# CLINICAL STUDY REPORT

## AN OPEN LABELED CLINICAL TRIAL TO EVALUATE EFFICACY AND SAFETY OF DIACARE IN PATIENTS WITH TYPE 2 DIABETES MELLITUS

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| **Protocol No.** | **:** | ICBio/CR/ AK/0823/17 |
| **Version** | **:** | 01, Dated 25/09/2012 |
| **Investigational product** | **:** | Diacare |
| **Indication** | **:** | Type II Diabetes Mellitus |

**Name & Address of sponsor** **:** **Admark Herbals Limited**
Jetpur Road, N.H.No.8-B
Dhoraji-360410
INDIA

**Name & Address of CRO** **:** **ICBio Clinical Research Pvt. Ltd.**
# 16, ICBio Tower, Yelahanka Main Road,
Chikkabetahalli, Vidyaranyapura
Bangalore - 560 097, INDIA

**STUDY SUMMARY**

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| **Name of sponsor** | Admark Herbals Limited |
| **Name of IP** | Diacare |
| **Name of CRO** | ICBio Clinical Research Pvt. Ltd. |
| **Date of report** | 17-JUL-2013 |
| **Title of study** | An open labeled clinical trial to evaluate efficacy and safety of Diacare in patients with type 2 diabetes mellitus |
| **Investigators** | Dr. Divya Dutt , MBBS,MD Medicine, FDE Endocrinology<br>Dr. Gurudev S., MBBS, DNB<br>Dr. Kiran Kumar B., BAMS |
| **Study Centres** | 1. Gayatri Poly Clinic, 5th Main Road,<br>Near RT Nagar Post, Ganga Nagar,<br>Bangalore – 560032<br>Mail ID: divyadutt39@ymail.com<br>Mobile No: 9886262667<br>2. Guru Clinic, Opp to BBMP Office,<br>Yelahanka Old Town<br>Bangalore-560064<br>Mail ID: drsgrdv1980@rediffmail.com<br>Mobile No: 9448106917<br>3. Amruth Poly Clinic, near Jana Priya Apartments,<br>Allalasandra, Yelahanka,<br>Bangalore – 560064<br>Mail ID: kiran107k@gmail.com<br>Mobile No: 9886172368 |
| **Study Period** | 6-8 Months |
| **Objectives** | **Primary objectives:**<br>To evaluate the efficacy of Diacare in patients with type 2 diabetes mellitus |

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| | **Secondary objectives:**<br>To evaluate the safety of Diacare in patients with type 2 diabetes mellitus |
| **Study design** | **Study type :** Interventional<br>**Allocation :** Non-Randomized<br>**Masking :** Open Labeled<br>**Comparator :** None<br>**Primary purpose :** Treatment |
| **No. of Subjects** | Number of subjects enrolled for the entire study is 100 |
| **Inclusion and exclusion criteria** | **Inclusion Criteria:**<br>Aged 30 to 65 years<br>Male and female patients with Type 2 diabetes<br>Patients with inadequate glucose control on any anti diabetic drugs<br>Body mass index between 20-35 kg/m2<br>Having fasting blood glucose > 126 mg/dL<br>Post prandial blood glucose > 200 mg/dL<br>Having no serious physical or biochemical abnormalities other than those generally associated with type 2 diabetes and who are willing to give written informed consent<br>**Exclusion Criteria:**<br>Patients having diabetes other than non insulin dependent diabetes mellitus<br>Having history of hypersensitivity, liver or kidney damage or gastrointestinal disorders, acute infections, diseases of blood or hematopoietic organs<br>Pregnant or lactating women and patients receiving any concomitant medication, which may have interacted with hypoglycemic action of study drug<br>Previous participation in a clinical trial in the last 6 months. |

