Name of Company: Boehringer Ingelheim		**Synopsis**	Boehringer Ingelheim
BI Proprietary Name: Not applicable		**EudraCT No.:** 2012-004384-48	
BI Investigational Product: BI 655066		**Page:** 1 of 11	
Report Date: 27 Jun 2016	**Trial No. / Doc. No.:** 1311.2 / c03589224-02	**Dates of Trial:** 26 Feb 2014 - 31 Jul 2015	**Date of Revision:** 05 Aug 2016

Title of Trial:	A 48 weeks study of three different dose regimens of BI 655066 administered subcutaneously in patients with moderate to severe chronic plaque psoriasis (randomised, dose-ranging, active-comparator-controlled (ustekinumab), double-blind within dose groups of BI 655066)
Coordinating Investigator:	[redacted]
Trial Sites:	Multicentre trial at 32 sites in Canada, Finland, France, Germany, Norway, Sweden, and USA
Publications:	Data from this trial have not been published at the time of this clinical trial report.
Clinical Phase:	II
Objectives:	To investigate efficacy, safety, tolerability, pharmacokinetics, pharmacodynamics, and immunogenicity of 3 different dose regimens of BI 655066 in patients with moderate to severe chronic plaque psoriasis.
Methodology:	The trial was randomised, active-comparator-controlled, double-blind within dose groups of BI 655066, single-blind between BI 655066 and ustekinumab (Stelara®) dose groups, parallel-designed, and dose-ranging with multiple doses. In total, 4 treatment groups were studied. The total duration of the trial was 48 weeks (24-week treatment period and 24-week follow-up period). An open-label extension trial of the study is ongoing.
No. of Patients:	
Planned:	Entered: 160 patients
Actual:	Enrolled: 231 patients
	Entered: 166 patients
	BI 18 mg:
	Entered: 43 Treated: 43 Analysed (for primary endpoint): 43
	BI 90 mg:
	Entered: 41 Treated: 41 Analysed (for primary endpoint): 41
	BI 180 mg:
	Entered: 42 Treated: 42 Analysed (for primary endpoint): 42

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	Stelara®: Entered: 40 Treated: 40 Analysed (for primary endpoint): 40
Diagnosis:	Moderate to severe chronic plaque-type psoriasis
Main Criteria for Inclusion:	Patients who were assessed by the investigator as having moderate to severe chronic plaque-type psoriasis with or without psoriatic arthritis involving ≥10% body surface area, with a psoriasis area severity index (PASI) score ≥12 at screening and randomisation, with a static physicians global assessment (sPGA) score ≥3 at screening and randomisation, with a psoriasis disease duration of ≥6 months before screening, and who were suitable for systemic psoriasis treatment or phototherapy as well as for ustekinumab (Stelara®) therapy (according to local Stelara® labelling).
BI Investigational Product:	BI 655066 solution for injection 90 mg/mL, 1 mL pre-filled syringe, and placebo to BI 655066 solution for injection, 1 mL pre-filled syringe
Dose:	BI 18 mg: 18 mg BI 655066 at Week 0; placebo at Weeks 4 and 16 BI 90 mg: 90 mg BI 655066 at Weeks 0, 4, and 16 BI 180 mg: 180 mg BI 655066 at Weeks 0, 4, and 16
Mode of Admin.:	Subcutaneous injection
Batch No.:	B131003151/E3746S01, B131003153/E3744S02
Comparator Product:	Ustekinumab (Stelara®) solution for injection 45 mg/0.5 mL pre-filled syringe and ustekinumab (Stelara®) solution for injection 90 mg/1.0 mL pre-filled syringe
Dose:	45 mg (patients with body weight ≤100 kg at randomisation) or 90 mg (patients with body weight >100 kg at randomisation) at Weeks 0, 4, and 16
Mode of Admin.:	Subcutaneous injection
Batch No.:	B131003480/DDS41MQ, B131003481/12K031MG, B131003684/13A052MG, B131003685/CHS0IND, B141000883/DAS4VMB, B141000884/DAS4UMA, B141000885/DJS1UMS, B141001777/EAS4ZMV, B141001779/DJS1UMM
Duration of Treatment:	Screening period: 30 days; treatment period: 24 weeks; follow-up period: 24 weeks. The total duration of the trial was 48 weeks.

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Criteria for Evaluation:

Efficacy:

The primary endpoint of efficacy was the achievement of ≥90% reduction from baseline in PASI score ($PASI_{90}$) at Week 12.

