Indian solutions to global health problems via Globally Patented RECEPTOL, Lab & Virtual specialty Hospital on Chip driven by Artificial Intelligence based knowledge acquisition Tools (AIKAT)

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After years of research, we have successfully isolated Nano peptides from bovine colostrum and conducted global clinical studies on 25,301 subjects suffering from HIV, Swine flu & other communicable/Immune disease via innovative oral spray drug delivery system that can provide solution to majority of health problems related to Poor Immunity.

What is NID/Receptol®

NID Active Pharmaceutical Ingredients (API) consist of Patented Nano - Informational Peptides extracted from mammalian/bovine colostrum via Ultra Nano filtration Technology having Radha 108 sequence id 1-8 & Proline Rich Poly Peptides

PRPs & NID 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.
Global Health Challenges — Millions suffer from Cancer, Auto Immune : RA, Lupus, IBS, HIV, TB.

RECEPTOL helps high unmet needs for above disease due to poor immunity.

Source: IPSOS & Times studies
MILLIONS MORE

SWINE FLU, CHRONIC VIREMIA, HUMAN PAPILLOMA VIRUS, Fungal Infections, Tuberculosis, Hypertension, Lupus (Discoid and Systemic), Oral Thrush, Autism, Premenstrual Syndrome, Rheumatoid & Osteo Arthritis, Spinal Muscular Atrophy

& C HERPES SIMPLEX I&II, ACUTE & CHRONIC VIRAL INFECTIONS, DENGUE FEVER, HUMAN PAPILLOMA VIRUS, GASTROINTESTINAL DIARRHEA, ALLERGIES & ASTHMA, EBOLA, SARS, RABIES, ROTA VIRAL DIARRHEA, HUMAN PAPILLOMA VIRUS, PHARYNGITIS (VIRAL), ALLERGIES & ASTHMA, EBOLA, SARS, RABIES, ROTA VIRAL DIARRHEA, HUMAN PAPILLOMA VIRUS, PHARYNGITIS (VIRAL), ALLERGIES & ASTHMA, EBOLA, SARS, RABIES, ROTA VIRAL DIARRHEA, HUMAN PAPILLOMA VIRUS, PHARYNGITIS (VIRAL), ALLERGIES & ASTHMA, EBOLA, SARS, RABIES, ROTA VIRAL DIARRHEA, HUMAN PAPILLOMA VIRUS, PHARYNGITIS (VIRAL), ALLERGIES & ASTHMA, EBOLA, SARS, RABIES, ROTA VIRAL DIARRHEA, HUMAN PAPILLOMA VIRUS, PHARYNGITIS (VIRAL), ALLERGIES & ASTHMA, EBOLA, SARS, RABIES, ROTA VIRAL DIARRHEA, HUMAN PAPILLOMA VIRUS, PHARYNGITIS (VIRAL), ALLERGIES & ASTHMA, EBOLA, SARS, RABIES, ROTA VIRAL DIARRHEA, HUMAN PAPILLOMA VIRUS, PHARYNGITIS (VIRAL), ALLERGIES & ASTHMA, EBOLA, SARS, RABIES, ROTA VIRAL DIARRHEA, HUMAN PAPILLOMA VIRUS, PHARYNGITIS (VIRAL), ALLERGIES & ASTHMA, EBOLA, SARS, RABIES, ROTA VIRAL DIARRHEA, HUMAN PAPILLOMA VIRUS, PHARYNGITIS (VIRAL), ALLERGIES & ASTHMA, EBOLA, SARS, RABIES, ROTA VIRAL DIARRHEA, HUMAN PAPILLOMA V
What if there was a way to treat all immunity disorders via RECEPTOL, The New Immunity drug that not only builds body’s own immune system but also prevents Recurrent infections in Cancer, Auto immune & AIDS patients
Innovations at Biomix to provide health for all via

Mission:
Develop & manufacture affordable Nano-Biotech orphan drugs & diagnostics for prevention & treatment of life threatening disease globally

