Indian Solution to Global Health Problems via Globally Patented New Immunity Drugs: NID (Radha 108 & Secretion of Biosimilars)

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• Dr. George Wald, Nobel laureate & Prof. Joseph Weizenbaum, father of artificial intelligence at MIT, USA brain stormed with the Biomix team.
• Poor Immunity was found to be the #1 reason for majority of diseases.

• Several immunity drugs existed, however none could; “build body’s own immunity like mother’s first milk”. This was the insight & lead for the research team.

• After 10 years of research, we have successfully isolated Nanopeptides from bovine colostrum and conducted global clinical studies on 30000 patients suffering from communicable disease and Immune disorders via innovative oral spray drug delivery system.
• Radha 108 which also produces Biosimilars like IL, IFN & TNF, at the most affordable price creating a paradigm shift in the pharmaceutical speciality and generic industry.

Creating paradigm shift in health care from ‘Prevention to Cure’

Fleming discovered Penicillin G, which saved millions from bacterial infections. Radha 108 will save billions from viral infections & immune disorders.
Value of discovery – Unique globally patented Radha108

Phases and Time of drug discovery

<table>
<thead>
<tr>
<th>Years</th>
<th>Discovery (2-10 yrs)</th>
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<tbody>
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<td>16</td>
</tr>
</tbody>
</table>

- **Phase I**: 20-80 Healthy volunteers Used to determine
- **Phase II**: Laboratory and Animal Testing
- **Phase III**: 100-300 Patient volunteers Used to look for Efficacy
- **Additional Post-marketing testing**: FDA Review/Approval

Major functions of a CRO consist of:
- Drug discovery stage
- Pre-clinical stage
- Clinical stage

The various activities of a contract research organization includes:
- Clinical study design
- Project management
- Quality assurance auditing
- Medical safety monitoring
- Biostatistics
- Central laboratory services
- Clinical data management
- Regulatory submissions
- Scientific communication

$150Mn. in addition to govt. funding & sweat equity is $500Mn.
Global Health Challenges – Millions suffer from

Pandemics like Swine flu, Allergies, Asthma, HIV, TB, Ebola, Zika impact global economies & 1 in 3 children miss school due to poor immunity

Source: Lancet & TOI studies
MILLIONS MORE SUFFER FROM IMMUNE SYSTEM RELATED ILLNESSES
Challenges with biosimilar

Current Therapeutic cost modalities

<table>
<thead>
<tr>
<th>Sr. No</th>
<th>Cytokine Biosimilar</th>
<th>Brand Name</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Interleukin 2</td>
<td>Proleukin (Aldesleukin), Denileukin Diftitox</td>
<td>Each vial price US $1000</td>
</tr>
<tr>
<td>2</td>
<td>Interferon α</td>
<td>Intron A/ Rebetron/ PEG- Intron, Roferon A</td>
<td>Each vial price US $300</td>
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<tr>
<td></td>
<td>Interferon γ</td>
<td>Actimmune</td>
<td>Each vial price- US $200</td>
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</table>
What if there was a way to treat most viral & all immunity disorders
Uniqueness of NID

Innovative & Affordable Patented

Broadspectrum Drug
Easy To Administer

Anti Viral/Immuno-Modulator with no side effects

Can be consumed by all.. has no age or sex barrier, drug , drug interaction
1 out of 3 Americans can be treated with Radha 108: $10+ billion drug globally

* Unit sale 250 Million for Auto Immune, Asthma, Allergy & HIV Patients in US alone

*US alone accounts for $5 Billion

Rest of the world can account for additional $8 billion market

* Radha 108 dosage of 4 times/day @ 3ml/dose - 3 bottles/month/patient @$40 = $1440/patient per year

Source: www.cdc.gov
Auto immune disorders

In US alone, more than 23M people are affected by autoimmune diseases!

More than $100Billion is spent by sufferers on drugs every year!
Asthma may affect as many as 334 million people.*

Global COPD and Asthma Devices Market is Expected to reach $34.3 Billion by 2020
Growing at a CAGR of 4.5% (2014-2020)

Global COPD and Asthma Devices Market By Product Type
- Inhalers
  - Drug powder inhalers (DPIs)
  - Metered Dose Inhalers (MDIs)
  - Soft Mist Inhalers (SMIs)
- Nebulizers
  - Compressor nebulizer
  - Ultrasonic nebulizer
  - Mesh nebulizer

Expected to grow by more than 100MM by 2025!

Allergies & Asthma


$25Billion$ is spent on Asthma drugs annually which has gone up by 50% since 2009!

30% adults and 40% of children worldwide are affected by allergies!
HIV is a major threat affecting ~40m people worldwide and the sales for HIV drugs are expected to increase steadily.

1.2M only in US

36.9 MILLION people worldwide are currently living with HIV/AIDS.

The vast majority of people living with HIV are in low- to middle-income countries, particularly in Sub-Saharan Africa.

