

Supplementary Table 1: Number (%) of patients with at least one treatment-emergent suspected adverse drug reaction (side effect) by System Organ Class and preferred term

| System Organ Class Preferred term | BET1 (n = 19) | BET2 (n = 19) | BVS (n = 19) | PLA (n = 19) |
|--|-------------------------|-------------------------|------------------------|------------------------|
| Gastrointestinal disorders | | | | |
| Nausea | --- | 1 (5.3) | --- | --- |
| Oral mucosal blistering | --- | 1 (5.3) | --- | --- |
| Bowel movement irregularity | --- | --- | 1 (5.3) | --- |
| Lip oedema | --- | --- | 1 (5.3) | --- |
| Infections and infestations | | | | |
| Oesophageal candidiasis / Fungal oesophagitis | 3 (15.8) | 3 (15.8) | 3 (15.8) | --- |
| <i>Thereof, histologically confirmed cases</i> | 2 (10.5) | 2 (10.5) | 2 (10.5) | --- |
| Investigations | | | | |
| White blood cell count increased | 1 (5.3) | --- | --- | --- |
| Blood cortisol decreased | --- | 1 (5.3) | --- | --- |
| Skin and subcutaneous tissue disorders | | | | |
| Pruritus | 1 (5.3) | --- | --- | --- |
| Urticaria | --- | --- | 1 (5.3) | --- |

BET1, effervescent tablets for orodispersible use 2 x 1 mg/d; BET2, effervescent tablets for orodispersible use 2 x 2 mg/d ; BVS, budesonide viscous suspension 2 x 5 ml [0.4 mg/ml]/d; PLA, placebo