FULL PRESCRIBING INFORMATION

1 NAME OF THE MEDICINAL PRODUCT

Kam*RAB*, Human-Rabies Immunoglobulin (HRIG) 150 IU/mL, Solution for i.m. Injection.

2 THERAPEUTIC INDICATIONS

Passive, transient post-exposure prophylaxis of rabies infection, when given immediately to individuals in cases of contact with rabid or possibly rabid animal.

Human rabies immunoglobulin must always be used in combination with a rabies vaccine as part of the post-exposure prophylaxis of rabies infection in patients exposed to animals suspected of being rabid.

Local or state public health officials should be consulted if questions arise about the need for rabies prophylaxis.

Recommendations for passive and/or active immunization after exposure to an animal suspected of having rabies have been outlined, among others by the World Health Organization (WHO) and by the U.S. public health Advisory Committee on Immunization Practices (ACIP).

3 DOSAGE AND ADMINISTRATION

Posology

Post-exposure prophylaxis consists of a regimen of one dose of immunoglobulin and full courses of rabies vaccination. Rabies immunoglobulin and the first dose of rabies vaccine should be given as soon as possible after exposure. Additional doses of rabies vaccine should be given according to official guidelines or the manufacturer's instructions.

Rabies prophylaxis exclusively with simultaneous vaccination: recommended dose of rabies immunoglobulin is 20 IU/kg body weight, preferably at the time of the first vaccine dose. It may also be given through the seventh day after the first dose of vaccine is given.

Kam*RAB* should never be administered in the same syringe or into the same anatomical site as the vaccine.

Because of the risk of interference with antibody production related to vaccination, neither the dose should be increased, nor a repeated rabies immunoglobulin dose be given (even if the onset of the simultaneous prophylaxis is delayed).

Method of Administration

Human rabies immunoglobulin should be administered via the intramuscular route.

If a large volume (>2 ml for children or >5 ml for adults) is required, it is recommended to administer this in divided doses at different sites.

Kam*RAB* should never be administered in the same syringe or into the same anatomical site as the vaccine.

The wound should be cleaned with soap and disinfectant.

Kam*RAB* should preferably be administered in the bitten site. Kam*RAB* should be carefully infiltrated as much of the dose as is anatomically possible in the area in the depth of and around the wound. Any remainder should be injected intramuscularly into the upper arm deltoid region or in small children into the anterolateral aspect of the thigh. Administration should be opposite the site of the rabies vaccine. Passive immunization into the gluteal region; where absorbance is unpredictable, should be avoided.

If intramuscularly administration is contra-indicated (bleeding disorders) the injection can be administered subcutaneously. However, it should be noted that there are no clinical efficacy data to support administration by the subcutaneous route.

Rabies Postexposure Prophylaxis

Local or state public health officials should be consulted if questions arise about the need for rabies prophylaxis.

Local treatment of wounds: Immediate and thorough washing of all bite wounds and scratches with soap and water is perhaps the most effective preventative measure for preventing rabies. Recommended first-aid procedures include immediate and thorough flushing and washing of the wound for a minimum of 15 minutes with soap and water, detergent, povidone iodine or other substances of proven lethal effect on rabies virus (WHO).

Tetanus prophylaxis and measures to control bacterial infection should be given as indicated.

4 DOSAGE FORMS AND STRENGTHS

Kam*RAB* is supplied in single-dose vials containing 2 mL, 5 mL, or 10 mL of ready-to-use solution with a nominal potency of 150 IU/mL (Note that more than one vial may be required for a single patient treatment).

- The 2 mL vial contains a total of 300 IU, which is sufficient for a child weighing 15 kg
- The 5 mL vial contains a total of 750 IU, which is sufficient for an individual weighing 37.5 kg
- The 10 mL vial contains a total of 1500 IU, which is sufficient for an adult weighing 75 kg

The final product is assayed with human rabies immunoglobulin reference standard that is calibrated against the WHO International Standard.

5 CONTRAINDICATIONS

Because of the life-threatening risk due to rabies, there are no contraindications to the administration of rabies immunoglobulin.