2.6 MILLION CHILDREN worldwide are living with HIV. Most of these children were infected by their HIV-positive mothers during pregnancy, childbirth or breastfeeding.

Forecast of HIV drug sales ($Billion)

Source: www.aids.gov
246M worldwide are affected by Diabetes!

$55Billion is spent on annually which has gone up by 55% since 2012!

*Source: www.cdc.gov*
Health for all via New Immunity drug*

Derived from Colostrum: Naturally producing Biosimilar like Cytokines & Chemokines from Cytotoxic T-cells of the innate immune system

* Radha 108 & Secretion of Biosimilar (IL, IF & TNF) via its MoA
What is NID (Radha 108 & its Biosimilar)

Radha 108 Active Pharmaceutical Ingredients (API)

- API consist of Patented Nano – Informational Peptides extracted from mammalian colostrum via Ultra Nano filtration Technology having sequence id 1-8 (provided on next slide) & Proline Rich Poly Peptides (PRPs)

- PRPs & Radha-108 are a class of nano informational peptide consisting of oligo-ribonucleotide attached to a peptide molecule that act as immunity drug via immune-modulation and anti-viral/bacterial activity.

- Dosage - 3ml QDS via oral buccal spray (1 ml contains 0.03 grams of Patented Nano Peptides that can be synthetically manufactured also) and tablets, capsules & MMS drug delivery systems

The ‘Biggest’ thing in Industry, just may be the ‘Smallest’ thing – Radha 108 Nanopeptides
# Patented Sequences of NID

Radha 108 containing Patented SEQID-8 that work in synergy with each other to build body’s strong immune system even in totally immuno-compromised AIDS patients

<table>
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<th>S. No.</th>
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<td>Alpha-S1-casein (MW – 1584.84)</td>
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<td>S-adenosylmethionine synthetase isoform type-1 (MW – 1229.47)</td>
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<td>5</td>
<td>SSLQVLNMSHN</td>
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<td>Toll-like receptor 4 (MW – 1229.37)</td>
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<td>EYQELMNVK</td>
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<td>Keratin, type II cytoskeletal 59 kDa, component IV (Fragment) (MW – 1153.32)</td>
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<td>Keratin, type II cytoskeletal 7 (MW – 1448.6)</td>
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<td>8</td>
<td>DGIVNENLAER</td>
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<td>Ribonucleoside-diphosphate reductase small chain (MW – 1229.31)</td>
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</table>
Chemical structure of NID

Proline Rich – Radha 108 (Class V PRP)

Chemical Structure

Mass Spectrum
Mode of action: Science behind NID (Radha 108 efficacy)

- Radha108 (PRP) promotes differentiation of B cells, differentiation and maturation of macrophages and monocytes.
- Activates natural killer (NK) cells, cytotoxic cells of the innate immune system.
- Mitigates cell fusion and docks on HIV glycoprotein like Gp120, 180, 160 and 41 mimicking receptor on the cell surface closing entry of viruses.
- Stimulates production of cytokines IL-1 to IL-11, TNF-α, INF-γ.
- Stimulates the maturation of immature thymocytes into either helper or suppressor T cells.
- Radha108 also functions as a molecular signaling device which works through receptors on target cell surfaces.
Mode of Action - Pharmacodynamics

- Radha108 series get absorbed in the blood through buccal mucosa and crosses BBB.
- Stimulates the maturation of immature thymocytes into either helper or suppressor T cells.
- Radha108 (PRP) promotes differentiation of B cells, differentiation and maturation of macrophages and monocytes.
- Activates natural killer (NK) cells, cytotoxic cells of the innate immune system.
- Stimulates production of cytokines IL-1 to IL-11, TNF-α, INF-γ.
- Mitigates cell fusion and docks on HIV glycoprotein like Gp120, 180, 160 and 41 mimicking receptor on the cell surface closing spectrum entry of viruses.
- Radha108 also functions as a molecular signaling device which works through receptors on target cell surfaces.
Mode of action - Pharmacokinetics

Pharmacokinetics

- Radha 108 present in the formulation are readily absorbed through the buccal mucosa into the blood stream to directly reach the immune system. As the molecular weight of the molecules is below 2kdal it can cross any biological barrier including the blood brain barrier. They are readily metabolized and excreted.

