days before the infection and was treated with

this dose for 7 days. All control rabbits died, while all Viroplazin-treated rabbits lived beyond 30 days when the monitoring ended.

4.5 Pig

- Swine Influenza (SIV)
- Porcine Circovirus type 2 (PCV2)
- Porcine Reproductive and Respiratory Syndrome Virus (PRRSV)

4.6 Bovine

- Experimental treatment with injectable Viroplazin/antibiotic in five 1-10-month-old calves with mixed viral and bacterial infection of Parainfluenza-3 and Pasteurella multocida.
- All calves were presented with the symptoms of: fever (40.5–40.8 ℃), inappetence, malaise, serous and mucopurulent discharge, dyspnoea, auscultation of the lungs, catharsis, moist crackles
- Treatment: Marbofloxacin injection and Viroplazin injection 5mg/kg dose 2 times per day.
- Treatment result: All calves survived, and recovery was remarkably fast. On the second day of the treatment, all calves started to eat normally, and on the 3rd day of the treatment, all were considered cured; the therapy was not continued beyond 3 days as it was unnecessary.
- A 3-week-old calf on a small farm had a high fever of 42 ℃, was recumbent, not eating or drinking, mucopurulent nasal discharge, coughing, dyspnoea, and open-mouth breathing. Had injectable antibiotic treatment for 3 days, but the symptoms just got worse; Rapid antigen test detected IBR.
- Viroplazin injection treatment was initiated on day 3 as the calf was to die without effective treatment. The dose was 5mg/kg twice/day. Full recovery after 3 days of treatment only with Viroplazin injections.

5. Ongoing and Future Investigations.

Current clinical trials are underway to evaluate Viroplazin's efficacy in livestock viral diseases, including:

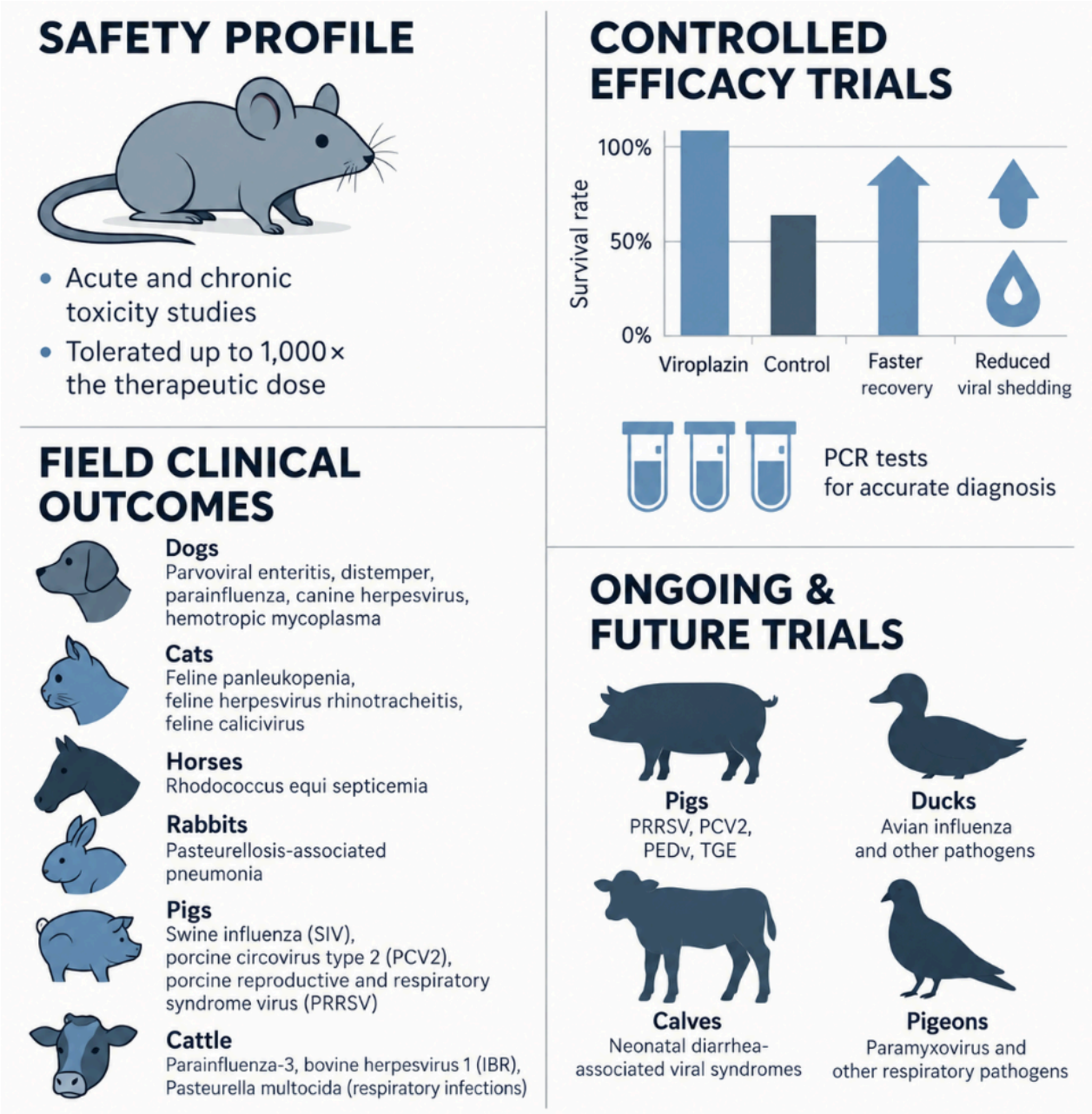
- **Pigs** – covering PRRSV, PCV2, PEDv, and TGE
- **Ducks** – avian influenza and other high-impact pathogens