6 WARNINGS AND PRECAUTIONS

6.1 Previous Rabies Vaccination

Patients who can document previous complete rabies pre-exposure prophylaxis or complete post-exposure prophylaxis should only receive a booster rabies vaccine without Kam*RAB* because Kam*RAB* may interfere with the anamnestic response to the vaccine (ACIP).

6.2 Hypersensitivity Reactions

Hypersensitivity reactions, including anaphylaxis, may occur with Kam*RAB*. History of prior systemic allergic reactions to human immunoglobulin preparations places patients at greater risk. Have epinephrine available for treatment of acute allergic symptoms. Patients with isolated immunoglobulin A (IgA) deficiency may develop severe hypersensitivity reactions to Kam*RAB* or, subsequently, to the administration of blood products that contain IgA.

6.3 Live Attenuated Virus Vaccines

Kam*RAB* administration may interfere with the development of an immune response to live attenuated virus vaccines. If feasible, delay immunization with measles vaccine for 4 months, and other live attenuated virus vaccines for 3 months, after Kam*RAB* administration.

6.4 Interference with Serologic Testing

- A transient rise of the various passively transferred antibodies in the patient's blood may result in misleading positive results of serologic tests after Kam*RAB* administration.
- Passive transmission of antibodies to erythrocyte antigens, e.g., A, B, and D, may interfere with serologic tests for red cell antibodies such as the antiglobulin test (Coombs' test).

6.5 Transmissible Infectious Agents

Because Kam*RAB* is made from human plasma donors hyper-immunized with rabies vaccine, it may carry a risk of transmitting infectious agents, e.g., viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent.

7 ADVERSE REACTIONS

The most common adverse reactions (>5%) observed in adult subjects were injection site pain, headache, muscle pain, joint pain, dizziness, and fatigue.

The most common adverse reactions (>5%) observed in pediatric patients were injection site pain, headache, pyrexia, pain in extremity, bruising, fatigue, and vomiting.

7.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in clinical trials of a drug cannot be directly compared to rates of adverse reactions in clinical trials of another drug and may not reflect the rates observed in clinical practice.

Kam*RAB* was evaluated in three single-center, controlled clinical trials in adults. Subjects in these clinical studies of Kam*RAB* were healthy adults, primarily white, and ranged in age from 18 to 72 years. A total of 160 adult subjects were treated in these three studies, including 91 subjects who received single intramuscular doses of Kam*RAB* (20 IU/kg) with or without rabies vaccine.

Table 1 summarizes adverse reactions occurring in >3% of adult subjects in the clinical trials of Kam*RAB*. (Table 1).

Table 1: Adverse Reactions Occurring in >3% of Subjects in All Combined Studies in Adults

	All Kam*RAB* (N=91)	**All Comparator HRIG (N=84)**	**Saline Placebo+Vaccine (N=8)**
Injection site pain	30 (33%)	26 (31%)	2 (25%)
Headache	14 (15%)	11 (13%)	3 (38%)
Muscle pain	8 (9%)	6 (7%)	0 (0%)
Joint Pain	5 (6%)	0 (0%)	1 (13%)
Dizziness	5 (6%)	3 (4%)	0 (0%)
Fatigue	5 (6%)	2 (2%)	0 (0%)
Abdominal pain	4 (4%)	1 (1%)	0 (0%)
Blood in urine (Hematuria)	4 (4%)	2 (2%)	0 (0%)
Nausea	4 (4%)	3 (4%)	0 (0%)
Feeling faint	4 (4%)	1 (1%)	0 (0%)

Data are presented as number of subjects (% of subjects).

Less frequent adverse reactions (≤3%) in adult subjects were diarrhea, vomiting, decreased appetite, musculoskeletal stiffness, malaise, weakness (asthenia), fainting (syncope), itching (pruritus), tingling sensation (paresthesia), rash, sunburn and elevation in liver function.

Kam*RAB* was also evaluated in a two-center, open-label clinical trial in 30 pediatric patients exposed or possibly exposed to rabies virus. They ranged in age from 0.5 to 14.9 years. Study treatment included a single dose of Kam*RAB* (20 IU/kg) and active rabies vaccine on Days 0, 3, 7 and 14 administered as per ACIP recommendations for rabies post-exposure prophylaxis.

