Study Design and Baseline Characteristics of Patients with T2DM in the Post-marketing Safety Study of Dulaglutide in China (TRUST-CHN)

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Table S1. Data collection schedule

| Timing                                      | Baseline Visit 1 | Post-baseline Visit 2 | Post-baseline Visit 3 |
|---------------------------------------------|------------------|-----------------------|-----------------------|
| Day 0 (predose)                             | X                | Day 28 (±7 days; 4±1 weeks) | Day 168 (±14 days; 24±2 weeks) |
| Confirmation of eligibility and consent to release information | X                |                        |                       |
| Demographics                                | X                |                        |                       |
| Initial history/pre-existing conditions      | X                |                        |                       |
| Treatment information                       | X                | X                     | X                     |
| Concomitant medications                     | X                | X                     | X                     |
| HbA1c                                       | X                |                        |                       |
| Vital signs                                  | X                |                        |                       |
| Diabetes Treatment Satisfaction Questionnaire|                  | X                     |                       |
| Safety assessments                           |                  | X                     | X                     |

Table S2. History of other T2DM treatment – Safety analysis population

| Previous T2DM treatments included:                   | Dulaglutide-experienced N=1047, n (%) | Dulaglutide-naïve N=2247, n (%) | Total N=3294, n (%) |
|-----------------------------------------------------|---------------------------------------|----------------------------------|---------------------|
| Patients with at least one other previous T2DM treatment | 785 (75.0)                           | 1461 (65.0)                      | 2246 (68.2)         |

| Number of oral anti-diabetic treatments used for T2DM prior to study entry (i.e. not including insulin and GLP-1 RAs): | | |
|-----------------------------------------------------|------------------|------------------|
| Any                                                 | 581              | 1079             | 1660              |
| =1                                                  | 237 (22.6)       | 444 (19.8)       | 681 (20.7)        |
| =2                                                  | 199 (19.0)       | 333 (14.8)       | 532 (16.2)        |
| ≥3                                                  | 145 (13.8)       | 302 (13.4)       | 447 (13.6)        |
Table S3. Dulaglutide treatment history – Safety analysis population

|                                | Dulaglutide-experienced | Dulaglutide-naive |
|--------------------------------|--------------------------|-------------------|
| **Total (N)**                  | 1047                     | 2247              |
| **Duration of previous dulaglutide treatment (days)** |                         |                   |
| n                              | 1032                     | 2115              |
| Mean (SD)                      | 82.0 (213.7)             | 81.4 (14.5)       |
| **Discontinued dulaglutide prior to study entry** | 24                       |                   |
| **Duration of previous dulaglutide treatment (days)** |                         |                   |
| n                              | 20                       |                   |
| Mean (SD)                      | 113.8 (101.0)            |                   |
| **Last dulaglutide dosage, n (%)** |                          |                   |
| n                              | 24                       |                   |
| 0.75 mg                        | 0                        |                   |
| 1.5 mg                         | 24 (100%)                |                   |
| **Last frequency of administration, n (%)** |                          |                   |
| n                              | 24                       |                   |
| Per week                       | 24 (100%)                |                   |
| **Dulaglutide ongoing at time of study entry (N)** | 1012                     |                   |
| **Duration of previous dulaglutide treatment (days)** |                         |                   |
| n                              | 1012                     |                   |
| Mean (SD)                      | 81.3 (215.3)             |                   |
| **Current dulaglutide dosage, n (%)** |                          |                   |
| n                              | 1012                     |                   |
| 0.75 mg                        | 2 (0.2%)                 |                   |
| 1.5 mg                         | 1010 (99.8%)             |                   |
| **Current frequency of administration, n (%)** |                          |                   |
| n                              | 1012                     |                   |
| Per week                       | 1011 (99.9%)             |                   |
| Other                          | 1 (0.1%)                 |                   |

N=Total number of patients per category; n=number of patients with available data.