Indications

- The Radha 108 is indicated for all immunity disorders including HIV and recurrent infections as approved by US PTO for 58 indications given in the book on www.biomix.in

Contraindications

- No adverse effect reported globally for the past 10 years, during global, clinical and operational studies including Acute & Sub- Acute Toxicology Animal study conducted by Indian council of medical research at National institute of nutrition, Hyderabad
Mode of action – T Helper Cell Differentiation

Mode of Action T Helper Cell Differentiation via Radha108 Nanopetides leads to secretion of IFN, IL, TNF and other cytokines
Radha108 Nano Peptide plays a role in differentiation and maturation of macrophages and monocytes.
The activity of Natural Killer cells, cytotoxic cells of the innate immune system, was increased up to 5 times by Nanopeptides of Radha108 Nano Peptide
Mode of action - Immuno Response Summary

Radha 108

Antigen

Macrophage

Displays copy of antigen

Cellular Immunity

Active Cytotoxic T-Cell

Kills Infected Cells

Memory T-Cell

Helper T-Cell

Active B-Cell

Plasma Cell

Antibodies

Deactivates Antigens

Memory B-Cell

Antibody Immunity
Radha108 Nano Peptide manufacturing plant is state of the art, nano biotech facility granted by TUV Nord Germany since 2012. GSK Consumer healthcare group UK & India due diligence done on product & the manufacturing facility.

Consistent raw material source: International quality from ISO/GMP certified, Amul, world’s largest 75 year old dairy with stringent QC/QA checks & balances, right at the origin of Colostrum.

Extraction of API, PRP (Radha108, Type of PRPs of molecular weight from 1800 to 500kDA) is done by Merck Millipore Molecular Exclusion Ultra filtration columns of 100 to 10 kDA at cGMP facility shown below.
NID – Product range

- Oral spray
- Oral liquid
- Capsules & Tablets
- Powder
Medical confirmation of NID for globally patented 58 indications
(US Patent # 9,249,188 PCC# IN2009/000749, WO2010/079511)

- Allergies, Asthma, HIV, Autoimmune Disorders,
- Viral Respiratory Infection, Rheumatoid Arthritis,
- Endometriosis, Cancer, Lupus, Severe Acute Respiratory Syndrome (SARS), Cold & Flu
- Benign Prostatic Hyperplasia,
- Premenstrual syndrome,
- & Alzheimer’s, Hypertension,
- Thrush, Autism, Perthes disease, Prion disease,
- Psoriasis,
- Sjogren’s syndrome, Spinal Muscular Atrophy,
- Thrombocytopenia, Burns, Infection, Insect bites,
- Daiper rash, Herpetic lesions, Pharyngitis, Porphyria,
- Raynaud’s phenomenon, Acute Viral Infection,
- Dengue fever, Shingles,
- , Plantar Warts,
- Lymphoma, Herpes Simplex I & II, Parvo,

- Sarcoidosis, Celiac disease, Chronic Pancytopenia,
- Crohn’s disease, Diabetes type II,
- Fibromyalgia Rheumatica, Mononucleosis,
- Multiple Sclerosis,
- Osteo Arthritis, Brown Recluse Spider Bite,
- Corneal Regeneration, Diarrhea,
- Guillain Barre Syndrome, Hemolytic Anemia,
- Idiopathic thrombocytopenia purpura,
- Myasthenia Gravis, Tuberculosis,
- Human Immunodeficiency Virus (HIV),
- Hepatitis A and C, Rabies in Dogs,
- Human Pappilloma Virus
## Entry barrier via Global product patents

<table>
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<tr>
<th>Jurisdiction</th>
<th>Application No./ Date</th>
<th>Title</th>
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<tr>
<td>USA</td>
<td>13/142,327 DT. 27.06.2011</td>
<td>Mammalian Colostrum Derived Nanopeptides For Broad spectrum Viral And Recurrent Infections With A Method Of Isolation Thereof</td>
<td>GRANTED (PATENT# US8518454)</td>
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<tr>
<td>USA</td>
<td>U.S. Patent Application No. 13/845,577</td>
<td>Mammalian Colostrum Derived Nanopeptides For Broad spectrum Viral And Recurrent Infections With A Method Of Isolation Thereof ( For approved 58 indications for Radha 108 )</td>
<td>GRANTED ( Patent No. 9,249,188 )</td>
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<td>SOUTH AFRICA</td>
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<td>SINGAPORE</td>
<td>201104717.2 DT. 29.12.2009</td>
<td>Mammalian Colostrum Derived Nanopeptides For Broad spectrum Viral And Recurrent Infections With A Method Of Isolation Thereof</td>
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<td>EP 09827010.1 DT. 30.06.2011</td>
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<td>PCT/IN2011/000522 09.08.2011</td>
<td>An Automated Integrated System, Method and Plate form For Healthcare Services</td>
<td>Granted(PATENT #:WO2012/020429)</td>
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<td>An Apparatus and Method For Detecting Biological State in Sample by Using Bio Marker ERS</td>
<td>Granted (PARENT #:WO2011/158246A1)</td>
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</table>
Business Opportunity through breakthrough innovation