Twelve pediatric patients (40%) experienced adverse reactions within 14 days of receipt of Kam*RAB* and first dose of rabies vaccine. There were no serious adverse reactions. Table 2 summarizes the adverse reactions that occurred in >5% of patients in the pediatric clinical trial within 14 days of receipt of Kam*RAB* and the first dose of the rabies vaccine.

Table 2: Adverse Reactions Occurring in >5% of Pediatric Patients within 14 Days of Post-exposure Prophylaxis with Kam*RAB* and Active Rabies Vaccine

	Kam*RAB*+ Rabies Vaccine N = 30
Injection site pain	8 (27%)
Headache	4 (13%)
Fever (Pyrexia)	4 (13%)
Pain in extremity	3 (10%)
Bruising (hematoma)	2 (7%)
Fatigue	2 (7%)
Vomiting	2 (7%)

Data are presented as number of patients (% of patients).

Less common adverse reactions (≤5%) in pediatric patients were injection site redness (erythema), injection site swelling (edema), muscle pain, oral pain, and wound complication.

Insomnia was reported as a less common adverse reaction (<5%) in pediatric patients occurring after 14 days of administration.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form

https://sideeffects.health.gov.il

Additionally, you should also report to Kamada Ltd to email address:

pharmacovigilance@kamada.com

8 DRUG INTERACTIONS

- Patients who can document previous complete rabies pre-exposure prophylaxis or complete post-exposure prophylaxis and have a confirmed adequate rabies antibody titer should receive only a booster rabies vaccine (without Kam*RAB*) because Kam*RAB* may interfere with the anamnestic response to the vaccine (ACIP).
- Kam*RAB* can interfere with the immune response to the rabies vaccine. For this reason, do not exceed the recommended Kam*RAB* dose or give additional (repeat) doses of Kam*RAB* once rabies vaccination has been initiated.
- Kam*RAB* can inactivate the rabies vaccine. For this reason, do not administer Kam*RAB* in the same syringe as the rabies vaccine or near the anatomical site of administration of the rabies vaccine.

- Kam*RAB* contains other antibodies that may interfere with the response to live vaccines such as measles, mumps, polio or rubella. Avoid immunization with live virus vaccines within 3 months after Kam*RAB* administration, or in the case of measles vaccine, within 4 months after Kam*RAB* administration.

9 USE IN SPECIFIC POPULATIONS

9.1 Pregnancy

Risk Summary

Kam*RAB* has not been studied in pregnant women. Therefore, the risk of major birth defects and miscarriage in pregnant women who are exposed to Kam*RAB* is unknown. Animal developmental or reproduction toxicity studies have not been conducted with Kam*RAB*. It is not known whether Kam*RAB* can cause harm to the fetus when administered to a pregnant woman or whether Kam*RAB* can affect reproductive capacity.

9.2 Lactation

Risk Summary

There is no information regarding the presence of Kam*RAB* in human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Kam*RAB* and any potential adverse effects on the breastfed infant from Kam*RAB* or from the underlying maternal condition.

9.3 Pediatric Use

Safety and effectiveness have been established in children. In a pediatric study of 30 patients ranging in age from 0.5 to 14.9 years, Kam*RAB* presented no serious adverse reactions through day 84. Of the 30 patients, 28 (93.3%) achieved a Day-14 RVNA titer ≥0.5 IU/mL, the WHO recommended level. None of the patients who were followed until the end of the study (28/30 patients) developed rabies infection through day 84. [see Clinical Studies (13)]

Adverse reactions that occurred in ≥3.3% of patients within the first 14 days of Kam*RAB* and the first rabies vaccination administration are listed in Section 7.1.

The clinical trial conducted in the pediatric population is described in Section 13.

Additional evidence to support the use of Kam*RAB* in children comes from Real World Evidence. Based on claims data, 172 U.S. children (≤17 years) were treated with Kam*RAB* between 2018-2020. Based on Centers for Disease Control and Prevention data, no children in the U.S. treated with post-exposure prophylaxis have been reported to have had rabies between 2018-April 2021.