Vision:
Health for all
Indian solutions to global health problems via globally patented RECEPTOL, Lab & Virtual specialty Hospital on Chip driven by Artificial Intelligence based knowledge acquisition Tools
Creating Paradigm shift via innovations in Pharma, Healthcare & Diagnostics

**Drug Discovery**
- Patents provide entry barrier for global Pharma MNCs in therapeutic areas of Oncology, Asthma, Auto immune: RA etc, Infectious disease, CNS & HIV Orphan drugs

**Lab on Chip**
- Mass screening for Cancer, Auto Immune, Viral Pandemic, biological & nuclear warfare

**Hospital on Chip**
- Taking health care to bottom of pyramid via telemedicine and tele diagnostic. Global hub for Pharma CRO & Drug discovery via AI based Virtual Hospiatl

**Granted Global PATENTS**
## Entry barrier via Global product patents

<table>
<thead>
<tr>
<th>Jurisdiction</th>
<th>Application No./ Date</th>
<th>Title</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<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 DT. 27.06.2011</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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<tr>
<td>SOUTH AFRICA</td>
<td>2011/4687 DT. 24.06.2011</td>
<td>Mammalian Colostrum Derived Nanopeptides For Broad spectrum Viral And Recurrent Infections With A Method Of Isolation Thereof</td>
<td>GRANTED ( PATENT # 2011/04687)</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>
<td>GRANTED (PATENT # 172793)</td>
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<td>INDIA</td>
<td>1353/MUM/08 DT. 27/06/2008</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>EUROPE</td>
<td>EP 09827010.1 DT. 30.06.2011</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>CANADA</td>
<td>2478449 DT. 29.12.2009</td>
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<tr>
<td>PCT</td>
<td>PCT/IN09/749 DT. 29.12.2009</td>
<td>Mammalian Colostrum Derived Nanopeptides For Broad spectrum Viral And Recurrent Infections With A Method Of Isolation Thereof</td>
<td>GRANTED</td>
</tr>
<tr>
<td>Hospital on chip</td>
<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>Lab on chip</td>
<td>PCT/IN2010/000424 DT. 18.06.2010</td>
<td>An Apparatus and Method For Detecting Biological State in Sample by Using Bio Marker ERS</td>
<td>Granted (PARENT #:WO2011/158246A1)</td>
</tr>
</tbody>
</table>
Business Opportunity through breakthrough innovation

• RECEPTOL 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 RECEPTOL is its clinically proven Mode of Action via global studies.

• Granted product patent in North America, Europe and Asia PAC.

• Innovation led RECEPTOL has potential to be a blockbuster drug as illustrated by a series of globally accredited market research conducted by IPSOS US & IRMA/Indian Institute of Management indicating RECEPTOL as Doctors First Choice based on its USP, convenience of use with no side effects.

• Clinically proven indications of RECEPTOL include Cancer, Asthma, Allergy, HIV, Auto Immune disorder like RA, Lupus & other that accounts for expenditure of over $500 billion in US alone. (Source- www.cdc.gov).

• 21st Century Innovation- Creating a Paradigm shift in healthcare Life Sciences Drug Innovation.
Phases of discovery NID: RECEPTOL
16 years to put RECEPTOL in Market *

Phases and Time of drug discovery

- **Discovery** (2-10 yrs)
  - 0 years
  - Pre-clinical Testing
    - Laboratory and Animal Testing
- Phase I
  - 2-4 years
  - 20-80 Healthy volunteers
  - Used to determine
- Phase II
  - 6-8 years
  - 100-300 Patient volunteers
  - Used to look for Efficacy
- Phase III
  - 10-12 years
  - 1000-5000 Patient volunteers
  - Used to monitor adverse reactions to long-term use
  - Additional Post-marketing testing
- FDA Review/Approval
  - 14-16 years

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
RECEPTOL has completed Phase III trials per slide above

and is in the Market*

Current global marketing channel : B2D
Approved by select regulatory agencies

Work in Progress for New Drug Approval by US FDA, EMA, TGA.