- Radha108(NID) enables people to lead longer & healthier lives via building body’s own immune system naturally and saves billions from viral infections & Immune disorders.
- USP of Radha108 is its clinically proven Mode of Action via global study.
- Granted product patent in North America, Europe and Asia PAC.
- Innovation led Radha 108 NID has potential to be a blockbuster drug($10 Billion+) as illustrated by a series of globally accredited market research conducted by IPSOS & IRMA/IIM indicating Radha 108 as doctors first choice based on its USP, convenience of use & no side effects.
- Clinically proven indications of NID include Asthma, Allergy, HIV, Auto Immune disorder, diabetes, cancer & other viral respiratory infections, cancer etc (that accounts for expenditure of $500 billion in US alone. Source- www.cdc.gov).
- Wonder drug of the 21st Century - Creating a Paradigm shift in healthcare/pharma industry from Prevention to Cure.
Global Clinical Trial
Radha 108 in Allergies

Reporting Patients* : 24
Duration of Treatment : 6 months

More than half the respondents experienced complete resolution of symptoms!
Global Clinical Trial
Radha 108 in Rheumatoid Arthritis

Reporting Patients*: 63
Duration of Treatment: 6 months

- **34%** Complete resolution of symptoms
- **22%** Significant benefits
- **22%** Some benefit
- **14%** Did not exhibit the same benefit
- **8%** Inconclusive

56% of patients found the product to be highly effective!
Global Clinical Trial
Radha 108 in Chronic Fatigue

Reporting Patients* : 108
Duration of Treatment : 6 months

70% of patients received significant benefits!
Global Clinical Trial
Radha 108 in Endometriosis

Reporting Patients*: 106
Duration of Treatment: 6 months

Similarly for Endometriosis, complete resolution in most cases!

- Complete resolution of symptoms
- Some benefit
- Inconclusive

34%
50%
16%
Indian Safety & Efficacy Trial

On Immuno compromised HIV subjects used as the model

Preclinical Safety: as per NIN National Toxicology Panel
- No Acute Toxicity & No Sub Chronic Toxicity

Revalidation Phase III Indian Trials – Stand alone MONOTHERAPY with Radha 108 Nano Peptide sponsored by Government of India, MOH/NACO and Monitored by ICMR/NARI*
- Study I (2006-07): By GoI on 50 Patients at LTMG Hospital Sion, Mumbai (Clinical trial registry No. : CTRI-2012-08-002931)
- Study II (2007-08): By GoI on 51 Patients at LTMG Hospital, Sion, Mumbai (Clinical Trial registry No. : CTRI-2012-09-002959)

• The study was fully controlled, conducted and sponsored, by Govt. of India, Biomix was facilitating the same & had no control on the specifications.

Safety and Efficacy Achieved by Global Trials:
Phase I: 12 cohort 30 days (completely safe) in Ohio, USA
Phase II: 30 cohort 90 days (highly effective with no side effects) in Nairobi – Kenya
Phase III: 60 cohort for 365 days (highly effective with no side effects) in Rwanda, Africa
**Toxicology study at National institute of nutrition (NIN)**

Pre-Clinical safety study has been undertaken as per schedule Y of DCGI guideline under the supervision of Dr. B. Dinesh Kumar, Asst. Director (Study director) at **National Institute of Nutrition, Hyderabad.**

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<tbody>
<tr>
<td>1.</td>
<td>Animal selected</td>
<td>SPRAGUE DAWLEY RATS (of both the sexes)</td>
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<td>2.</td>
<td>Weight of the animal</td>
<td>150–180 gm (for both the studies)</td>
</tr>
<tr>
<td>3.</td>
<td>Age of the animal</td>
<td>4 to 6 weeks (for both the studies)</td>
</tr>
<tr>
<td>4.</td>
<td>Route of Administration</td>
<td>Oral</td>
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</tbody>
</table>

**Acute toxicity**

**RESULTS**

No pre-terminal deaths after administration of 50 times of intended therapeutic dose through oral route

All rats were found to be active and with normal body weight.

No Acute toxicity found.

*Indian council of medical research (ICMR)*
## NIN Study: Sub acute data

### No mortality was observed & product is safe

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<tr>
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<td>No. of Rats used</td>
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<td>Categories</td>
<td>Vehicle control (VC), Therapeutic dose (TD – 1.08ml), Average dose (AD – 5XTD), (five times of TD) and High Dose (HD – 10XTD), (ten times of TD)</td>
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<tr>
<td>3</td>
<td>Days of trial</td>
<td>45</td>
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<td>Period of Observation</td>
<td>Biweekly for live phase, cage side, physical and neurological parameters. At 48hrs and 15th day hematology and biochemistry profile along with gross necropsy and histopathology of major organs were evaluated.</td>
</tr>
</tbody>
</table>

### RESULTS

- No significant difference in physical activity and neurological activity between control and test groups throughout the study period.
- No significant abnormalities in hematology, clinical chemistry profile in blood/serum samples.
- No gross lesions were found in any organ and no significant difference in histopathology of various organs.
- No sub chronic toxicity found
Global Trial Results
Phase I – Ohio State University, USA

