Proposal for Industrial Commercialization of Topical Dermatological gel RP: NG/P/2019/87, and Certificate No. 010232) of 2019,

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1.0 Title: Industrialization and Commercialization of *Shamacure*^{R}: A Topical Dermatological Gel for treatment of skin disease Animals

2.0 Background to the Research

Shamacure^{R} topical gel is a Tetfund funded research product vid Tetfund/Dess/Unimaid/Maiduguri/rp/vol.VI, and titled "Developing a Petrolatum Based *Ganoderma lucidum* (P. Karst) Powder against Some Dermatological Conditions in Ruminants", at a cost of N1, 858,000.00**.** It was developed as a topical gel for Veterinary use against skin disease causative organisms of veterinary and zoonotic (Public Health) importance. It is equally a product of extensive fundamental (basic) Veterinary research (over 10 years), involving preclinical evaluation and three years of field clinical trials in diseased animals. It has been scientifically proved to possess more efficacies against animals' skin diseases, when compared with the existing gels/ointments currently in the market used against some skin diseases in animals. This topical veterinary gel has secured patent approval from NOTAP; RP: NG/P/2019/87, via certificate No. 010232. The commercialization and utilization of this product in veterinary practice in Nigeria and beyond, is of immense economic advantages. The product was developed from raw materials that are 100 % locally sourced**.** These raw materials are environmentally friendly and easily biodegradable with no unwanted negative environmental impact. The business will be agro-allied in nature, targeting herds and pet animals. Investing in establishing this product of agro-allied industry in Nigeria will be in line with the Federal Government of Nigeria's agricultural development plan to drive for utilization of local content in products, which shall provide quality raw materials to other industry, enhance animal farming activity, job and wealth creation among citizens and farmers, enhancement of human health through controlling diseases of animal origin (zoonosis) and boosting the gross domestic product (GDP) of the country. In addition, it will also have an added value chain in terms of gainful employment to teaming youths. We are presenting two budgetary requests for both short and long-time partnership to produce this drug. The proposed short-term budget is budget for this investment is fourty seven million, thirty-six thousand naira (N47,036,000.00) only, with an annual turnover of N86.6 Million/year, while the proposed budget for full industrialization is four hundred and sixty million, forty-six thousand, twenty-seven-naira, fifty-one kobo. (N460,046,027.51) only**.** It is expected that this investment will have a market potential yield of an annual turnover of N786.6 Million/year.

3.0 Statement of the Problem

The current treatment of dermatological problem includes prolonged parenteral administration of procaine penicillin over a long period of time. The bioavailability of this drug to the target parasite is very low due to poor blood flow to the skin. Besides Penicillin-G basically works effectively against gram positive bacteria (Actinomycetes), which a secondary infection, while the causative organism is *Dermatophylus Congolese,* together with other fungus species, thus creating a gap by making penicillin G ineffective. To bridge this gap, a new safe and effective herbal based *Shamacure*^{R} topical gel for treatment of many dermatological conditions in animals is developed. This drug has a tremendous market potential not only in Nigeria, but within African continent. From the clinical trials, there is already a huge demand for the product especially with a recorded 98 % dermatological conditions in animals coming from the Northern Nigeria. Therefore, with this high infection rates and a cheaper means of effective treatment, and with nearly 1.3 million of Nigeria's 10.8 million cattle affected annually, and coupled with a reported estimate of N12. 4 million spent in treatment using conventional drugs, *Shamacure*^{R} with a comparative advantage over the present conventional drugs used against dermatophilosis available in the Nigerian market, has a huge market potential not only in Nigeria, but in Africa and beyond.

4.0 Specific Objectives

i. To build an industrial complex that will produce ***Shamacure***^{R} topical gel, based on the principles of dermatologic therapy, for effective and easy use in animals.

ii. To cultivate and process *Ganoderma sp* for production of ***Shamacure***^{R} topical gel, thus providing an alternative medicine for dermatological conditions in animals.

iii. To commercialize and market ***Shamacure***^{R} topical gel to the global market.