Key focus :

Oncology, Auto Immune, ID: AIDS, Immunology: Asthma
Medical confirmation of NID for globally patented 58 indications
(US Patent # 9,249,188 PCC# IN2009/000749 WO2010/079511)

- 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
- 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
- Pharangitis
- Porphyria
- Raynaud’s phenomenon
- Acute Viral Infection
NID / RECEPTOL the differentiator

Checkpoint inhibitors
- Adoptive cell transfer
- Monoclonal antibodies
- Treatment vaccines

Cytokines
- Bacillus Calmette-Guérin

Act directly against the cancer

Enhance the body’s immune response to fight cancer

RECEPTOL Acts when All fail

Patent No – US 9,249,188 B2

Builds bodies own immune system.
Stimulates
Tumor Necrosis Factors
NK cells
Interleukin-1 to IL-11,
Interferon-α, INF-γ.
“Cancer cells retain parts of healthy cells that can prevent damage by the immune system, resulting in a condition of immune gridlock. Cancer immunology zeroes in on this dynamic of competing signals and drives the immune response toward recognising cancer as dangerous” Glenn Dranoff, Global Head of Immuno-oncology, at the Novartis Institutes for BioMedical Research.

NID helps strengthen the Immune System to be able to perform and destroy tumour cells efficiently.

NID helps release Tumour Necrosis Factors and help build the immune system of the body thereby preventing recurrent infections.

It is a perfect fit for Immune Oncology as recommended by Oncologists world over including Dr Suresh Advani Medical Oncologist and Founder Tata Memorial Cancer Hospital, Mumbai and President Asian Cancer Society.
Current invention related to mammalian colostrum that provides answers to high unmet needs due to poor immunity in Cancer, AIDS, Swine Flu, Arthritis and other auto-immune disorders.


The present invention relates to nanopeptides isolated from mammalian colostrums with vaccine like antiviral and immunomodulator activity via building body’s own immune system and attachment inhibition on the cell surface receptors.
PRPs get absorbed in the blood through buccal mucosa and crosses BBB

- 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.

Mode of action: Science behind MoA

- 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

- RECEPTOL get absorbed in the blood through buccal mucosa and crosses BBB.
- Stimulates maturation of immature thymocytes into either helper or suppressor T cells.
- Stimulates secretion of Tumor Necrosis Factor & cytokines IL-1 to IL-11, INF-α, INF-γ.
- 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 spectrum entry of viruses.
- RECEPTOL also functions as a molecular signalling device which works through receptors on target cell surfaces.
Mode of action – 5 times increased Immuno Response by RECEPTOL

Cellular Immunity

Antigen Presentation

Macrophage

Displays copy of antigen

Helper T-Cell

Active Cytotoxic T-Cell

Active B - Cell

Plasma Cell

Memory B-Cell

Antibodies

Deactivates Antigens

Kills Infected & Cancer Cells

Memory T-Cell
Innovative, Affordable & Globally Patented

Builds bodies own immune system.

Stimulates Tumor Necrosis Factors NK cells, Interleukin-1 to IL-11, Interferon-α, INF–γ.

Easy to administer

No side effects

Can be consumed by all.. has no age or sex barrier, drug , drug interaction
Manufacturing Facility, Tox Study & Product Range

FDA Approved Manufacturing facility

➢ GMP Facility
  • State of the art, nano biotech facility granted by TUV Nord Germany since 2012.
  • Extraction of API, PRP is done by Merck Millipore Molecular Exclusion Ultra filtration columns

Toxicology study at FDA Approved National Institute of Nutrition (NIN), Hyderabad
  • Acute (14 Days) Sub-chronic (60 Days-45 Days treatment 15 days recovery) repeated dose through oral route in sprague Dawley rats.

➢ Acute Tox Study
  • 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.

➢ Sub Acute Tox Report
  • No significant difference in physical & 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.