Planned future studies will expand into:

- **Calves** – neonatal diarrhea-associated viral syndromes
- **Pigeons** – paramyxovirus and other respiratory pathogens

6. Summary of Findings

Safety: Demonstrated a **remarkably high therapeutic index** across species.
Efficacy: Controlled studies show **dramatically improved survival**, **faster recovery**, and **reduced viral shedding**.



Broad-spectrum activity: Effective across **multiple viruses, species, and clinical contexts**. **Clinical adoption:** Supported by **hundreds of documented field cases** over six years. Viroplazin's extensive clinical record positions it as a **first-in-class antiviral therapy** with the potential to significantly reduce **morbidity, mortality, and viral transmission** in both companion animals and livestock.

7. Summary

Viroplazin has demonstrated **substantial therapeutic benefits** across a wide spectrum of **viral infections in multiple animal species**, supported by six years of experimental research, controlled clinical trials, and extensive field experience. These findings establish Viroplazin as a **first-in-class, host-directed antiviral therapy** with the potential to address major unmet needs in veterinary and, eventually, human medicine.

Across all studies to date, **side effects have been minimal to absent**, even at doses significantly exceeding the therapeutic range. This exceptional **safety profile**, combined with its unique **broad-spectrum mechanism of action**, positions Viroplazin as a promising tool for managing viral diseases that currently lack effective treatment options.

Our immediate focus is on **veterinary applications**, supported by ongoing **experimental, toxicological, and clinical trials** designed to meet rigorous regulatory standards for animal health products. At the same time, the **universality of Viroplazin's antiviral mechanism** provides cautious but compelling grounds for exploring **future human applications**.

We fully recognize that the transition to human therapeutics will require a **thorough, highly structured, and multi-phase regulatory approval process**, involving extensive safety, pharmacokinetic, and efficacy studies. To achieve this, **collaboration and support from scientific institutions, regulatory authorities, and funding partners** will be critical.

Viroplazin represents a **transformative opportunity**: an innovative, well-tolerated, and **mechanistically distinct antiviral therapy** with the potential to redefine treatment strategies for viral diseases across species.

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