- 12 cohort, 30 days, moderate dose
- Patients may have previous exposure to AZT
- Balanced diet with vitamin-minerals provided
- 10 patients had weight gain and 7 patients had gained an average 6 lbs
- Highest weight gain was 12 lbs for a patient who was HIV positive for 10 years
- All 12 pt had improved symptom assessment score and average reduction approached 63 %

Free of side effects
Phase II – Nigeria, Africa

- Advanced HIV / AIDS, Limited access to conventional treatment
- 30 cohorts, 30 days Mono therapy
- No previous exposure to ART
- Some signs of detoxification, relieved by increase water intake
- Resolution or reduction in all Clinical symptoms
- Weight gain observed in all patients

Efficacious & Free of side effects
Phase III – Rawanda, Africa

- Safety and efficacy trial
- 60 AIDS patients – 365 days
- Patients were unaware of positive potential of drug
- Weight gain consistently observed
- After day 1 moderate level of relief of diarrhea and fever
- After 14 days, relief from skin lesion, mouth thrush, fever, diarrhea, tuberculosis symptoms
- After 90 days relief of all symptoms with increase in Absolute CD4 Counts & Reduction in Viral Load

No adverse effects observed over 12 months follow up with improved Quality of Life even after 5 years of therapy.

Highly Efficacious & Free of side effects
Stand alone Mono-therapy Safety and Efficacy in HIV+ AIDS Patients:

• Study I – Sion Hospital, Mumbai on 50 HIV+ Patients
  • Absolute CD4 cell count & HIV Viral Load – tested at NABL accredited Metropolis lab, Mumbai
  • Clinical & Physical symptoms study - at ART Center, OPD Center, Sion Hospital, Mumbai
  • **Inclusion criteria** – absolute CD4 cell count greater than 100 cells/mm³
  • **Exclusion criteria** – no pre- exposure to ART
  • Mean HIV log viral load has statistically significantly dropped (p < 0.001)
  • Statistically significant increase in CD4 cell count (p = 0.06)
  • Clinical symptoms disappeared in 3 weeks of treatment in All Patients (p<0.05)
  • Statistically significant weekly weight gain in All Patients (p<0.001).
### Visit (Weeks)

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<th>No. of Subjects with Nausea</th>
<th>No. of Subjects with Vomiting</th>
<th>No. of Subjects with Fatigue/ Malaise</th>
<th>No. of Subjects with Diarrhea</th>
<th>No. of Subjects with Fever</th>
<th>No. of Subjects with Cough</th>
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**Sr. No.**

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<th>CD4 count N=48</th>
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<th>After 12 Weeks</th>
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<tr>
<td>1. Median</td>
<td>312.5</td>
<td>363.5</td>
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<tr>
<td>2. 25th Percentile</td>
<td>275.5</td>
<td>294.2</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>3. 75th Percentile</td>
<td>430</td>
<td>435</td>
<td></td>
</tr>
</tbody>
</table>

**Sr. No.**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Before</th>
<th>After 12 Weeks</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Log of HIV-1, RNA (N=34)</td>
<td>5.11(0.090)</td>
<td>4.103(1.32)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>2. Median</td>
<td>206057</td>
<td>25280</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>3. 25th Percentile</td>
<td>62884</td>
<td>1665</td>
<td></td>
</tr>
<tr>
<td>4. 75th Percentile</td>
<td>508038</td>
<td>87511</td>
<td></td>
</tr>
</tbody>
</table>

**Summary of study 1 data (Mumbai, India phase III)**
India mono-therapy snapshot

• **Study II – Sion Hospital, Mumbai on 51 AIDS Patients**
  • Absolute CD4 cell count & HIV Viral Load – tested at IIH (ICMR)
  • Clinical & Physical symptoms study - at ART Center, Sion Hospital
  • **Inclusion criteria** – absolute CD4 cell count greater than 100 cells/mm$^3$ and 100% symptomatic patients at basal.
  • **Exclusion criteria** – no pre-exposure to ART
  • Mean HIV log viral load has statistically significantly dropped ($p < 0.009$)
  • Statistically significant increase in CD4 cell count ($p < 0.042$)
  • Clinical symptoms disappeared in 3 weeks of treatment in All Patients ($p<0.001$)
  • Statistically significant weekly weight gain in All Patients ($p<0.001$).
### Summary of study 2 data (Mumbai, India phase III)