Secondary endpoints of efficacy were:

- Achievement of ≥75% reduction from baseline in PASI score ($PASI_{75}$) at Weeks 12 and 24
- Achievement of 100% reduction from baseline in PASI score ($PASI_{100}$) at Week 12
- Achievement of ≥50% reduction from baseline in PASI score ($PASI_{50}$) at Week 12
- Achievement of $PASI_{90}$ at Week 24
- Achievement of sPGA clear or almost clear at Week 12
- Percentage of PASI reduction from baseline at Week 12
- Time to loss of $PASI_{50}$ response

Safety:

Safety and tolerability were assessed based on:

- Adverse events (AEs)
- Discontinuation of therapy due to AEs
- Serious AEs (SAEs)
- Changes in the safety laboratory analysis
- Tolerability, changes in vital signs and physical examination

Statistical Methods:

Primary endpoint ($PASI_{90}$ at Week 12) and secondary endpoints ($PASI_{75}$, $PASI_{100}$, $PASI_{50}$, $PASI_{90}$ at Week 24, and sPGA clear or almost clear)

For the primary analysis of the primary endpoint achievement of $PASI_{90}$, the superiority of BI 90 mg + 180 mg vs. Stelara® was tested with Cochran-Mantel-Haenszel risk difference estimates stratified by the randomisation factors weight (≤100 kg vs. >100 kg) and prior exposure to tumour necrosis factor (TNF) antagonists with discontinuation due to lack of efficacy (<2 vs. ≥2). Secondary endpoints ($PASI_{75}$, $PASI_{100}$, $PASI_{50}$, and sPGA clear or almost clear) and further treatment comparisons (BI 18 mg, BI 90 mg, and BI 180 mg vs. Stelara®) were tested analogously.

Percentage of PASI reduction

The statistical significance of the difference in median percent change from baseline at Week 12 between BI 655066 treatment groups (BI 18 mg,

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BI 90 mg, BI 180 mg, and BI 90 mg + 180 mg) vs. Stelara® was tested with the van Elteren test.

Time to loss of $PASI_{50}$ response

BI 655066 treatment groups (BI 18 mg, BI 90 mg, BI 180 mg, and BI 90 mg + 180 mg) were tested vs. Stelara® using a stratified Kaplan-Meier estimate and the log-rank test.

An interim analysis, after all patients completed the Week 12 visits, was planned in the protocol and performed.

SUMMARY - CONCLUSIONS:

Trial Patients and Compliance with Trial Protocol:

In this study, a total of 231 patients were enrolled by 32 centres across Canada, Finland, France, Germany, Norway, Sweden, and USA. Of these patients, 166 were randomised in a 1:1:1:1 ratio to the 4 treatment groups (BI 18 mg: 43 patients; BI 90 mg: 41 patients; BI 180 mg: 42 patients; Stelara®: 40 patients). All 166 patients were treated with ≥1 dose of trial medication, with most patients receiving all 3 planned doses (94.0% overall). The proportion of patients that discontinued trial medication prematurely was higher in the BI 18 mg group (4 patients, 9.3%) than in the other treatment groups (BI 90 mg: 2 patients, 4.9%; BI 180 mg: 2 patients, 4.8%; Stelara®: 1 patient, 2.5%). Overall, 64.5% of patients completed the trial, i.e. both the 24-week treatment period and the 24-week follow-up period. Premature discontinuation from the trial was more common in the BI 18 mg group (29 patients, 67.4%) and the Stelara® group (19 patients, 47.5%) than in the other treatment groups (BI 90 mg: 4 patients, 9.8%; BI 180 mg: 7 patients, 16.7%). The main reason for premature discontinuation was roll-over to study 1311.13 by patients losing a $PASI_{50}$ response.

In general, the demographic data and baseline characteristics were balanced across the treatment groups. In the entire study population, there were more males (65.7%) than females (34.3%), and most patients were White (91.0%). The mean baseline age was 45.9 years (SD 13.5). The majority of patients had no prior exposure to TNF antagonists (73.5%). Baseline disease characteristics are summarised in Table 1.

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Trial Patients and Compliance with Trial Protocol (cont.):

Table 1 Baseline disease characteristics by treatment – FAS

	BI 18 mg	BI 90 mg	BI 180 mg	BI 90 mg + BI 180 mg	Stelara®
PASI total score					
Patients, N	43	41	42	83	39[1]
Median	16.2	15.6	18.3	16.5	19.2
(min, max)	(12.2, 38.5)	(12.2, 42.9)	(12.0, 52.0)	(12.0, 52.0)	(12.0, 35.2)
sPGA					
Patients, N	43	41	42	83	40[1]
Moderate, N (%)	27 (62.8)	26 (63.4)	26 (61.9)	52 (62.7)	18 (45.0)
Marked, N (%)	15 (34.9)	13 (31.7)	16 (38.1)	29 (34.9)	21 (52.5)
Severe, N (%)	1 (2.3)	2 (4.9)	0	2 (2.4)	0
NAPSI total score					
Patients, N	24	23	27	50	22
Median	22.0	27.0	25.0	26.5	26.5
(min, max)	(1.0, 62.0)	(4.0, 61.0)	(2.0, 64.0)	(2.0, 64.0)	(1.0, 80.0)
PSSI total score					
Patients, N	41	40	39	79	36
Median	18.0	15.0	21.0	18.0	22.5
(min, max)	(2.0, 54.0)	(3.0, 72.0)	(3.0, 66.0)	(3.0, 72.0)	(2.0, 60.0)
PPASI total score					
Patients, N	13	13	9	22	7
Median	5.4	2.4	3.6	3.2	7.1
(min, max)	(0.9, 13.2)	(0.8, 15.5)	(0.6, 43.0)	(0.6, 43.0)	(1.2, 27.6)