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| **Test product, dose and mode of administration** | Approximately 5 gm (1 tea spoon) weighed powder was taken and mixed with 1 glass of water, (Approx. 200 ml.) followed proper stirring for uniform mixing and the mix was kept aside for overnight. Supernatant water from the mix was taken at early morning with empty stomach leaving the powder at the bottom of the glass. (20-30 minutes after having the drink, tea, coffee or breakfast was taken) There after ½ glass fresh water was added to same glass and again mixed it evenly and kept aside all the day up to evening, similarly supernatant water was taken half an hour prior to dinner, (leaving the powder at the bottom of the glass). Sediment was discarded and fresh medicine was prepared for the next day as explained earlier. |
| **Criteria for evaluation Efficacy and Safety** | **Primary outcomes**<br>Reduction in plasma glucose levels (fasting and post prandial glucose)<br>Reduction in HbA1c level (glycosylated hemoglobin) as compared with Baseline<br>**Secondary outcomes**<br>Incidence of any related adverse effects<br>Vital signs and physical examinations (pulse rate, blood pressure, weight)<br>Selected biochemistry and hematology parameters at Baseline and after treatment |
| **Statistical methods** | The data will be analyzed with 5% significance level and 80 % power for study using SAS. The Two Sample Mean will be assessed using paired t-test. The difference between the groups will be assessed using One Way ANOVA. |
| **Efficacy and safety results** | All 100 enrolled subjects were advised to take study drug twice a day before breakfast and dinner respectively and they were advised to follow up every visit for a period of 3 months. The data has been collected and analyzed from 94 subjects who have completed all the protocol specified visits (i.e till Visit 4 (Day 90)) and it was found that |

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| | there was significant reduction of Fasting Blood Glucose, Post Prandial Glucose levels and HbA1C levels with gradual percentage of reduction throughout the study duration.<br><br>**Fasting Blood Glucose (FBG (mg/dL)):**<br><br>Mean fasting blood sugar on Screening (day-0), day 45 and day 90 was found to be 216.30 ± 6.96, 185.72 ± 5.80 and 163.31 ± 5.39 respectively. However statistical reduction of 14.14 % and 24.50 % in blood glucose level was found on day 45 and day 90 respectively when compared to Screening line glucose level.<br><br>**Post Prandial Blood Glucose (PPBG (mg/dL)):**<br><br>Mean post prandial blood glucose on Screening (day-0), day 45 and day 90 was found to be 314.75 ± 9.22, 275.35 ± 7.65 and 242.35 ± 6.71 respectively. However statistical reduction of 12.52 % and 23 % in blood glucose level was found on day 45 and day 90 respectively when compared to Screening line glucose level.<br><br>**HbA1C Levels:**<br><br>Mean HbA1C level on Screening (day-0), day 45 and day 90 was found to be 9.74 ± 0.20, 9.09 ± 0.18 and 8.63 ± 0.17 respectively. However statistical reduction of 6.74 % and 11.44 % in HbA1C level was found on day 45 and day 90 respectively when compared to Screening line HbA1C level. |

**DISCUSSION & CONCLUSION**

All 100 enrolled subjects were advised to take study drug twice a day before breakfast and dinner respectively and they were advised to follow up every visit for a period of 3 months. The data has been collected and analyzed from 94 subjects who have completed all the protocol specified visits (i.e till Visit 4) and it was found that there was significant reduction of Fasting Blood Glucose

(14.14 % and 24.50 % on day 45 and day 90 respectively when compared to Screening line glucose level), Post Prandial Glucose levels (12.52 % and 23 % on day 45 and day 90 respectively when compared to Screening line glucose level) and HbA1C levels (6.74 % and 11.44 % on day 45 and day 90 respectively when compared to Screening line glucose level) with gradual percentage of reduction throughout the study duration.

There were found to be 6 drop out subjects during the study tenure with Subject ID: 01-001, 02-003, 02-009, 02-018, 03-022 and 03-029.

Glucose estimation was known to be the primary parameter for diagnosis of diabetes and HbA1c levels depend on the blood glucose concentration. That is, the higher the glucose concentration in blood, the higher the level of HbA1c. Levels of HbA1c are not influenced by daily fluctuations in the blood glucose concentration. Therefore, HbA1c is a useful indicator of how well the blood glucose level has been controlled in the recent, past and may be used to monitor the effects of drug therapy on blood glucose in diabetic patients.

From the data obtained, it was found that the investigational product **Diacare** was showing significant percentage of increase in reduction of Fasting Blood Glucose (FBG) and Post Prandial Blood Glucose (PPBG) levels with gradual positive trend in increase in reduction throughout the study duration. The effect showed on Day-90 was superior to the activity showed on Day-45; However Diacare was showing significant increase in reduction effect on HbA1c levels, which was considered as an important parameter in diabetic controlling.