NID Product Range:
Oral spray, Oral gargle, Capsules & Tablets & Powder
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 Ultrafiltration columns of 100 to 10 kDA at cGMP facility shown below.
Product range

Oral spray
Oral liquid
Capsules & Tablets
Powder
## Pharmaceutical Data on Formulation

### Dosage and Administration

| 4 Sprays of 0.75ml metered dose (3ml), two each on each side of inner cheek 4 times daily |

### Route of Absorption & Distribution

- API (PRPs) absorbed through the buccal mucosa
- Crosses blood brain barrier due to low mol. wt below 2kDa.
- Distributed all over the body through the blood streams.

### Indications

- Treatment of HIV therapy & for associated recurrent infections.
- Immunity enhancer for immune disorders like Asthma, Rheumatoid Arthritis & others

### Contraindications

- Proven to be safe in acute as well as chronic use.
- No incompatibility along with any other medication.
- No minor or serious contraindication reported.

### Warnings & Precautions

None, Since its over dose does not harm anyone even neonates

### Adverse Effects

No adverse effects observed.

### Storage

Keep in cool & dry place.
Keep under refrigeration once the bottle is opened and consume within 30 days after opening.
Market Analysis suggests 1 out of 3 Americans can be treated with NID: IMS US Data Poised to be $10+ billion block bUSTER drug globally

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

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

More than $100Billion is spent by sufferers on drugs every year!
Respiratory Disorder - Asthma

Asthma may affect as many as 334 million people.*

25MM alone in US

EXPECTED TO GROW BY MORE THAN 100MM BY 2025!

Allergies & Asthma

30% adults and 40% of children worldwide are affected by allergies!

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

Infectious Diseases - HIV is a major threat affecting ~40m people worldwide and the sales for HIV drugs are expected to increase steadily.

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

Forecast of HIV drug sales ($Billion)

Source: www.aids.gov
• Market Research conducted in India, UK, USA.

• Sample Size: 800 respondents.

• **Target population:** Households of SEC A in society consuming HFDs and FMCG products.

• **Product:** Radha 108 powder additive & Oral Spray in two concepts.
1. Concept P (50% lesser infection) - A trusted nourishment and dependable immune power of cow colostrum.

• Reduces common infections like those of stomach, nose and throat by up to 50% lesser infection using Radha 108 powder.

• ITP index 100 and ITP score 40%.

- ITP index (Concept Performance vs Success Norm)
- ITP score (Maximum trial potential in % within target)
2. Concept Q (108 immunity superchargers) : Packed with 108 immunity superchargers.

• Builds protection against all Pathogen types- Viruses, bacteria and fungi.

• ITP index 97 and ITP score 39%.
Respondents agreed that both the formulations of the product are much better than their existing products in use.
IPSOS studied Customer’s perceptions towards two concepts of the immune powder (as infection reducer & immunity super charger) and their willingness to buy HFDs (Health Food Drinks), and FMCG products with Radha 108 as an additive. Results were as follows:

The ITP index was around 97-100%, while the ITP score was around 39-40 in both the above mentioned concepts.

- Our product met mandate from 800 subjects who were willing to use our product as standalone / additive to various immunity building foods.
- 80% of the respondents surveyed were ready to pay a higher price for our product as compared to the all current brands.
**RECEPTOL as Vaccine types and distribution**

Vaccine Market Growth

- **Vaccine Market Share 2014 (US$ Approximate Value)**
  - UMICS: 23%
  - LMICs: 8%
  - HICs: 65%
  - LICs: 4%

**Concerns:**
- Oligopoly, limited supply for DC and Shortage risks
- Upstream factors: Technology transfer and IPRs, R&D for most needed vaccines, DC/VM R&D capacity
- New vaccine costs and prices
- Financial sustainability? Govt responsibilities role
- Future of international initiatives
- Future of Emerging Manufacturers
- Impact of the financial crisis?

50% of the vaccines bought (volume wise) signify only 5% of value overall.

*Source: WHO*
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
Allergies

Reporting Patients : 24
Duration of Treatment : 6 months

More than half the respondents experienced complete resolution of symptoms!

Rheumatoid Arthritis

Reporting Patients : 63
Duration of Treatment : 6 months

56% of patients found the product to be highly effective!
Global Studies on Immunity Disorders

**Chronic Fatigue Syndrome**
- Reporting Patients: 108
- Duration of Treatment: 6 months

- 70% of patients received significant benefits!