9.4 Geriatric Use

Clinical studies of Kam*RAB* did not include sufficient numbers of subjects aged 65 years and over to determine whether they respond differently from younger subjects. Clinical experience with HRIG products has not identified differences in effectiveness between elderly and younger patients (ACIP).

10 DESCRIPTION

Kam*RAB* is a sterile, non-pyrogenic aqueous solution of anti-rabies immunoglobulin (≥95% protein as IgG). The product is stabilized with 0.3 M glycine and has a pH of 5.5 ± 0.5. It does not contain preservatives and the vial stopper is not made with natural rubber latex. Kam*RAB* is a clear to slightly opalescent liquid.

Kam*RAB* is prepared from human plasma from donors hyper-immunized with rabies vaccine. Individual plasma units are tested using FDA-licensed serologic assays for hepatitis B surface antigen (HBsAg) and for antibodies to hepatitis C virus (HCV) and human immunodeficiency virus types 1 and 2 (HIV-1/2), as well as by FDA-licensed Nucleic Acid Testing (NAT) for hepatitis B virus (HBV), HCV and HIV-1. Each plasma unit must be non-reactive (negative) in all tests. Plasma is also tested by in-process NAT procedures for HAV and parvovirus B19. Each plasma unit must be non-reactive to HAV, while the limit in the manufacturing pool is set not to exceed 10^4 IU per mL for parvovirus B19. The Kam*RAB* manufacturing process includes three validated and effective viral elimination steps:

- Solvent/detergent (S/D) treatment - inactivates enveloped viral agents
- Heat inactivation (pasteurization) - inactivates both enveloped and non-enveloped viruses
- Nanofiltration (NF) - physically removes viruses

The effectiveness of the S/D treatment, pasteurization and nanofiltration procedures for reducing viral content has been assessed using a series of viruses with a range of physico-chemical characteristics. The results of the viral challenge studies are summarized in Table 3.

Table 3: Log_{10} Virus Reduction during Manufacture of Kam*RAB*

Process Step	**Enveloped Viruses**				**Non-enveloped Viruses**	
	HIV-1	**BVDV**	**PRV**	**WNV**	**EMCV**	**PPV**
S/D treatment	>4.99	>5.70	>4.38	>5.46	Not tested	Not tested
Heat treatment	>6.21	>5.67	Not tested	>6.33	3.30	Not tested
Nanofiltration	Not tested	Not tested	>6.58	Not tested	>7.66	3.41
Global Log_{10} Reduction Factor	**>11.20**	**>11.37**	**>10.96**	**>11.79**	**>10.96**	**3.41**

Abbreviations: BVDV: bovine viral diarrhea virus; EMCV: encephalomyocarditis virus; HIV-1: human immunodeficiency virus 1; HRIG: human rabies immune globulin; PPV: Porcine parvovirus; PRV: Pseudorabies virus; S/D: solvent/detergent; WNV: West Nile Virus.

11 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Rabies is a zoonotic disease caused by RNA viruses in the family Rhabdoviridae, genus *Lyssavirus*. Virus is typically present in the saliva of rabid mammals and is transmitted primarily through a bite. Kam*RAB* is infiltrated into the inoculation site(s) in previously unvaccinated persons, to provide immediate passive rabies virus neutralizing antibody protection until the patient's immune system responds to vaccination by actively producing antibodies.

12.2 Pharmacodynamics

A protective threshold for rabies virus neutralizing activity (RVNA) has never been established. However, the WHO has generally accepted a RVNA of at least 0.5 IU/mL measured 14 days after initiation of post-exposure prophylaxis as protective.

12.3 Pharmacokinetics

A randomized, single-dose, two-period, two-treatment, two-sequence, double-blind, crossover study assessed the pharmacokinetics of Kam*RAB*. Twenty-six healthy volunteer subjects were randomized to receive a single IM injection of 20 IU/kg HRIG on two separate occasions (Kam*RAB* or Comparator HRIG). Subjects received the second treatment (A or B) following the 42-day test period and a 21-day washout period. Single dose IM injection of Kam*RAB* resulted in maximum plasma RVNA levels of 0.25 IU/mL. The median T_{max} was 7 days (range: 3-14 days). The elimination half-life was approximately 17.9 days. A statistical analysis of the pharmacokinetic parameters showed that Kam*RAB* was not bioequivalent to the Comparator HRIG (Table 4).