5.0 Literature Review:

One of the most common disease that affects animals are those of bacterial, dermatophytosis and parasitic diseases (Hill *et al*, 2006). The demands for prophylaxis and treatment for these diseases are broad (Tresch *et al* 2019). A wide range of bacteria, including antibiotic resistant bacteria can be involved, thus making the treatment challenging with anthropo-zoonotic potential ((Tresch *et al* 2019). Treatment of infection associated with antimicrobial resistant bacteria can be challenging, besides, close contact between man and animals give opportunities for microbial exchange. It is therefore important to reduce the use of antibiotics in antimicrobial therapy by developing new alternative antimicrobial therapy.

Shamacure^{R} is an alternative treatment to antimicrobial resistant dermatophytes and parasites in animal. The product is developed form sources that are 99% Nigerian, and scientifically proven to treat and cure, completely, some dermatological conditions in animals. If

implemented, it will revolutionize livestock production in Nigeria. This can improve the country's GDP through stimulation of agricultural and commercial activities, thus creating added value chain in terms of job creation and commercial activities through stimulation of agricultural production and other industrial activities dependent on animal productivities.

6.0 **Theoretical Framework:** This invention is better than available conventional means/methods of treating dermatophilosis in animals, in that it's a topical gel that can easily be prepared and applied on the lesion on the animal skin. Its novelty is that it is a new invention and simple to prepare and administer, it stays longer on the skin giving a depot effect, thus providing slow absorption with maximum effect in providing cure within a period of seven days. It solved the problem of ineffective treatment of the disease (Dermatophilosis) in animals at a minimal cost, thus providing good economic returns to the farmer, and healthy protein source to humans, healthy Hyde and skin to the leather industries. It also will solve the problem of prolonged parenteral administration of ineffective Injectable drugs that may have residual effects in food animals with consequences on human health.

7.0 Methodology

To build and develop an industrial complex that will be producing an effective *Shamacure*^{R} topical gel for eventual commercialization in the global market, and to be used against animal skin diseases.

8.0 Expected Outcome: Our approach is to build and develop an industrial complex that will develop, produce and commercialize our indigenous research product, so as to provide an alternative, simple to prepare and administer, effective, readily available, and nontoxic treatment first line therapy to skin diseases in animals and within a very short time of its application.

9. 0 Innovations

It is a newly invented effective topical gel for veterinary use against skin disease causative organisms of veterinary and zoonotic (Public Health) importance. It is equally a product of extensive fundamental (basic) Veterinary research (over 10 years), involving preclinical evaluation and three years of field clinical trials in diseased animals. It has been scientifically proved to possess more efficacies against animals' skin diseases, when compared with the existing gels/ointments currently in the market used against some skin diseases in animals.

10.0 A**dvantages of investing *Shamacure*^{R} Topical gel.**

1. Provision of safe, effective, cheap, readily available remedy that is 100% local content.
2. Enhancing heard health with maximal return of profit on investment to farmers.
3. Reduce the spread of zoonotic diseases (from animal to man, especially with pet and domestic animal example; cats, dogs, rabbits and small ruminants).
4. Provision of healthy meat proteins of animal source with no residual unwanted toxic effect as associated with synthetic drugs. (since the herb can also be used by man and is rapidly eliminated from the system- 24 hours post administration).
5. Enhance milk production in milk producing animals (with no ordour, texture, colour or viscosity changes in the milk)
6. Enhance livestock production. (Reduce skin irritation, enhance feeding and utilization of consumed feed), especially in a war-torn zone (Borno) where source of livelihood has been denigrated, and now highly needed now.
7. Export of Veterinary herbal gel from Nigeria to sister African countries will enhance balance of trade for Nigeria and strengthen the Naira value.
8. Enhanced supply of healthy hyde and skin to the tannery and leather company at cheaper rates.
9. Job creation (through value added chain) to Veterinary health workers and others.
10. Wealth creation through increase profit margins on investment, sales to the farmers, Veterinary health workers and to government (through boosting the annual gross domestic production-GDP).
11. There is the possibility of expansion of the business to produce beverages, poultry products and to be of human health benefits, thereby creating more job opportunities.
12. The investment in the development of this company is environmentally friendly, since all the raw materials to be used are natural and easily biodegradable.