<table>
<thead>
<tr>
<th>Clinical Symptoms</th>
<th>N</th>
<th>At Baseline</th>
<th>Responders At Week-2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diarrhea</td>
<td>51</td>
<td>51(100%)</td>
<td>12(23.53%)</td>
</tr>
<tr>
<td>Nausea</td>
<td>51</td>
<td>51(100%)</td>
<td>3(5.9%)</td>
</tr>
<tr>
<td>Vomiting</td>
<td>51</td>
<td>51(100%)</td>
<td>17(33.3%)</td>
</tr>
<tr>
<td>Fever</td>
<td>51</td>
<td>51(100%)</td>
<td>13(25.5%)</td>
</tr>
<tr>
<td>Cough</td>
<td>51</td>
<td>51(100%)</td>
<td>13(25.5%)</td>
</tr>
<tr>
<td>Paraesthesia</td>
<td>51</td>
<td>51(100%)</td>
<td>16(31.4%)</td>
</tr>
<tr>
<td>Disturbed Sleep</td>
<td>51</td>
<td>51(100%)</td>
<td>0(0%)</td>
</tr>
<tr>
<td>Skin Rash</td>
<td>51</td>
<td>51(100%)</td>
<td>7(13.7%)</td>
</tr>
<tr>
<td>Fatigue/Malaise</td>
<td>51</td>
<td>51(100%)</td>
<td>51(100%)</td>
</tr>
<tr>
<td>Herpes Zoster</td>
<td>51</td>
<td>51(100%)</td>
<td>18(35.3%)</td>
</tr>
<tr>
<td>Hair Changes</td>
<td>51</td>
<td>51(100%)</td>
<td>16(31.4%)</td>
</tr>
<tr>
<td>Leukoplakia</td>
<td>51</td>
<td>51(100%)</td>
<td>5(9.8%)</td>
</tr>
<tr>
<td>Oral Thrush</td>
<td>51</td>
<td>51(100%)</td>
<td>51(100%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Baseline Mean ± SD</th>
<th>Week 12 Mean ± SD</th>
<th>Difference ( Week 12- Baseline) Mean ± SD</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>CD4 Counts (cells/ cmm)</td>
<td>317.16 ± 128.67</td>
<td>344.24 ± 165.79</td>
<td>+ 27.08 ± 92.47</td>
<td>0.042</td>
</tr>
<tr>
<td>CD8 Counts (cells / cmm)</td>
<td>1037.06 ± 285.02</td>
<td>1139.75 ± 386.76</td>
<td>+102.69 ± 267.44</td>
<td>0.008</td>
</tr>
</tbody>
</table>
Indian Study: STAND ALONE MONOTHERAPY

SION HOSPITAL MUMBAI
Weight gain after treatment

Statistically significant gain in weight p<0.05 in both the Study I and Study II

Study I: average weight gain of 4.73 kg after 12 weeks of Radha 108 therapy. statistically significant (p < 0.05)
Mean weight was 50.48 kg at start of study.

Study II: average weight gain of 4.68 ± 1.9 kg after 12 weeks of Radha108 therapy. statistically significant (p < 0.05)
Mean weight was 49.21 kg at start of study and 53.89 kg after 12 wks.
Data on chronic fatigue syndrome after therapy

Statistically significant reduction in Fatigue / Malaise in both the Study I and Study II

**Study I:**
- 88 % of the total study cases had fatigue at basal.
- After 6th week onwards only one or two patients had fatigue, statistically significant.

**Study II:**
- 100 % of the total study cases had a symptom of fatigue at basal. At the end of 2nd week proportion of symptoms of fatigue had a statistically significant fall from basal.
Statistically significant reduction in Fever and Cough in both the Study I and Study II

Study 1: Fever and cough was reported by 24% and 28% of total study cases at basal respectively. After treatment at the end of 4th week proportion of patients with symptom of fever and cough had a statistically significant fall.

Study 2: 100% of the total study cases had fever and cough. after treatment from 3rd week onwards all the patients had relief from fever and cough, statistically significant.
Data on Diarrhea after Therapy

Study I: 18% of the total study cases had diarrhea at basal and after treatment from 5th week onwards all the patients had relief from diarrhea, statistically significant.

Study II: 100% of the total study cases had diarrhea at basal and after treatment from 3rd week onwards all the patients had relief from diarrhea, statistically significant.

Statistically significant reduction in Diarrhea in both the Study I and Study II
## Data on HIV viral load after Therapy

### Statistically significant reduction in HIV Viral Load

<table>
<thead>
<tr>
<th>Study 1</th>
<th>Viral Load baseline</th>
<th>Viral Load 3 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>335278.23</td>
<td>141053.42</td>
</tr>
<tr>
<td>Median</td>
<td>92457.50</td>
<td>25332.50</td>
</tr>
</tbody>
</table>

### Study 1: The mean HIV log viral load has statistically significantly dropped from 4.63 to 4.18 after 12 weeks of treatment. (p = 0.03)

Metropolis Health Services (I) PVT. LTD. Laboratory, Mumbai (NABL & CAP accredited)