**Endometriosis**
- Reporting Patients: 106
- Duration of Treatment: 6 months

- Similarly for Endometriosis, complete resolution in most cases!
### CHANGES IN MEAN BODY WEIGHT AMONG STUDY CASES

<table>
<thead>
<tr>
<th>Duration (Weeks)</th>
<th>Mean weight $\bar{X}$ (± SD)</th>
<th>(N = 10000)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>50.30 ± 10.02</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>50.65 ± 10.01</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>51.01 ± 09.96</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>51.47 ± 09.94</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>52.00 ± 09.96</td>
<td></td>
</tr>
<tr>
<td>Mean Diff. (Baseline – Wk1) (P value)</td>
<td>*0.35 ± 0.66</td>
<td>(0.001)</td>
</tr>
<tr>
<td>Mean Diff. (Baseline – Wk2) (P value)</td>
<td>*0.71 ± 0.24</td>
<td>(0.001)</td>
</tr>
<tr>
<td>Mean Diff. (Baseline – Wk3) (P value)</td>
<td>*0.17 ± 0.95</td>
<td>(0.001)</td>
</tr>
<tr>
<td>Mean Diff. (Baseline – Wk4) (P value)</td>
<td>*0.70 ± 0.15</td>
<td>(0.001)</td>
</tr>
</tbody>
</table>

*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>
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<tr>
<td>2</td>
<td>51.07 ± 09.82</td>
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<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 ± 00.57 (0.001)
Mean Diff. (Baseline – 2 months) (P value) \*00.69 ± 00.91 (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 NID 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>
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</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 2\(^{nd}\) week, mean weight showed significant change from baseline i.e. mean change of 1.44 kg.
- At the end of 4\(^{th}\) 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 (X ± 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>
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<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.
Safety & Efficacy Studies on 301 HIV+ Subjects


- **Study I**: 50 HIV Positive Patients at Tertiary Care LTMG Hospital Sion, Mumbai
  (Clinical trial registry No. : CTRI-2012-08-002931)

- **Study II**: 51 HIV Positive Patients at Tertiary Care LTMG Hospital, Sion, Mumbai
  (Clinical Trial registry No. : CTRI-2012-09-002959)

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

*The study was fully controlled, conducted and sponsored, by Govt. of India with Indian Council of Medical Research proposed Protocols.*
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.

**Acute toxicity**

<table>
<thead>
<tr>
<th>RESULTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>No pre-terminal deaths after administration of 50 times of intended therapeutic dose through oral route</td>
</tr>
<tr>
<td>All rats were found to be active and with normal body weight.</td>
</tr>
<tr>
<td>No Acute toxicity found.</td>
</tr>
</tbody>
</table>
NIN Study : Sub acute data

No mortality was observed & product is safe

<table>
<thead>
<tr>
<th>1.</th>
<th>No. of Rats used</th>
<th>48</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.</td>
<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>
</tr>
<tr>
<td>3.</td>
<td>Days of trial</td>
<td>45</td>
</tr>
<tr>
<td>4.</td>
<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
Summary of Mumbai, India phase III study on AIDS patients

- Tertiary care, Sion Hospital, Mumbai 51 AIDS Patients Study
  - 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/mm³ 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).
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 Radha108 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.
Data on fever & cough after Therapy

Statistically significant reduction in Fever and Cough in both the Study I and Study II

- Study I: 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 II: 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.
Statistically significant reduction in Diarrhea in both the Study I and Study II

**Study 1**

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 2**

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.
## Data on HIV viral load after Therapy

### Statistically significant reduction in HIV Viral Load

<table>
<thead>
<tr>
<th>Study 1</th>
<th>Study 2</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Viral Load baseline</strong></td>
<td><strong>Viral Load baseline</strong></td>
</tr>
<tr>
<td>Mean</td>
<td>335278.23</td>
</tr>
<tr>
<td>Median</td>
<td>92457.50</td>
</tr>
</tbody>
</table>