11.0 Estimated budget for short term commercialization (Sponsorship):

Serial No.	Item	Quantity	Unit price (N)	Total amount (N)
1.	Production equipments & energy	-	24 Million	26 Million
2.	Herb cultivation (Green house)	4 ($100m^2/200m^2$)	1,250,000 Million/house	5 Million
3.	Containers	1000/gel/day	1,000/container	1 million /month
4.	Labels	1000/labels/day	1000/labels	1 million/month
5.	Reagents (petroleum jelly, gum arabic, chemicals	-	-	3,500 Million/month
6.	Distribution Van	1	6 Million/van	6 Million
7.	Gel container caps	1000/day/container	60/cap	60,000.00/month
8.	Registration of product with relevant agencies NAFDAC and Corporate affair Commission (CAC).	-	100,000/ agency (2)	200,000.00
9.	Sub Total			N 42,760,000.00
10.	Miscellaneous (10 % of sub-total)			N 4,276.000.00
			Grand Total =	**N47,036,000.00**

12.0 Estimated budget for full industrialization (partnership):

Serial No.	Item	Quantity	Amount/Item(s) (N)	Total amount (N)
1.	Land	10 hectares	10.5 million/hectare	105 million
2.	Industrial complex	1	85 Million	85 Million
3.	Production equipments & energy	-	45 Million	45 Million
4.	Herb cultivation (Green house)	10 ($100m^2/200m^2$)	2 Million/house	20 Million
5.	Containers	1000/gel/day	250,000/container	7.5million /month
6.	Labels	1000/labels/day	1000/labels	1,000,000.00/month
7.	Reagents (petroleum jelly, gum arabic, chemicals	-	-	2 Million/month
8.	Distribution Van	2	4.8 Million/van (2)	9.6 Million
9.	Gel container caps	1000/day/container	60/cap	60,000.00/month
10.	Registration of product with relevant agencies NAFDAC and Corporate affair Commission (CAC).	-	200,000/ agency (2)	400,000.00
11.	Sub Total			N 460,000,000.00
12.	Miscellaneous (10 % of sub-total)			N 46,027.51
			Grand Total =	**N460,046,027.51**

11.0 References

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5. Hill, P. B., Lo, A., Eden, C. A., Huntley, S., Morey, V., Ramsy, S., Richardson, C., Smith, D. J., Sutton, C., and Taylor M. D. (2006): Survey of the prevalence, diagnosis and treatment dermatological conditions in small animals in general practice. Vet. Rec. 158 (6):533-539.

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7. Hapuarachchi, K.K., Wen, T.C., Jeewon, R., Wu, X. L., Kang, J. C and Hyde, K.D. (2016): Mycosphere essay 7. *Ganoderma lucidum*-are the beneficial anticancer properties substantiated? Mycosphere 7 (3): 305-332.

12.0 Research Team

S/No.	Name	Highest Academic Qualifications	Rank	Specialization/Institution
1.	Shamaki Bala Usman	PhD, FCVSN	Professor (PI)	Clinical Pharmacologists/FVM/UniMaid
2.	Umar Kyari Sandabe	PhD	Professor	Physiologist
3.	Fanna Inna Abdulrahman	PhD	Professor	Organic Chemist
4.	Yusuf Abba	PhD	Professor	Pathologist
5.	Hassan Garba Zakari	HND (Animal Production)	Chief Livestock Superintendent	Livestock Superintendent

13.0 Prayers:

We pray for sponsorship of the production and commercialization of this research product on short time basis, or outright partnership with NEDC (PPP) for industrialization and commercialization of this research product that is 100% developed from our local resources, and of immense economic value to both farmer and government.

