

## STUDY REPORT

ON

AN OBSERVATIONAL STUDY OF HIV POSITIVE  
PATIENTS TO DETERMINE THE EFFICACY & SAFETY  
OF RECEPTOL<sup>®</sup> ORAL SPRAY USED AS A STAND-  
ALONE MONO THERAPY

PROTOCOL NO: BNL0001

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## 1. INTRODUCTION

The advent of HIV/ AIDS has graphically demonstrated that our knowledge of viruses and how to treat viral infections was not adequate. According to the joint United Nations program on HIV / AIDS and World Health Organization (WHO), some 25 million people have died of HIV / AIDS in the past 25 years and an estimated 38.6 million are infected with the virus, making it one of the most lethal epidemics in the history of mankind.

Currently five classes of drugs are approved by US FDA for treatment of HIV infected patients. These five classes are Nucleoside Reverse Transcriptase Inhibitor (NRTI/NtRTI), Non-Nucleoside Reverse Transcriptase Inhibitor (NNRTI), Protease Inhibitor (PI), entry inhibitors and Integrase Inhibitor. Anti Retroviral Therapy (ART) regimen is complicated due to the high cost of treatment, poor compliance, pill burden, peculiar storage requirements, drug-drug interactions, co-morbidities like tuberculosis, liver disease, cardiovascular complications and importantly treatment failure due to resistance to drugs acquired by the virus through mutation. All the antiviral drugs developed so far to fight HIV infection, exhibit serious side effects like nausea, Diarrhoea, Vomiting, Pancreatitis, Anemia, Peripheral Neuropathy, Lactic Acidosis, Dyslipidemia and others. There is an imminent need for additional lines of nutritional defense against

the potential ravages of both infectious and non-infectious disease processes which currently plague people all around the world, from all walks of life, at all stages in the life cycle which promise to incur irreversible harm to human health and well-being.

## 2. OBJECTIVE

### Primary Objective:

To evaluate the efficacy of RECEPTOL<sup>®</sup> Oral spray in HIV/AIDS patients in terms of weight gain as weight gain is the indication of overall wellness.

## 3. METHODOLOGY AND STUDY PLAN

a) **Study Design:** Observational study

b) **Population:** 5000 cases

c) **Methods:** This trial was a 6-Month, Stand-Alone, single arm, open label study to evaluate the Efficacy and Safety/Tolerability of RECEPTOL<sup>®</sup> oral spray in HIV/ AIDS patients in terms of weight gain. The potential subjects were screened after obtaining a written informed consent from (As per Schedule Y) the subject or LAR (Legally Acceptable Representative)/impartial witness. The study was designed to investigate efficacy of RECEPTOL<sup>®</sup> therapy in terms of change in body weight. The study subjects received RECEPTOL<sup>®</sup> as a spray self-administered by patients on either side of the oral buccal surface 4 times daily at every 4 hour's interval. Each administration consist a metered dose of 0.75 ml spray directly on the buccal mucosa.

Body weight of subjects was monitored at every visit to determine the effect of RECEPTOL<sup>®</sup> therapy on change in the weight.