<table>
<thead>
<tr>
<th>Study 2</th>
<th>Viral Load baseline</th>
<th>Viral Load 3 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>119243.49</td>
<td>38814.33</td>
</tr>
<tr>
<td>Median</td>
<td>38108.00</td>
<td>14073.00</td>
</tr>
</tbody>
</table>

### Study II: The mean HIV log viral load has statistically significantly dropped from 4.41 to 4.02 after 12 weeks of treatment. (p = 0.009)

Institute of Immuno Hematology (IIH), an ICMR Institute, KEM Hospital, Mumbai
Statistically significant increase in CD4 Cell Count

<table>
<thead>
<tr>
<th>Study 1</th>
<th>Study 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>CD4 baseline</td>
<td>CD4 3 months</td>
</tr>
<tr>
<td>Mean</td>
<td>370.63</td>
</tr>
<tr>
<td>Median</td>
<td>312.50</td>
</tr>
</tbody>
</table>

**Study I:** There was an increase in CD4 count on the average by 51 (median CD4 cell counts from 312 to 363). This is of statistical significance ($p = 0.06$).

**Study II:** There was an increase in CD4 count on the average by 27 (median CD4 cell counts from 276 to 305). This is of statistical significance ($p = 0.042$).
**Meta Analysis on 25000 Patients**

- Meta Analysis is a combined Statistical analysis of 25,000 subjects across HIV, Swine Flu, Allergy/Asthma, Rheumatoid Arthritis, Endometriosis & NCD: Chronic Fatigue Syndrome showing increase in weight gain as an Indication of overall wellness showing Safety & Efficacy of Radha108 Nano Peptide.

<table>
<thead>
<tr>
<th>Sr.No.</th>
<th>Stand Alone Receptol Therapy in Global clinical studies</th>
<th>No. of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Healthy people</td>
<td>10,000</td>
</tr>
<tr>
<td>2</td>
<td>HIV Patient in USA, Africa, India</td>
<td>5000</td>
</tr>
<tr>
<td>3</td>
<td>Swine Flu</td>
<td>5000</td>
</tr>
<tr>
<td>4</td>
<td>Other Indications like allergy, asthma, Rheumatoid Arthritis, Chronic Fatigue Syndrome, Endometriosis Study etc.</td>
<td>5000</td>
</tr>
</tbody>
</table>

Stand Alone Radha 108 Therapy in Global Clinical Studies
Efficacy & safety of on Healthy Population

CHANGES IN MEAN BODY WEIGHT AMONG STUDY CASES

<table>
<thead>
<tr>
<th>Duration (Weeks)</th>
<th>Mean weight ($\bar{x}$ ± SD) (N = 10000)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>50.30 ± 10.02</td>
</tr>
<tr>
<td>1</td>
<td>50.65 ± 10.01</td>
</tr>
<tr>
<td>2</td>
<td>51.01 ± 09.96</td>
</tr>
<tr>
<td>3</td>
<td>51.47 ± 09.94</td>
</tr>
<tr>
<td>4</td>
<td>52.00 ± 09.96</td>
</tr>
</tbody>
</table>

| Mean Diff. (Baseline – Wk1) (P value) | *0.35 ± 00.66 (0.001) |
| Mean Diff. (Baseline – Wk2) (P value) | *0.71 ± 01.24 (0.001) |
| Mean Diff. (Baseline – Wk3) (P value) | *1.17 ± 01.95 (0.001) |
| Mean Diff. (Baseline – Wk4) (P value) | *1.70 ± 02.15 (0.001) |

By ANOVA P<0.05, * Significant

- After 1 week of treatment with Radha 108 Nano Peptide, mean weight showed a significant rise of 0.7% from baseline.
- After 2 week of treatment with Radha 108 Nano Peptide, mean weight showed a significant rise of 1.4% from baseline.
- Same trend was observed till the end of 4 weeks.
### Efficacy & safety of on HIV+ patients in USA, India

#### CHANGES IN MEAN WEIGHT AMONG STUDY CASES

<table>
<thead>
<tr>
<th>Duration (Months)</th>
<th>Mean weight ((\bar{x} \pm SD)) (N = 5000)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>50.38 ± 09.89</td>
</tr>
<tr>
<td>1</td>
<td>50.72 ± 09.88</td>
</tr>
<tr>
<td>2</td>
<td>51.07 ± 09.82</td>
</tr>
<tr>
<td>3</td>
<td>51.51 ± 09.79</td>
</tr>
<tr>
<td>4</td>
<td>52.11 ± 09.75</td>
</tr>
<tr>
<td>5</td>
<td>52.54 ± 09.76</td>
</tr>
<tr>
<td>6</td>
<td>52.89 ± 09.77</td>
</tr>
</tbody>
</table>

Mean Diff. (Baseline – 1 month) (P value) = *00.34 ± 0.57 (0.001)