FAS: full analysis set; PASI: psoriasis area and severity index; sPGA: static physician global assessment; NAPSI: nail psoriasis severity index; PSSI: psoriasis scalp severity index; PPASI: palmoplantar psoriasis area severity index

[1] 1 patient excluded for taking prohibited concomitant medication Diprosone (active ingredient: betamethasone dipropionate)

Treatment compliance was high and comparable between treatment groups: overall, treatment compliance was 100.0% at Week 0, 98.2% at Week 4, and 94.6% at Week 16. Nearly all patients received all 3 planned doses of trial medication (94.0%).

Efficacy Results:

Psoriasis area severity index (PASI)

Achievement of $PASI_{90}$, $PASI_{75}$, $PASI_{50}$, and $PASI_{100}$

The analysis of the primary endpoint, achievement of $PASI_{90}$ at Week 12, is presented in Table 2. The proportion of patients that achieved $PASI_{90}$ at Week 12 was similar for the 2 higher doses of BI 655066 (BI 90 mg and BI 180 mg). A greater proportion of patients in these treatment groups achieved

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Efficacy Results (cont.):

$PASI_{90}$ than did in the BI 18 mg and Stelara® treatment groups. The proportion of patients that achieved $PASI_{90}$ at Week 12 was comparable between the BI 18 mg group and the Stelara® group. In the pre-specified primary analysis, BI 90 mg + 180 mg was superior to Stelara® in terms of achieving $PASI_{90}$. The effect of BI 180 mg was maintained up to Week 24, with the combined BI 90 mg + 180 mg doses remaining superior versus Stelara® with regard to achieving $PASI_{90}$.

Table 2 Achievement of $PASI_{90}$ at Week 12 and Week 24, Cochran-Mantel-Haenszel risk difference estimates – LOCF, FAS

	Analysed N	Achieved $PASI_{90}$ N (%)	BI 655066 vs. Stelara®		
			Estimated difference[1]	95% CI	p-value
Week 12					
BI 18 mg	43	14 (32.6)	-7.4	-27.5, 12.6	0.4667
BI 90 mg	41	30 (73.2)	33.0	12.9, 53.1	0.0013
BI 180 mg	42	34 (81.0)	39.5	20.5, 58.5	<0.0001
BI 90 mg + 180 mg	83	64 (77.1)	36.4	19.0, 53.8	<0.0001
Stelara®	40	16 (40.0)	–	–	–
Week 24					
BI 18 mg	43	13 (30.2)	-24.7	-44.6, -4.8	0.0150
BI 90 mg	41	27 (65.9)	10.1	-11.2, 31.3	0.3528
BI 180 mg	42	36 (85.7)	29.0	10.5, 47.6	0.0021
BI 90 mg + 180 mg	83	63 (75.9)	19.8	1.9, 37.7	0.0300
Stelara®	40	22 (55.0)	–	–	–

CI: confidence interval; LOCF: last observation carried forward; FAS: full analysis set
[1] Cochran-Mantel-Haenszel risk difference estimates stratified by the randomisation factors weight (≤100 kg vs. >100 kg) and prior exposure to TNF antagonists with discontinuation due to lack of efficacy (<2 vs. ≥2). A positive difference favours BI 655066 over Stelara®.

The proportion of patients that achieved $PASI_{75}$ at Week 12 was comparable between the 2 higher doses of BI 655066 (BI 90 mg and BI 180 mg). A greater proportion of patients in these treatment groups achieved $PASI_{75}$ than did in the BI 18 mg and Stelara® treatment groups. The proportion of patients that achieved $PASI_{75}$ at Week 12 was similar in the BI 18 mg group and the Stelara® group. The proportion of patients that achieved $PASI_{75}$ was significantly higher in the pooled BI 90 mg + 180 mg group than in the Stelara® group. The effect of the higher doses of BI 655066 (BI 90 mg and BI 180 mg) was maintained up to Week 24, with significantly more patients having achieved $PASI_{75}$ than in the Stelara® group. The analysis of the achievement of $PASI_{75}$ at Weeks 12 and 24 is presented in Table 3.