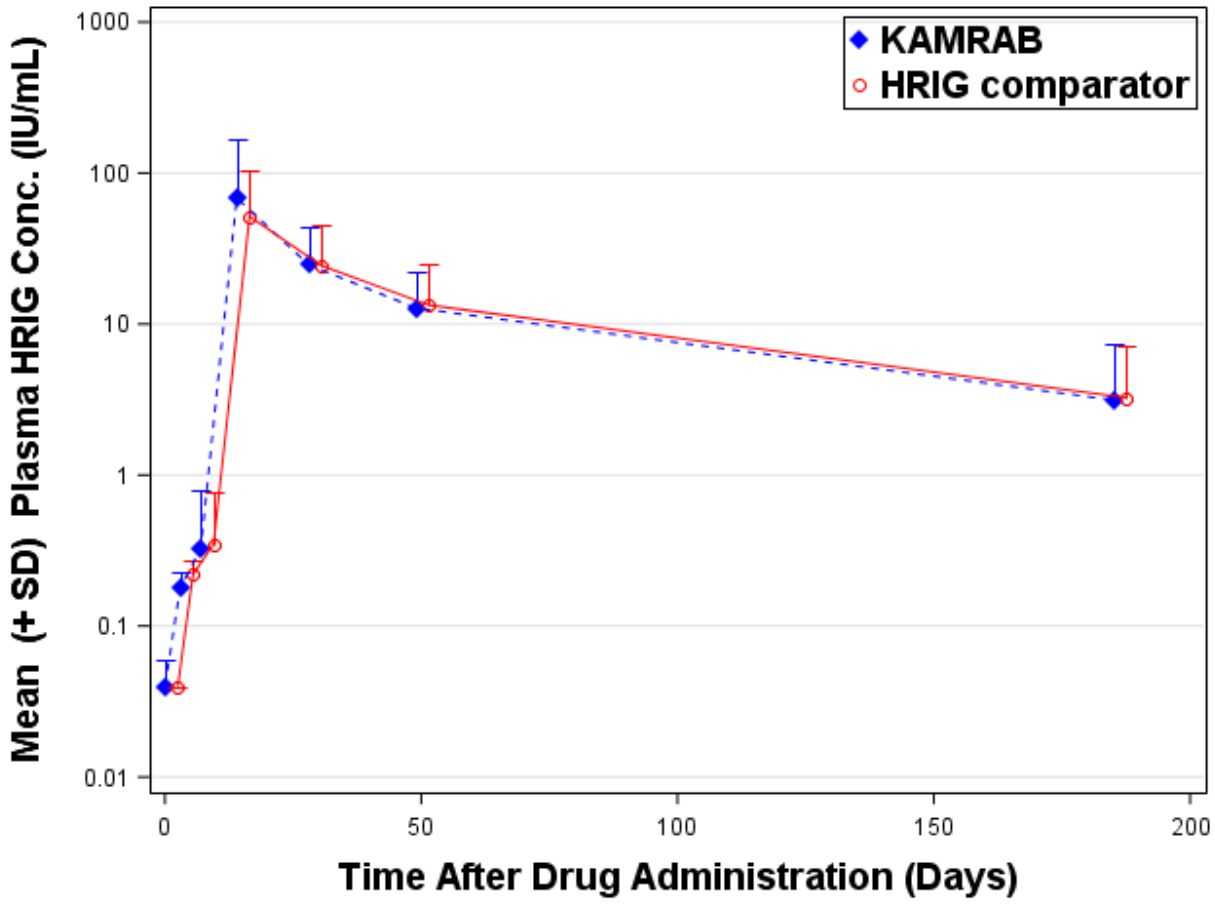
Table 4: Statistical Analysis of Rabies Virus Neutralizing Antibody Pharmacokinetic Parameters - Crossover Study of Kam*RAB*