14.0 **Therapeutic effects of *Shamacure*^{R} topical gel in some selected skin diseases in animals**

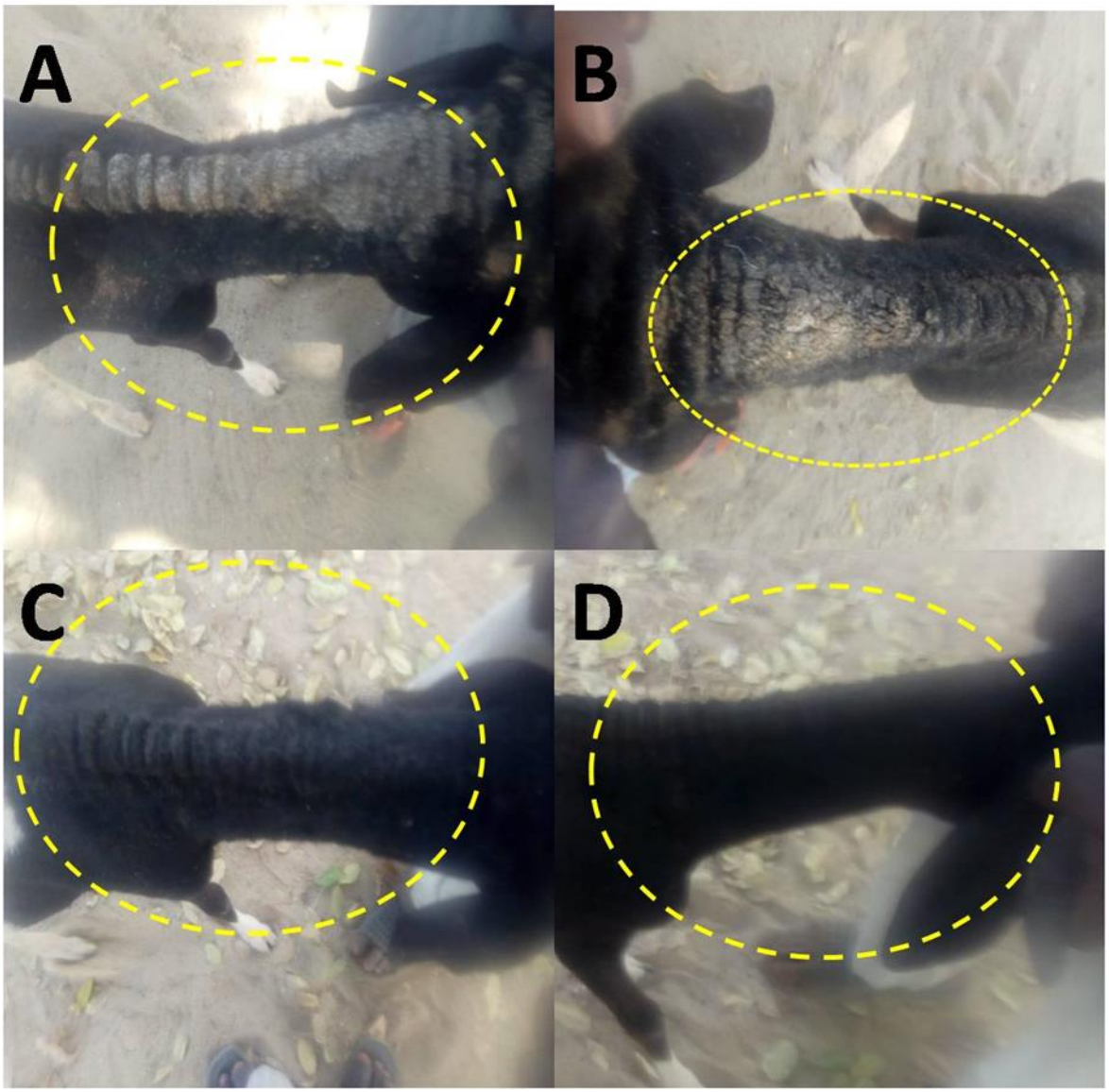

Figure 1 (A, B, C, D): The pictorial presentation of the treatment of mange in Balami breed of sheep with ***Shamacure*^{R} Topical dermatological gel**, showing progressive reduction of the infestation (crust). The neck of the sheep showing mange infestation before commencement of treatment (A), treatment with the ***Shamacure*^{R} gel**, on day 2 (B), progressive reduction of scab/mange patches on the neck at day 7 (C) and total absence of the scab/crusts on day 14 (D).