Mean Diff. (Baseline – 2 months) (P value) = *00.69 ± 0.91 (0.001)

Mean Diff. (Baseline – 3 months) (P value) = *01.13 ± 01.39 (0.001)

Mean Diff. (Baseline – 4 months) (P value) = *01.73 ± 01.71 (0.001)

Mean Diff. (Baseline – 5 months) (P value) = *02.16 ± 01.76 (0.001)

Mean Diff. (Baseline – 6 months) (P value) = *02.51 ± 02.07 (0.001)

By ANOVA - Significant
- After 1 month of treatment, mean weight showed a significant rise of 0.7% from baseline.
- After 2 months of treatment, mean weight showed a significant rise of 1.4% from baseline, similar trend was observed till the end of 6 Months.
Efficacy & safety of on Swine flu

CHANGES IN MEAN WEIGHT AMONG STUDY CASES

<table>
<thead>
<tr>
<th>Duration (Weeks)</th>
<th>Mean weight (\bar{X} \pm SD)) (N = 5000)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>51.07 ± 9.82</td>
</tr>
<tr>
<td>2</td>
<td>*51.51 ± 9.79</td>
</tr>
<tr>
<td>3</td>
<td>*52.11 ± 9.75</td>
</tr>
<tr>
<td>4</td>
<td>*52.53 ± 9.76</td>
</tr>
</tbody>
</table>

By ANOVA  P < 0.05, * Significant

• At the end of 2nd week, mean weight showed significant change from baseline i.e. mean change of 1.44 kg.
• At the end of 4th week mean weight increased significantly that is 1.46 kg from baseline.
Efficacy & safety of other indications like allergy, asthma, arthritis, diarrhea, fever, fatigue-malaise, anemia, endometriosis

<table>
<thead>
<tr>
<th>Duration (Weeks)</th>
<th>Mean weight ((\bar{X} \pm SD)) (N = 5000)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>50.41 ± 10.03</td>
</tr>
<tr>
<td>1</td>
<td>50.76 ± 10.01</td>
</tr>
<tr>
<td>2</td>
<td>51.11 ± 09.94</td>
</tr>
<tr>
<td>3</td>
<td>51.60 ± 09.91</td>
</tr>
<tr>
<td>4</td>
<td>52.15 ± 09.91</td>
</tr>
</tbody>
</table>

Mean Diff. (Baseline – Wk1) (P value) *00.35 ± 00.57 (0.001)
Mean Diff. (Baseline – Wk2) (P value) *00.70 ± 01.05 (0.001)
Mean Diff. (Baseline – Wk3) (P value) *01.19 ± 01.77 (0.001)
Mean Diff. (Baseline – Wk4) (P value) *01.74 ± 01.95 (0.001)

By ANOVA

* Significant

• After 1 week of treatment, mean weight showed a significant rise of 0.7% from baseline.
• After 2 week of treatment, mean weight showed a significant rise of 1.4% from baseline, similar trend was observed till the end of 4 weeks.
Conclusion by Dr. Kailash Ghandewar, Biostatistician

• This observation study reveals that after Radha108 Nano Peptide oral spray therapy provide significant efficacy & safety in all groups of patients with increased QoL with weight increase in chronic patients.

• Hence these results indicate that Radha108 Nano Peptide oral spray is very effective and safe among cases with indications like HIV, Swine flu, Allergy, Asthma, Arthritis, Diarrhea, Fever, Fatigue-Malaise, Anemia, Endometriosis etc. showing increase in weight gain as a parameter for overall wellness and improved quality of life, even in healthy population.
Team

• Founder CEO
  – Dr. Pawan Saharan, MS, PhD (JNU, WVU)
    • AMP (ASCI in tie up with Harvard business school)
    • Best US graduate student award by AAAS with fellowship at Stanford University
    • Email id: biomix108@gmail.com / drpawan@biomix.in

• Research Director
  – Dr. C. R. Bhatia, Ph.D., Post Doc. (BNL, NY, US)
    • DBT Secretary Govt. of India & Director: BARC, Advisor: IAEC, Vienna
    • Email id: bhatia@gmail.com

• Project Director
  – Amitabh Thakore, B. Tech., MBA (IIM- Ahmadabad)
    • Email id: agthakore@yahoo.com

• Medical Directors
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  • Oncologist & President - Asian Cancer Society
  • Padamvibhushan awardee by President of India
  • Email id: shadvani2000@yahoo.com

• Dr. Sushil Indoria, MD
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• Dr. Sandhya Saharan, MD, DGO, Gynecologist and IVF specialist.
  Email id: drsandhyasaharan@hotmail.com

• Dr. Ali Irani - President API, Ortho & Sports Medicine
  Former Physiotherapist of Indian Cricket Team (12 years)
  Email Id: dralirani@gmail.com

Eminent scientists, engineers, doctors from World over with over 300 years of collective experience