

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