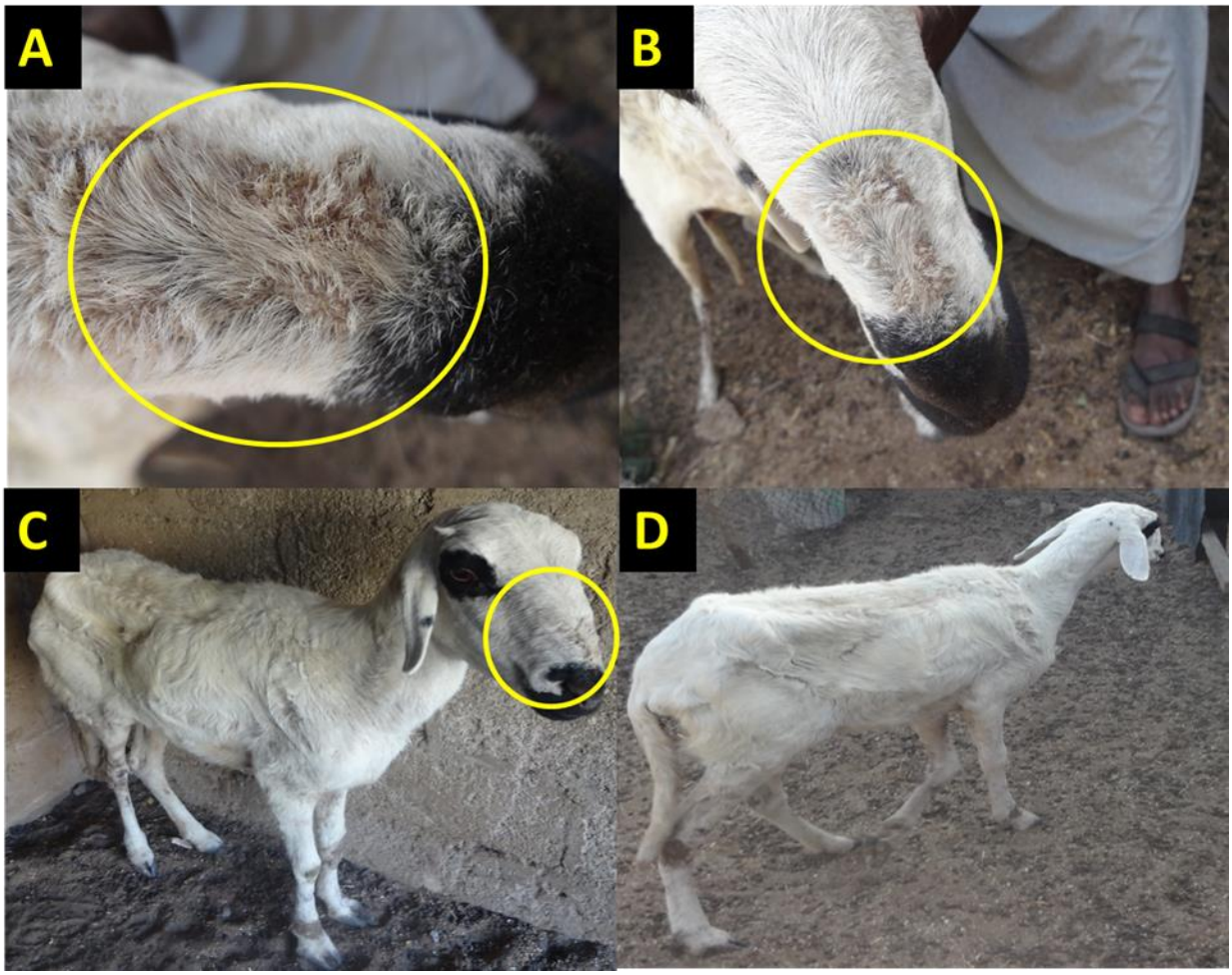

Figure 2: Photograph of the face of showing (A) growth of squamous cell carcinoma before application of treatment (B) squamous carcinoma lesion treated with 6.7 mg/mL *G* based petrolatum paste 14 days after treatment (C&D) The ewe showing considerable regression in tumor 30 days after treatment with 6.7 mg/mL *G* based petrolatum paste.