**Study I:** 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)

**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
## Data on CD4 Cell Count after therapy

### Statistically significant increase in CD4 Cell Count

<table>
<thead>
<tr>
<th>Study 1</th>
<th>Study 2</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CD4 baseline</strong></td>
<td><strong>CD4 baseline</strong></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 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 increase in CD4 count on the average by 27 (median CD4 cell counts from 276 to 305). This is of statistical significance ($p = 0.042$)
### Summary of Mumbai, India phase III study on AIDS patients

<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(100%)</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>0(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>0(100%)</td>
</tr>
<tr>
<td>Oral Thrush</td>
<td>51</td>
<td>51(100%)</td>
<td>0(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>
# SUMMARY - GLOBAL SAFETY & EFFICACY STUDY DATA ON AIDS SUBJECTS

<table>
<thead>
<tr>
<th>KEY DIMENSIONS</th>
<th>PHASE I, II &amp; III INTERNATIONAL TRIALS</th>
<th>INDIA PHASE III STUDY 1</th>
<th>INDIA PHASE III STUDY 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase</td>
<td>Phase I - HIV trial, US</td>
<td>Phase III validation trial by GOI on HIV patients, Standalone monotherapy</td>
<td>Phase III validation trial by GOI on HIV patients, Standalone monotherapy</td>
</tr>
<tr>
<td></td>
<td>Phase II - HIV trial, Nairobi, Kenya</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Phase III - HIV trial, Rwanda</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No. of patients</td>
<td>Phase I - 12 cohorts</td>
<td>50 HIV seropositive patients</td>
<td>51 HIV seropositive patients</td>
</tr>
<tr>
<td></td>
<td>Phase II - 30 cohorts</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Phase III - 60 cohorts</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Duration</td>
<td>30 to 365 days</td>
<td>180 days</td>
<td>180 days</td>
</tr>
<tr>
<td>Compliance</td>
<td>Very good</td>
<td>Very good</td>
<td>Very good</td>
</tr>
<tr>
<td>Side effect</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Weight gain</td>
<td>6 lbs average gain</td>
<td>4.73 kg per patient, p&lt;0.05</td>
<td>4.68 ± 1.9 kg per patient, p&lt;0.001</td>
</tr>
<tr>
<td>Clinical symptoms</td>
<td>90 days relief from symptoms</td>
<td>Improved within 3 weeks from starting of therapy</td>
<td>Improved within 3 weeks from starting of therapy</td>
</tr>
<tr>
<td>CD4 cell count</td>
<td>Phase II: Average by 31</td>
<td>Average by 51, median CD4 cell count from 312 to 363 (p = 0.06)</td>
<td>On an average by 27 (p = 0.042)</td>
</tr>
<tr>
<td>HIV Viral load</td>
<td>Phase II: Mean HIV log viral load from 4.6 to 2.5</td>
<td>Mean HIV log viral load from 4.63 to 4.18 (p = 0.001)</td>
<td>Mean HIV log viral load from 4.41 to 4.02 (p = 0.009)</td>
</tr>
</tbody>
</table>
Treatment of HIV with Biomix NID per Global Clinical Trial Results

67% Patients Viral load decreased as per controlled clinical trial data conducted by ICMR at Tertiary Care Sion Hospital, Mumbai

20% Virus free in 3 months time

8 year followup - Disease free survival
Founders, Directors:

- 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

- Business Development Executive
  - Hemangi Saharan, Bachelor of Management, HR College of Commerce and Economics, Mumbai University
    - Email ID - hemangisasaharan@gmail.com

- Medical Directors
  - Dr. S.H. Advani, MD, FICP, FNAMS
  - Oncologist & President - Asian Cancer Society
  - Padamvibhusan awardee by President of India
  - Email id: shadvani2000@yahoo.com

- Dr. Sushil Indoria, MD
  - Medical Director Life care Hospital, Thane
  - Email id: Sushilindoria@yahoo.in

- 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

Team:

- Eminent scientists, engineers, doctors from all over the world with over 300 years of collective experience