**Table B8. Oral Hypoglycemic Agents: Data Abstraction: Outcomes**

|  | **Clinicaltrials.gov registration (or other registry) information** |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Author, year** | **Proposed/ Target N** | **Relevant original primary outcome in the registry** | **Relevant current primary outcome in the registry** | **Date of change in the relevant primary outcome** | **Original relevant secondary outcomes in the registry** | **Current relevant secondary outcomes in the registry** | **Date of change in the relevant secondary outcome** | **F/U 1  F/U 2  F/U 3  (weeks)** | **Results reported in the registry?** |
| Aschner 2010 | 1050 | HbA1c after 24 weeks | Change from baseline in hemoglobin A1c (HbA1c) at week 24 | NA | None | None | NA | 24  NA  NA | Yes |
| Bakris 2006 | 336 | Percent change from baseline in ACR after 32 weeks of treatment | Percent change from baseline in ACR after 32 weeks of treatment | NA | None | None | NA | 32  NA  NA | No |
| Bunck 2009 | 69 | None | None | NA | None | Change in HbA1c from week 0 to week 52. | 12/24/10 | 52  56 (reported for some secondary outcomes)  NA | Yes |
| Defronzo 2009 | 1462 | Change from baseline in HbA1c to week 24 | Baseline and change from baseline in Hemoglobin A1c (A1C) at week 24 | NA | None | Percentage of participants achieving therapeutic glycemic response (A1C < 7.0%) at week 24 | 07/15/11 | 24  NA  NA | Yes |
| Defronzo 2010 | 137 | None | None | NA | None | Change in HbA1c at week 20 | 07/21/09 | 20  NA  NA | Yes |
| Garber 2009 | 746 | Change in A1c at 52 weeks | Change in A1c at week 52, 104, 156 | NA# | Glycemic control | None | 03/24/11 | 52  104  156 | Yes |
| Goldberg 2005 | 719 | None | None | NA | None | Change in A1c | 12/11/08 | "Anticipated to be about 39 weeks"  NA  NA | No |
| Goldstein 2007;   Williams-Herman 2009 | 1208 | HbA1c | Change from baseline in HbA1c (Hemoglobin A1C) at week 24 | 04/07/10 | None | Change from baseline in HbA1c (Hemoglobin A1C) at week 54, week 104 | NA# | 24  54  104 | Yes |
| Gupta 2009 | 60 | None | None | NA | None | None | NA | 4 months  NA  NA | No |
| Hamann 2008 | 544 | Change in HbA1c level from baseline following 52 weeks of treatment | Change in HbA1c level from baseline following 52 weeks of treatment | NA | None | None | NA | 52  NA  NA | No |
| Jadzinsky 2009 | 1306 | Mean reduction in baseline A1C values after 24 weeks of treatment | Change from baseline in hemoglobin A1c (A1C) at week 24 | NA | Subjects achieving a glycemic response defined as A1C < 7.0% | Percentage of participants achieving A1C < 7% and ≤6.5% at Week 24 | 06/30/10 | 24  NA  NA | Yes |
| Kaku 2009 | 160 | NR\* | Change in HbA1C at the end of the treatment period | NA | None | None | NA | 28   NA  NA | Says yes but unable to locate |
| Nauck 2007;   Seck 2010 | 1172 | After 52 weeks, reduction in HbA1C | Change From Baseline in HbA1c at week 52 | NA | Reduction in A1c at 104 weeks, durability of glycemic efficacy | Change from baseline in HbA1c at week 104 | NA | 52  104  NA | Yes |
| Nauck 2009 | 1091 | HbA1c after 26 weeks of treatment | Change in Glycosylated A1c (HbA1c) at week 26 and week 104 | NA# | None | None | NA | 26  104  NA | Yes |
| Perez 2009 | 600 | The change from baseline in hemoglobin Alc. [Time Frame: 24 Weeks] | Percent Change From baseline in Glycosylated Hemoglobin [Time Frame: Baseline and Week 24] | NA | None | None | NA | 24  NA  NA | Yes |
| Pratley 2010 | 665 | HbA1c (Time Frame: after 26 weeks of treatment) | Mean Change From Baseline in HbA1c at Week 26, 52, 78 | NA# | None | Percentage of subjects achieving treatment target of HbA1c < 7.0%, < 6.5% at Week 26, 52, 78. Based on the FAS. | 06/01/11 | 26  52  78 | Yes |
| Raskin 2009 | 560 | HbA1c after 26 weeks of treatment | HbA1c; Time Frame: after 26 weeks of treatment | NA | Percentage of subjects achieving sudden levels of HbA1c | None | NA | 26  NA  NA | No |
| Raz 2008 | 190 | HbA1c after 18 weeks, safety and tolerability | Change from baseline in A1C at week 18 | NA | None | Change in A1c at week 30 | 04/29/10 | 18  30  NA | Yes |
| Rigby 2009 | 169 | Change in HbA1c from baseline to week 16 endpoint | Mean percentage of change in HbA1c from week 0 (Baseline) to week 16 endpoint | NA | Mean Percentage of Change in HbA1c | Mean percentage of change in HbA1c | NA | 16  8  NA | Yes |
| Robbins 2007 | 320 | HbA1C | HbA1C | NA | None | None | NA | NR  NA  NA | No |
| Rosenstock 2006 | 453 | Change from baseline in hemoglobin A1c (HbA1c) at week 32 | Change from baseline in hemoglobin A1c (HbA1c) at week 32. | NA | HbA1c | HbA1c | NA | 32  NA  NA | No |
| Scott 2008 | 273 | Hemoglobin A1C (A1C) at week 18 | Hemoglobin A1C (A1C) at week 18 | NA | None | None | NA | 18  NA  NA | Yes |
| Seino 2010 | 400 | HbA1C after 24 weeks of treatment | HbA1c after 24 weeks of treatment | NA | A1c at 52 weeks | A1c at 52 weeks | NA | 24  52  NA | Yes |
| van der Meer 2009 | 90 | NR\* | None | NA | None | None | NA | 24  NA  NA | No |

Abbreviations: ADA, American Diabetes Association; ANCOVA, analysis of covariance; ANOVA, analysis of variance; APT, all patients treated; AUC, area under curve; BMI, body mass index; CI, confidence interval; FAS, full analysis set; ITT, intent to treat; LOCF, last observation carried forward; LSM, least squares mean; NA, not applicable; NI, non-inferiority; NR, not reported; RCT, randomized controlled trial; SD, standard deviation.

\* Not reported because registry did not capture original outcome.

# Open-label extension not considered a change in outcome.