**Table 1. Baseline characteristics of the patients meeting the entry criteria\***

|  |  |
| --- | --- |
| Parameter | Patients meeting criteria (n = 1493) |
| Age, years | 60.9 ± 9.1 |
| Age group, N (%) |
| < 65 years | 932 ( 62.4) |
| 65–75 years | 479 (32.1) |
| ≥ 75 years | 82 (5.5) |
| Gender, N (%) |
| Male | 524 (35.1) |
| Female | 969 (64.9) |
| BMI, kg/m2 | 37 ± 5.4 |
| BMI groups, N (%) |
| < 25 | 105 (9.0) |
| 25–30 | 357 (30.6) |
| 30–35 | 431 (36.9) |
| ≥ 35 | 274 (23.5) |
| History of cardiovascular diseases, N (%) |
| Arterial hypertension | 995 (66.6) |
| Dyslipidemia | 838 (56.1) |
| Ischemic heart disease | 200 (13.4) |
| Myocardial infarction | 54 (3.6) |
| Chronic heart failure | 115 (7.7) |
| Atrial fibrillation | 25 (1.7) |
| Coronary revascularization | 23 (1.5) |
| Stroke | 37 (2.5) |
| Peripheral artery disease | 114 (7.6) |
| Other cardiovascular disorders | 37 (2.6) |
| Mean diabetes duration, years (± SD) | 9.9 ± 5.7 |
| Diabetes duration (years), N (%) |
| 1–5 | 252 (16.9) |
| 5–10 | 571 (38.2) |
| ≥ 10 | 670 (44.9) |
| Late diabetic complications, N (%) |
| Diabetic retinopathy | 431 (28.9) |
| Autonomous neuropathy | 21 (1.4) |
| Peripheral neuropathy | 975 (65.3) |
| Chronic kidney disease | 198 (13.3) |
| Duration of treatment with OHAs (median [Q1; Q3]) | 9.0 [5; 13] |
| Number of OHAs at baseline, N (%) |
| 1 | 302 (20.2) |
| 2 | 944 (63.2) |
| ≥ 3 | 247 (16.5) |
| Baseline OHAs, N (%) |
| Biguanides | 1298 (86.9) |
| Sulfonylureas | 1206 (80.8) |
| Glinides | 4 (0.3) |
| DPP-4 inhibitors | 329 (22.0) |
| SGLT2 inhibitors | 100 (6.7) |
| Other | 0 |
| Baseline HbA1c, % (mean ± SD) | 9.3 ± 0.9 |
| Baseline HbA1c groups (%), N (%) |
| 7 to < 7.5 | 23 (1.5) |
| ≥ 7,5 to < 8 | 101 (6.8) |
| ≥ 8 to < 9 | 455 (30.5) |
| ≥ 9 to < 10 | 534 (35.8) |
| ≥ 10 | 380 (25.5) |
| Target HbA1c (%), N (%) |
| < 7.0 | 154 (10.3) |
| ≥ 7 to < 7.5 | 936 (62.7) |
| ≥ 7,5 to < 8 | 335 (22.4) |
| ≥ 8 | 68 (4.6) |
| Fasting plasma glucose, mmol/L (mean ± SD) | 10.9 ± 2.3 |
| Self-measured fasting plasma glucose, mmol/L (mean ± SD) | 10.7 ± 2.0 |

Baseline OHAs, agents used within 6 months before screening; BMI, body mass index; DPP-4, dipeptidylpeptidase type 4; Gla-300, insulin glargine 300 U/mL; OHAs, oral hypoglycemic agents; SD, standard deviation; SGLT2, sodium glucose co-transporter type 2

\* The patients meeting criteria: all patients included into the study, who had signed their informed consent, met inclusion/exclusion criteria and started treatment with insulin Gla-300 within ± 31 days from the study beginning

**Table 2. Prognostic factors for the achievement of the target HbA1c level at 6 months**

|  |  |  |  |
| --- | --- | --- | --- |
| Factor | Patient numbers | OR (95% CI) | P value |
| Total, N | Achieved target HbA1c, N (%) |
| Gender |
| Male | 518 | 128 (24.7) | Reference | 0.456 |
| Female | 955 | 253 (26.5) | 1.1 (0.9–1.4) |
| Age, years |
| < 65 | 922 | 208 (22.6) | Reference | < 0.001 |
| 65–75 | 473 | 141 (29.8) | 1.5 (1.1–1.9) |
| ≥ 75 | 78 | 32 (41) | 2.4 (1.5–3.8) |
| BMI, kg/m2 |
| < 25 | 103 | 27 (26.2) | Reference | 0.495 |
| 25–30 | 353 | 90 (25.5) | 0.9 (0.6–1.6) |
| 30–35 | 427 | 121 (28.3) | 1.1 (0.7–1.8) |
| ≥ 35 | 268 | 62 (23.1) | 0.8 (0.5–1.4) |
| Baseline HbA1c, % |
| 7–8 | 123 | 62 (50.4) | Reference | < 0.001 |
| 8–9 | 449 | 141 (31.4) | 0.4 (0.3–0.7) |
| 9–10 | 527 | 114 (21.6) | 0.3 (0.2–0.4) |
| ≥ 10 | 374 | 64 (17.1) | 0.2 (0.1–0.3) |
| Comorbidities, N |
| 0 | 273 | 88 (32.2) | Reference | 0.010 |
| 1 | 147 | 44 (29.9) | 0.9 (0.6–1.4) |
| 2 | 223 | 43 (19.3) | 0.5 (0.3–0.8) |
| 3 | 253 | 55 (21.7) | 0.6 (0.4–0.9) |
| 4 | 199 | 47 (23.6) | 0.6 (0.4–0.9) |
| ≥ 5 | 378 | 104 (27.5) | 0.8 (0.6–1.1) |

BMI, body mass index; CI, confidence interval; OR, odds ratio

**Table 3. Incidence of hypoglycemia, N (%)\***

|  |  |  |
| --- | --- | --- |
| Type of hypoglycemia / period of the follow-up | All hypoglycemic episodes | Nighttime hypoglycemic episodes |
| Any hypoglycemic episode |
| 6 months | 19 (1.3) | 1 (0.07) |
| 12 months | 30 (2.0) | 2 (0.13) |
| Symptomatic hypoglycemic episodes (≤ 3.9 mmol/L) |
| 6 months | 9 (0.6) | 1 (0.07) |
| 12 months | 17 (1.1) | 2 (0.13) |
| Symptomatic hypoglycemic episodes (≤ 3,0 mmol/L) |
| 6 months | 2 (0.13) | 0 |
| 12 months | 5 (0.3) | 0 |
| Severe hypoglycemia |
| 6 months | 1 (0.07) | 0 |
| 12 months | 2 (0.13) | 0 |

\* N (%), numbers and proportions of the patients with a hypoglycemic episode

**Table 4. Most common adverse events during the study\***

|  |  |
| --- | --- |
| Type of events | Number of events, N (%) |
| Increased blood pressure | 2 (0.1) |
| Infections (acute upper respiratory tract infection, cellulitis) | 2 (0.1) |
| Respiratory | 2 (0.1) |
| Neurologic | 2 (0.1) |

\* Adverse events which were registered more than once during the study