Parameter	Units	Geometric LS Mean Values		Test/Reference (%)	90% Confidence Interval (%)
		Kam*RAB*	Comparator HRIG		
C_{max}	IU/mL	0.24	0.30	81.71	75.34-88.62
$AUC_{0\text{-last}}$	Day*IU/mL	5.08	6.17	82.35	77.39-87.63
$AUC_{0\text{-inf}}$	Day*IU/mL	6.64	7.86	84.44	78.63-90.68

Abbreviations: AUC: area under the concentration-time curve; C_{max}: maximum concentration; inf: infinity; IU: international units; mL: milliliter; PK: Pharmacokinetic; RVNA: rabies virus neutralizing antibody

A plot of plasma rabies virus neutralizing antibody titer concentration versus time (Figure 1) demonstrated that, in both treatment groups, plasma rabies virus neutralizing antibody concentrations declined in a biphasic manner after the absorption phase was complete.

Figure 1: Plasma HRIG Concentrations [Mean (±SD)] at Scheduled PK Sampling Days (Semi-log Scale), Phase 2/3 Study, Pharmacokinetic Analysis



Additionally, a prospective, randomized, double-blind, non-inferiority, study evaluated the pharmacokinetics, safety, and effectiveness of simulated post-exposure prophylaxis with Kam*RAB* with co-administration of active rabies vaccine in 118 healthy subjects. Subjects were randomized into two treatment groups (59 per treatment group) to receive intramuscular Kam*RAB* or comparator HRIG at a dose of 20 IU/kg on Day 0, and rabies vaccine on Days 0, 3, 7, 14 and 28. The peak plasma RVNA was 71.9 IU/mL and 53.9 IU/mL for Kam*RAB* and comparator HRIG respectively. For both treatment groups, the median T_{max} was 14 days (range: 14-49 days). The half-lives were 48.6 hours and 52.7 hours for Kam*RAB* and comparator HRIG respectively.

Bioequivalent assessment showed that Kam*RAB* was not bioequivalent to the comparator HRIG when co-administered with a five-dose rabies vaccine regimen (Table 5). Furthermore, the RVNA on Day 3 was lower in the Kam*RAB* with rabies vaccine group relative to the comparator HRIG with vaccine group (0.188+0.051 vs 0.229+0.054, P=0.0005). However, these pharmacokinetic differences are not expected to affect clinical outcomes.

Table 5: Pharmacokinetic Comparison of Rabies Virus Neutralizing Antibody between Kam*RAB* and a Comparator HRIG Administered with Rabies Vaccine

Parameter	Units	Geometric LS Mean Values		Test/Reference (%)	90% Confidence Interval (%)
		Kam*RAB* (Test)	Comparator HRIG (Reference)		
Cmax	IU/mL	44.87	36.02	124.59	90.62-171.28
$AUC_{0\text{-last}}$	Day*IU/mL	1741.40	1686.03	103.28	79.03-134.98
$AUC_{0\text{-inf}}$	Day*IU/mL	2045.87	1916.90	106.73	80.48-141.54

Abbreviations: AUC: area under the concentration-time curve; C_{max}: maximum concentration; inf: infinity; IU: international units; mL: milliliter; RVNA: rabies virus neutralizing antibody

Please see *Clinical Studies (13)* section for clinical efficacy.

12 NONCLINICAL TOXICOLOGY

12.2 Animal Toxicology and/or Pharmacology

Intramuscular administration of a single dose of Kam*RAB* to rats at 60 and 120 IU/kg (3-fold and 6-fold higher than the recommended human dose of 20 IU/kg) did not result in any signs of toxicity.

13 CLINICAL STUDIES

The efficacy of Kam*RAB* administered concurrently with rabies vaccine was studied in a single-center, randomized, comparator HRIG-controlled clinical study in adults. Study subjects were healthy adults 18 to 72 years of age who were without significant acute or chronic illness. A total of 118 subjects (59 per treatment group) received intramuscular Kam*RAB* or comparator HRIG at a dose of 20 IU/kg on Day 0, and rabies vaccine on Days 0, 3, 7, 14 and 28. The mean age of study subjects was 45 years; subjects were, predominantly white (93%), and 64% were women. The efficacy variable was RVNA, as assessed by Rapid Fluorescent Focus Inhibition Test (RFFIT), on Day 14. Efficacy analyses were performed on the As-Treated Population, which comprised the 116 study subjects who received Kam*RAB* or comparator HRIG and at least 3 of the 5 doses of rabies vaccine before Day 14.