#### 4. RESULT

**Table 1:**

#### CHANGES IN MEAN WEIGHT AMONG STUDY CASES

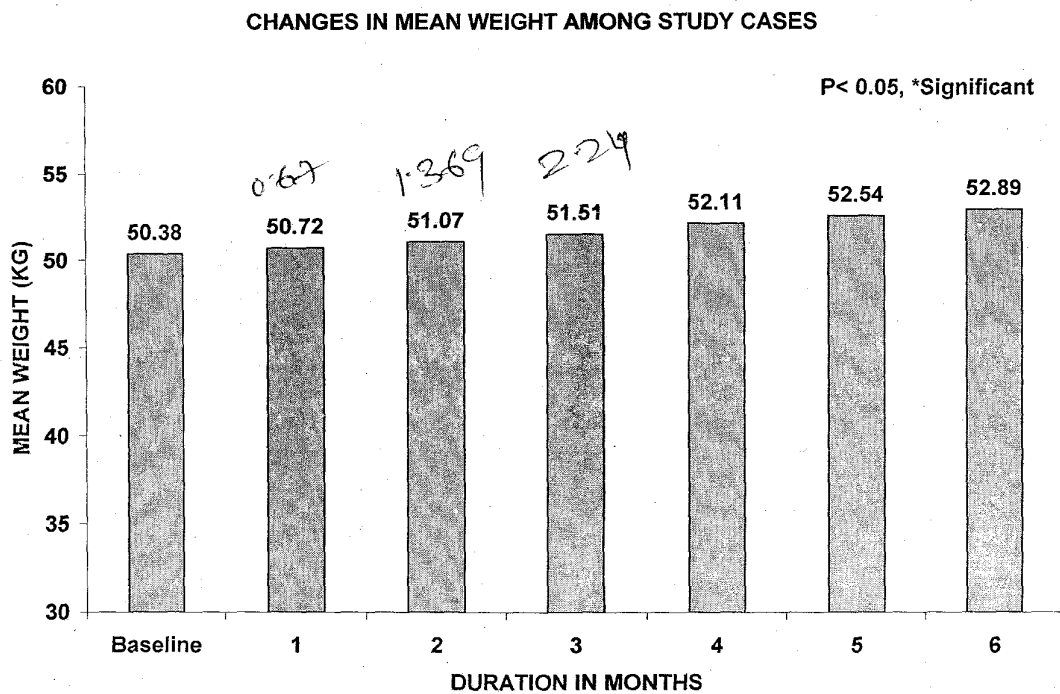
<b>Duration (Months)</b>	<b>Mean weight (<math>\bar{X} \pm SD</math>) (N = 5000)</b>
Baseline	50.38 $\pm$ 09.89
1	50.72 $\pm$ 09.88
2	51.07 $\pm$ 09.82
3	51.51 $\pm$ 09.79
4	52.11 $\pm$ 09.75
5	52.54 $\pm$ 09.76
6	52.89 $\pm$ 09.77
Mean Diff. (Baseline – 1 month) (P value)	*00.34 $\pm$ 00.57 (0.001)
Mean Diff. (Baseline – 2 months) (P value)	*00.69 $\pm$ 00.91 (0.001)
Mean Diff. (Baseline – 3 months) (P value)	*01.13 $\pm$ 01.39 (0.001)
Mean Diff. (Baseline – 4 months) (P value)	*01.73 $\pm$ 01.71 (0.001)
Mean Diff. (Baseline – 5 months) (P value)	*02.16 $\pm$ 01.76 (0.001)
Mean Diff. (Baseline – 6 months) (P value)	*02.51 $\pm$ 02.07 (0.001)

By ANOVA

\* Significant

- As per this data mean weight at baseline was **50.38kg**.
- 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. Same trend was observed till the end of 6 months.

- **Figure1**



According to above figure, mean weight increased after treatment of Receptol from baseline upto 6 months.

Table 2:

**CHANGES IN MEAN WEIGHT AS PER GENDER**

Duration (Months)	Mean weight ( $\bar{X} \pm SD$ )		P Value
	Male (N = 2745)	Female (N = 2255)	
Baseline	50.54 $\pm$ 09.90	50.18 $\pm$ 09.88	0.201 NS
1	50.88 $\pm$ 09.89	50.53 $\pm$ 09.87	
2	51.23 $\pm$ 09.82	50.87 $\pm$ 09.81	
3	51.69 $\pm$ 09.80	51.30 $\pm$ 09.77	
4	52.28 $\pm$ 09.76	51.90 $\pm$ 09.74	
5	52.70 $\pm$ 09.77	52.33 $\pm$ 09.75	
6	53.03 $\pm$ 09.79	52.71 $\pm$ 09.75	
Mean Diff. (Baseline – 1 month) (P value)	*00.34 $\pm$ 00.62 (0.001)	*00.35 $\pm$ 00.49 (0.001)	0.524 NS
Mean Diff. (Baseline – 2 months) (P value)	*00.69 $\pm$ 00.85 (0.001)	*00.69 $\pm$ 00.98 (0.001)	0.703 NS
Mean Diff. (Baseline – 3 months) (P value)	*01.15 $\pm$ 01.10 (0.001)	*01.12 $\pm$ 01.67 (0.001)	0.625 NS
Mean Diff. (Baseline – 4 months) (P value)	*01.74 $\pm$ 01.56 (0.001)	*01.72 $\pm$ 01.88 (0.001)	0.686 NS
Mean Diff. (Baseline – 5 months) (P value)	*02.16 $\pm$ 01.62 (0.001)	*02.15 $\pm$ 01.93 (0.001)	0.844 NS
Mean Diff. (Baseline – 6 months) (P value)	*02.49 $\pm$ 02.17 (0.001)	*02.53 $\pm$ 01.96 (0.001)	0.494 NS