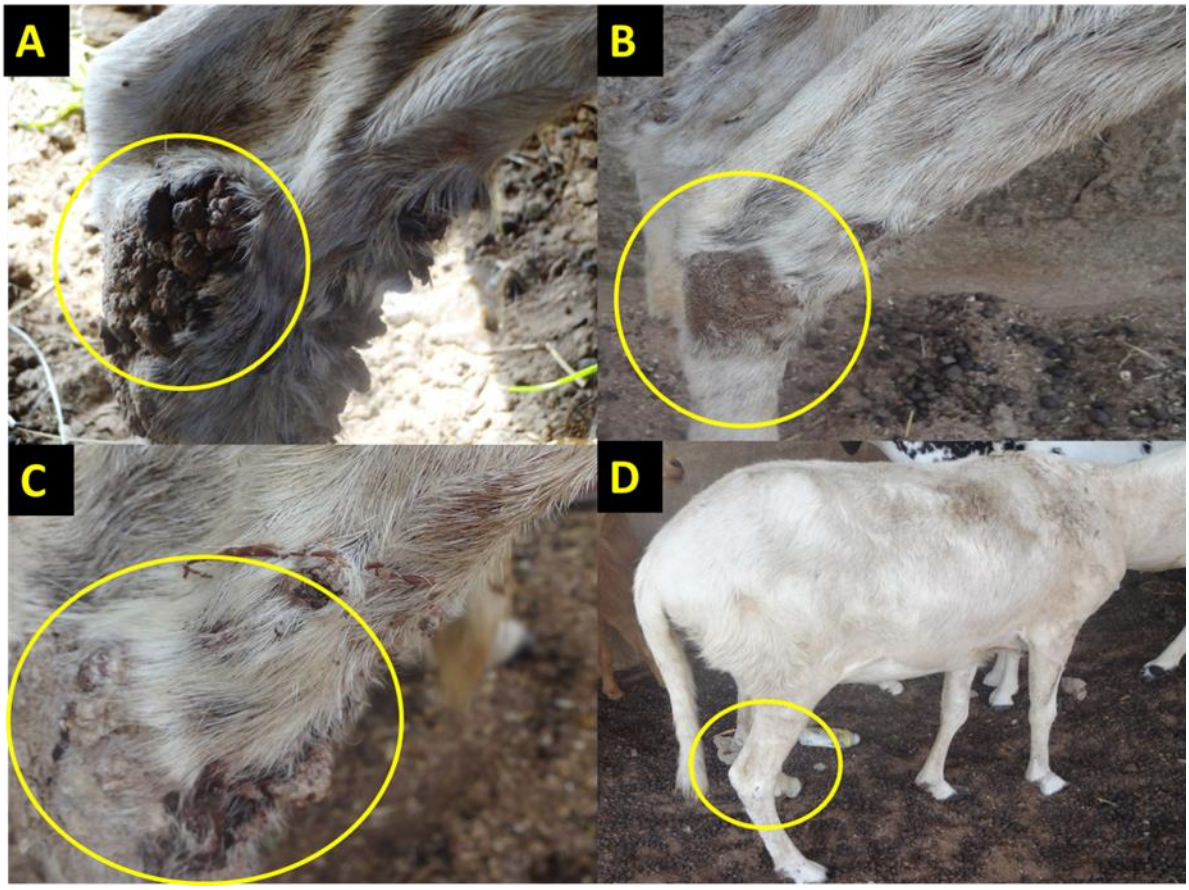

Figure 3: Photograph of the hind leg of sheep showing (A) growth of squamous cell carcinoma before application of treatment (B) squamous carcinoma lesion treated with 6.7 mg/mL *G* based petrolatum paste 14 days after treatment (C&D) The ewe showing considerable regression in tumor 30 days after treatment with 6.7 mg/mL *G* based petrolatum paste.

