**Online suppl. Table S1.** Specific reasons for premature discontinuation of the clinical trial

N: number of patients; n (%): number (percentage) of patients; ICF: informed consent form; TEAE: treatment emergent adverse event.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Reason for premature discontinuation | One strength  N= 45 | | Standard  N= 41 | |
| N | % | N | % |
| ICF withdrawal | 2 | 4.4 | 1 | 2.4 |
| protocol deviation | 1 | 1.8 | 3 | 7.3 |
| TEAE | 2 | 4.4 | 0 | 0 |

**Online suppl. Table S2.** TEAEs in ≥ 3% of patients overall: e: number of events (TEAEs); N: number of patients; n (%): number (percentage) of patients with at least one TEAE; PT: preferred term; SAF: safety set; SOC: system organ class; TEAE: treatment emergent adverse event.

| SOC  PT | One Strength N = 45 | | Standard N = 41 | | Overall N = 86 | |
| --- | --- | --- | --- | --- | --- | --- |
| n (%) | e | n (%) | e | n (%) | e |
| Overall | 37 (82.2) | 200 | 35 (85.4) | 244 | 72 (83.7) | 444 |
| General disorders and administration site conditions | 27 (60.0) | 116 | 21 (51.2) | 129 | 48 (55.8) | 245 |
| Injection site swelling | 21 (46.7) | 49 | 14 (34.1) | 38 | 35 (40.7) | 87 |
| Injection site erythema | 13 (28.9) | 28 | 15 (36.6) | 51 | 28 (32.6) | 79 |
| Injection site pruritus | 14 (31.1) | 24 | 7 (17.1) | 26 | 21 (24.4) | 50 |
| Injection site pain | 2 (4.4) | 2 | 3 (7.3) | 7 | 5 (5.8) | 9 |
| Injection site warmth | 3 (6.7) | 5 | 0 | 0 | 3 (3.5) | 5 |
| Pyrexia | 1 (2.2) | 1 | 2 (4.9) | 2 | 3 (3.5) | 3 |
| Infections and infestations | 15 (33.3) | 28 | 15 (36.6) | 27 | 30 (34.9) | 55 |
| Viral upper respiratory tract infection | 6 (13.3) | 9 | 9 (22.0) | 14 | 15 (17.4) | 23 |
| Upper respiratory tract infection | 3 (6.7) | 3 | 3 (7.3) | 3 | 6 (7.0) | 6 |
| Conjunctivitis | 2 (4.4) | 3 | 1 (2.4) | 2 | 3 (3.5) | 5 |
| Respiratory tract infection | 2 (4.4) | 2 | 1 (2.4) | 1 | 3 (3.5) | 3 |
| Rhinitis | 2 (4.4) | 3 | 1 (2.4) | 1 | 3 (3.5) | 4 |
| Nervous system disorders | 9 (20.0) | 15 | 12 (29.3) | 22 | 21 (24.4) | 37 |
| Headache | 9 (20.0) | 15 | 10 (24.4) | 20 | 19 (22.1) | 35 |
| Respiratory, thoracic and mediastinal disorders | 10 (22.2) | 16 | 6 (14.6) | 13 | 16 (18.6) | 29 |
| Cough | 2 (4.4) | 2 | 2 (4.9) | 2 | 4 (4.7) | 4 |
| Rhinorrhoea | 2 (4.4) | 3 | 2 (4.9) | 3 | 4 (4.7) | 6 |
| Dyspnoea | 2 (4.4) | 3 | 1 (2.4) | 2 | 3 (3.5) | 5 |
| Investigations | 3 (6.7) | 4 | 9 (22.0) | 16 | 12 (14.0) | 20 |
| Forced expiratory volume decreased | 2 (4.4) | 3 | 6 (14.6) | 7 | 8 (9.3) | 10 |
| Gastrointestinal disorders | 4 (8.9) | 5 | 4 (9.8) | 5 | 8 (9.3) | 10 |
| Musculoskeletal and connective tissue disorders | 4 (8.9) | 4 | 3 (7.3) | 8 | 7 (8.1) | 12 |
| Pain in extremity | 2 (4.4) | 2 | 2 (4.9) | 7 | 4 (4.7) | 9 |
| Skin and subcutaneous tissue disorders | 3 (6.7) | 5 | 3 (7.3) | 12 | 6 (7.0) | 17 |
| Pruritus | 1 (2.2) | 2 | 3 (7.3) | 6 | 4 (4.7) | 8 |
| Cardiac disorders | 2 (4.4) | 2 | 1 (2.4) | 1 | 3 (3.5) | 3 |
| Tachycardia | 2 (4.4) | 2 | 1 (2.4) | 1 | 3 (3.5) | 3 |
| Eye disorders | 1 (2.2) | 1 | 2 (4.9) | 5 | 3 (3.5) | 6 |
| Reproductive system and breast disorders | 1 (2.2) | 1 | 2 (4.9) | 3 | 3 (3.5) | 4 |

**Online suppl. Table S3.** Time to Onset of TEAEs related to AIT

e: number of events (TEAEs); IMP: investigational medicinal product; N: number of patients; SAF: safety set; TEAE: treatment emergent adverse event.

|  |  |  |  |
| --- | --- | --- | --- |
|  | One Strength  N = 45 | Standard  N = 41 | Overall  N = 86 |
| e | e | e |
| Number of TEAEs related to IMP | 129 | 132 | 261 |
| ≤ 30 min | 23 | 22 | 45 |
| > 30 min, ≤ 6 h | 56 | 50 | 106 |
| > 6 h, ≤ 24 h | 36 | 46 | 82 |
| > 24 h | 14 | 14 | 28 |