By ANOVA

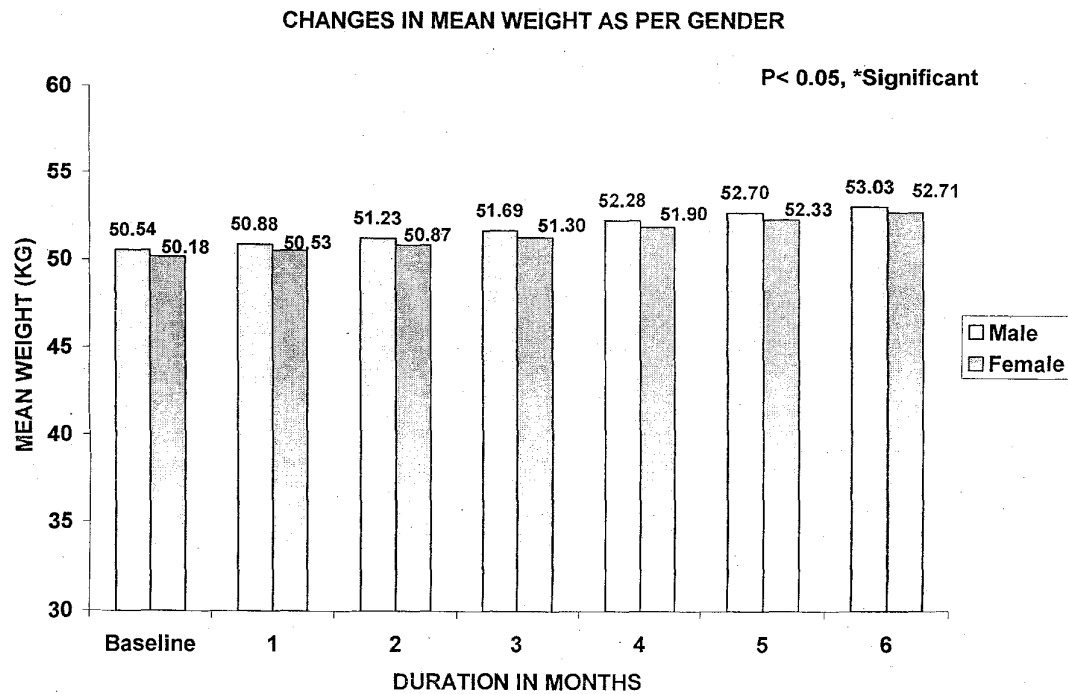
\* Significant NS = Not Significant

- This analysis indicates that mean weight at baseline was **50.54kg** in males which was comparable to **50.18kg** in females and the difference was not significant.
- After 1 month of treatment, mean weight showed a significant increase of **0.7%** among male and female each from baseline. If compared the

increase was same among both the Group and difference was not significant.

- Same trend was observed till the end of 6 months.

**Figure 2:**



There was change in weight among male and female from baseline to end of treatment.



## 5. CONCLUSION:

The results of this observational study reveals that after RECEPTOL oral spray therapy, mean weight of study cases showed significant increase from baseline to end of treatment and that change were observed in both the genders.

Hence we can conclude that, RECEPTOL oral spray is very effective and safe in HIV/AIDS cases to increase the weight and overall wellness.