Efficacy, considered when RVNA titer is 0.5 IU/mL or higher on Day 14 (as established by the WHO), was met by 56/57 subjects (98.2%) in the Kam*RAB* group and 59/59 subjects in the comparator HRIG group (Table 6). The lower limit of the 90% CI was greater than the pre-specified non-inferiority margin of -10%; thus, Kam*RAB* was non-inferior to comparator HRIG.

Table 6: Subjects with Geometric Mean RVNA ≥0.5 IU/mL on Day 14 (As-Treated Population)

	Kam*RAB* with Rabies Vaccine (N=57)	Comparator HRIG with Rabies Vaccine (N=59)
Rabies virus neutralizing antibody titer ≥0.5 IU/mL, n (%)	56 (98.2)	59 (100)
Exact 95% CI for proportion (%)	(90.6, 100)	(93.9, 100)
Difference (Pa-Pb)[a] (%)	-1.8	
Exact 90% CI for difference[b] (%)	(-8.1, 3.0)	

[a] 'Pa' and 'Pb' are the proportion of participants with IgG antibody titer ≥0.5 IU/mL on Day 14 in Groups A and B, respectively. Group A = Kam*RAB* +Rabies Vaccine, Group B = Control HyperRAB®+Rabies Vaccine.
[b] based on Farrington-Manning score statistic.
Abbreviations: CI: confidence interval; HRIG: human rabies immune globulin; IU: international units; mL: milliliter

Additional efficacy analyses in adult subjects included pharmacokinetics [see *Clinical Pharmacology (11)*].

Kam*RAB* was also evaluated in a two-center, open-label clinical trial in 30 pediatric patients exposed or possibly exposed to rabies virus for whom post-exposure prophylaxis was indicated. The patients were treated with Kam*RAB* at a dose of 20 IU/kg on Day 0 and active rabies vaccine on Days 0, 3, 7, and 14 as per ACIP recommendations for rabies post-exposure prophylaxis. The patients ranged in age from 0.5 to 14.9 years, 46.7% were females, 6.7% were Asian, 23.3% were Black and 70% were White, 10% were Latino. The efficacy variables were RVNA as assessed by RFFIT on Day 14 and occurrence of rabies disease through Day 84 after administration of Kam*RAB*. Efficacy analyses were performed on the As-Treated Population, which comprised all 30 study patients.

In the As-Treated Population, the geometric mean (SD) Day-14 RVNA titer was 18.89 (31.61) IU/mL and the median Day-14 RVNA titer was 8.81 (range 0.21 – 153.62) IU/mL. Of the 30 treated pediatric patients, 28 patients (93.3%) had a Day-14 RVNA titer ≥ 0.5 IU/mL, the WHO recommended level. None of the 28/30 patients who were followed for the duration of the study developed rabies infection through day 84.

14 PHARMACEUTICAL PARTICULARS

14.1 List of Excipients

Glycine, Water for injection

15 HOW SUPPLIED/STORAGE AND HANDLING

- Each package of Kam*RAB* contains a single-dose vial containing 2 mL, 5 mL or 10 mL of ready-to-use solution with a potency of 150 IU/mL (Note that more than one vial may be required for a single patient treatment).

- The 2-mL vial contains a total of 300 IU. The 5-mL vial contains a total of 750 IU. The 10-mL vial contains a total of 1500 IU.
- Keep vial in package until use.
- Store Kam*RAB* at 2-8 °C. DO NOT FREEZE.
- The expiry date of the product is indicated on the packaging materials. Do not use after the expiration date printed on the label.

Manufactured by:
Kamada Ltd., Beit Kama, ISRAEL

LICENSE NUMBER: 138-88-31771

Revised in September 2021 according to MOHs guidelines