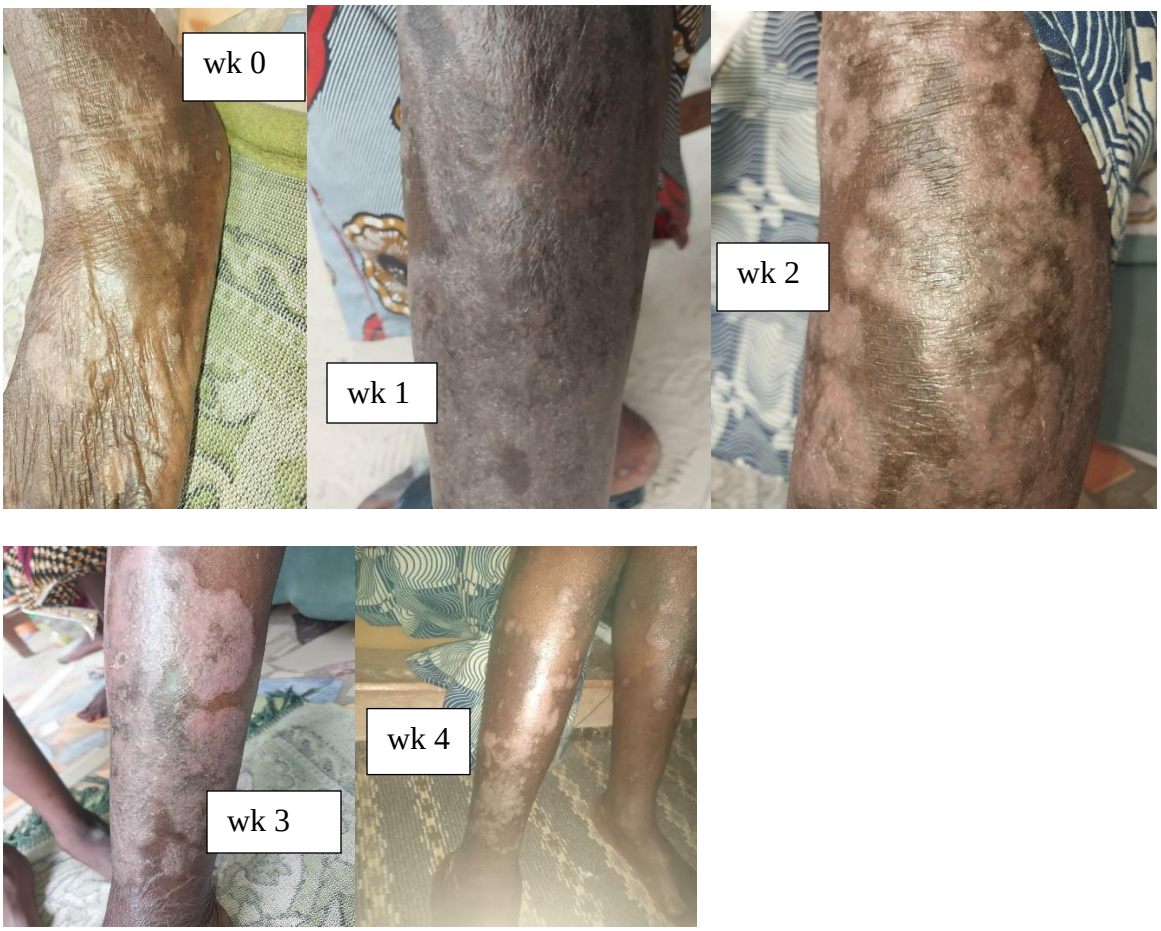

Figure 4: Treatment of massive and invasive cutaneous Aspergillosis infection on the leg of a female volunteer from week 0-4, following daily (bd) application of ***Shamacure^{R}*** topical gel.