Table S4. Vital signs at baseline – Safety analysis population

|                                | Dulaglutide-experienced N=1047 | Dulaglutide-naive N=2247 | Total N=3294 |
|--------------------------------|--------------------------------|--------------------------|--------------|
| **Systolic blood pressure (mmHg)** |                                |                          |              |
| n                              | 996                            | 2115                     | 3111         |
| Mean (SD)                      | 130.0 (13.4)                   | 131.1 (14.5)             | 130.7 (14.2) |
| **Diastolic blood pressure (mmHg)** |                               |                          |              |
| n                              | 996                            | 2115                     | 3111         |
| Mean (SD)                      | 82.0 (9.4)                     | 81.4 (10.3)              | 81.6 (10.1)  |
| **Heart rate (bpm)**           |                                |                          |              |
| n                              | 942                            | 2033                     | 2975         |
Table S5. Laboratory measurements at baseline – Safety analysis population

|                                    | Dulaglutide-experienced N=1047 | Dulaglutide-naïve N=2247 | Total N=3294 |
|------------------------------------|---------------------------------|---------------------------|--------------|
| **Fasting insulin (mU/L)**         |                                 |                           |              |
| n                                  | 218                             | 633                       | 851          |
| Mean (SD)                          | 19.1 (27.5)                     | 20.3 (29.2)               | 20.0 (28.8)  |
| < LLN, n (%)                       | 8 (3.7%)                        | 12 (1.9%)                 | 20 (2.4%)    |
| Within normal limit, n (%)         | 164 (75.2%)                     | 448 (70.8%)               | 612 (71.9%)  |
| > ULN, n (%)                       | 46 (21.1%)                      | 172 (27.2%)               | 218 (25.6%)  |
| **Fasting blood glucose (mmol/L)** |                                 |                           |              |
| n                                  | 317                             | 862                       | 1179         |
| Mean (SD)                          | 8.7 (3.2)                       | 9.3 (3.7)                 | 9.1 (3.6)    |
| < LLN, n (%)                       | 3 (0.9%)                        | 9 (1.0%)                  | 12 (1.0%)    |
| Within normal limit, n (%)         | 64 (20.2%)                      | 149 (17.3%)               | 213 (18.1%)  |
| > ULN, n (%)                       | 250 (78.9%)                     | 704 (81.7%)               | 954 (80.9%)  |
| **Fasting C-peptide (ng/mL)**      |                                 |                           |              |
| n                                  | 313                             | 769                       | 1082         |
| Mean (SD)                          | 2.5 (1.8)                       | 2.4 (1.6)                 | 2.4 (1.6)    |
| < LLN, n (%)                       | 30 (9.6%)                       | 86 (11.2%)                | 116 (10.7%)  |
| Within normal limit, n (%)         | 239 (76.4%)                     | 597 (77.6%)               | 836 (77.3%)  |
| > ULN, n (%)                       | 44 (14.1%)                      | 86 (11.2%)                | 130 (12.0%)  |
| **2h post-prandial blood glucose (mmol/L)** |                |                           |              |
| n                                  | 203                             | 513                       | 716          |
| Mean (SD)                          | 15.6 (5.5)                      | 15.5 (5.4)                | 15.5 (5.4)   |
| < LLN, n (%)                       | 1 (0.5%)                        | 2 (0.4%)                  | 3 (0.4%)     |
| Within normal limit, n (%)         | 34 (16.7%)                      | 102 (19.9%)               | 136 (19.0%)  |
| > ULN, n (%)                       | 167 (82.3%)                     | 399 (77.8%)               | 566 (79.1%)  |
| **Triglycerides (mmol/L)**         |                                 |                           |              |
| n                                  | 523                             | 1142                      | 1665         |
| Mean (SD)                          | 2.5 (1.9)                       | 2.8 (3.4)                 | 2.7 (3.0)    |
| < LLN, n (%)                       | 1 (0.2%)                        | 3 (0.3%)                  | 4 (0.2%)     |
| Within normal limit, n (%)         | 222 (42.4%)                     | 482 (42.2%)               | 704 (42.3%)  |
| > ULN, n (%)                       | 300 (57.4%)                     | 657 (57.5%)               | 957 (57.5%)  |
| **Total cholesterol (mmol/L)**     |                                 |                           |              |
| n                                  | 525                             | 1140                      | 1665         |
| Mean (SD)                          | 6.1 (32.3)                      | 5.0 (2.0)                 | 5.3 (18.2)   |
| < LLN, n (%)                       | 27 (5.1%)                       | 39 (3.4%)                 | 66 (4.0%)    |
| Within normal limit, n (%)         | 396 (75.4%)                     | 791 (69.4%)               | 1187 (71.3%) |
| > ULN, n (%)                       | 102 (19.4%)                     | 310 (27.2%)               | 412 (24.7%)  |
| **Low-density lipoprotein (mmol/L)** |                                 |                           |              |
| n                                  | 493                             | 1117                      | 1610         |
|                                      | Mean (SD)         | Mean (SD)         | Mean (SD)         |
|--------------------------------------|-------------------|-------------------|-------------------|
|                                      | 2.7 (1.0)         | 3.0 (1.0)         | 2.90 (1.0)        |
| < LLN, n (%)                         | 58 (11.8%)        | 105 (9.4%)        | 163 (10.1%)       |
| Within normal limit, n (%)           | 318 (64.5%)       | 683 (61.1%)       | 1001 (62.2%)      |
| > ULN, n (%)                         | 117 (23.7%)       | 329 (29.5%)       | 446 (27.7%)       |
| **High-density lipoprotein (mmol/L)**|                   |                   |                   |
| n                                    | 491               | 1113              | 1604              |
| Mean (SD)                            | 1.1 (0.4)         | 1.1 (0.3)         | 1.1 (0.4)         |
| < LLN, n (%)                         | 169 (34.4%)       | 366 (32.9%)       | 535 (33.4%)       |
| Within normal limit, n (%)           | 307 (62.5%)       | 707 (63.5%)       | 1014 (63.2%)      |
| > ULN, n (%)                         | 15 (3.1%)         | 40 (3.6%)         | 55 (3.4%)         |
| **Uric acid (µmol/L)**               |                   |                   |                   |
| n                                    | 493               | 1116              | 1609              |
| Mean (SD)                            | 844.1 (3146.9)    | 1237.2 (17751.8)  | 1116.8 (14885.3)  |
| < LLN, n (%)                         | 11 (2.2%)         | 24 (2.2%)         | 35 (2.2%)         |
| Within normal limit, n (%)           | 366 (74.2%)       | 766 (68.6%)       | 1132 (70.4%)      |
| > ULN, n (%)                         | 116 (23.5%)       | 326 (29.2%)       | 442 (27.5%)       |
| **Blood urea nitrogen (mmol/L)**     |                   |                   |                   |
| n                                    | 384               | 870               | 1254              |
| Mean (SD)                            | 5.7 (2.5)         | 5.5 (2.0)         | 5.6 (2.2)         |
| < LLN, n (%)                         | 12 (3.1%)         | 22 (2.5%)         | 34 (2.7%)         |
| Within normal limit, n (%)           | 333 (86.7%)       | 772 (88.7%)       | 1105 (88.1%)      |
| > ULN, n (%)                         | 39 (10.2%)        | 76 (8.7%)         | 115 (9.2%)        |
| **Creatinine (µmol/L)**              |                   |                   |                   |
| n                                    | 498               | 1124              | 1622              |
| Mean (SD)                            | 200.8 (1795.7)    | 91.5 (402.2)      | 125.1 (1050.4)    |
| < LLN, n (%)                         | 104 (20.9%)       | 194 (17.3%)       | 298 (18.4%)       |
| Within normal limit, n (%)           | 355 (71.3%)       | 864 (76.9%)       | 1219 (75.2%)      |
| > ULN, n (%)                         | 39 (7.8%)         | 66 (5.9%)         | 105 (6.5%)        |
| **Microalbuminuria (mg/dL)**         |                   |                   |                   |
| n                                    | 301               | 687               | 988               |
| Mean (SD)                            | 18.5 (88.1)       | 12.7 (46.4)       | 14.5 (62.2)       |
| < LLN, n (%)                         | 14 (4.7%)         | 9 (1.3%)          | 23 (2.3%)         |
| Within normal limit, n (%)           | 169 (56.1%)       | 394 (57.4%)       | 563 (57.0%)       |
| > ULN, n (%)                         | 118 (39.2%)       | 284 (41.3%)       | 402 (40.7%)       |

LLN, lower limit normal; ULN, upper limit normal.
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