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Efficacy Results (cont.):

Table 3 Achievement of $PASI_{75}$ at Week 12 and Week 24, Cochran-Mantel-Haenszel risk difference estimates – LOCF, FAS

	Analysed N	Achieved $PASI_{75}$ N (%)	BI 655066 vs. Stelara® Estimated difference[1]	95% CI	p-value
Week 12					
BI 18 mg	43	29 (67.4)	-10.0	-28.4, 8.4	0.2866
BI 90 mg	41	40 (97.6)	18.0	4.4, 31.6	0.0096
BI 180 mg	42	38 (90.5)	10.8	-4.5, 26.0	0.1673
BI 90 mg + 180 mg	83	78 (94.0)	14.6	1.0, 28.2	0.0355
Stelara®	40	31 (77.5)	–	–	–
Week 24					
BI 18 mg	43	24 (55.8)	-14.2	-34.1, 5.8	0.1646
BI 90 mg	41	38 (92.7)	21.0	4.8, 37.2	0.0111
BI 180 mg	42	39 (92.9)	21.0	5.0, 37.0	0.0102
BI 90 mg + 180 mg	83	77 (92.8)	21.1	6.0, 36.2	0.0062
Stelara®	40	28 (70.0)	–	–	–

CI: confidence interval; LOCF: last observation carried forward; FAS: full analysis set
[1] Cochran-Mantel-Haenszel risk difference estimates stratified by the randomisation factors weight (≤100 kg vs. >100 kg) and prior exposure to TNF antagonists with discontinuation due to lack of efficacy (<2 vs. ≥2). A positive difference favours BI 655066 over Stelara®.

The proportion of patients achieving $PASI_{50}$ was numerically greater in all BI 655066 treatment groups than in the Stelara® group; the estimated difference for BI 90 mg versus Stelara® was statistically significant. The analysis of the achievement of $PASI_{50}$ at Week 12 is presented in Table 4.

Table 4 Achievement of $PASI_{50}$ at Week 12, Cochran-Mantel-Haenszel risk difference estimates – LOCF, FAS

	Analysed N	Achieved $PASI_{50}$ N (%)	BI 655066 vs. Stelara® Estimated difference[1]	95% CI	p-value
BI 18 mg	43	40 (93.0)	5.6	-7.0, 18.2	0.3834
BI 90 mg	41	41 (100.0)	12.1	1.5, 22.7	0.0250
BI 180 mg	42	40 (95.2)	7.5	-4.7, 19.6	0.2301
BI 90 mg + 180 mg	83	81 (97.6)	10.1	-0.8, 21.1	0.0706
Stelara®	40	35 (87.5)	–	–	–

CI: confidence interval; LOCF: last observation carried forward; FAS: full analysis set
[1] Cochran-Mantel-Haenszel risk difference estimates stratified by the randomisation factors weight (≤100 kg vs. >100 kg) and prior exposure to TNF antagonists with discontinuation due to lack of efficacy (<2 vs. ≥2). A positive difference favours BI 655066 over Stelara®.

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Efficacy Results (cont.):

The analysis of the achievement of $PASI_{100}$ at Week 12 is presented in Table 5. The proportion of patients achieving $PASI_{100}$ at Week 12 was significantly higher in the BI 90 mg and BI 180 mg treatment groups than in the Stelara® treatment group; the pooled analysis of BI 90 mg + BI 180 mg was also significant. The proportion of patients achieving $PASI_{100}$ at Week 12 was similar in the BI 18 mg and the Stelara® groups.

Table 5 Achievement of $PASI_{100}$ at Week 12, Cochran-Mantel-Haenszel risk difference estimates – LOCF, FAS

	Analysed N	Achieved $PASI_{100}$ N (%)	BI 655066 vs. Stelara®		
			Estimated difference[1]	95% CI	p-value
BI 18 mg	43	6 (14.0)	-3.6	-19.1, 11.9	0.6497
BI 90 mg	41	17 (41.5)	22.9	4.0, 41.8	0.0178
BI 180 mg	42	21 (50.0)	31.5	12.7, 50.3	0.0011
BI 90 mg + 180 mg	83	38 (45.8)	27.1	11.3, 42.9	0.0008
Stelara®	40	7 (17.5)	–	–	–

CI: confidence interval; LOCF: last observation carried forward; FAS: full analysis set
[1] Cochran-Mantel-Haenszel risk difference estimates stratified by the randomisation factors weight (≤100 kg vs. >100 kg) and prior exposure to TNF antagonists with discontinuation due to lack of efficacy (<2 vs. ≥2). A positive difference favours BI 655066 over Stelara®.

Time to loss of $PASI_{50}$

The time to first loss of $PASI_{50}$ response was significantly shorter for the 18 mg dose of BI 655066 than for Stelara®, whereas it was significantly longer for the BI 90 mg and BI 180 mg doses than for Stelara® (Table 6).

Table 6 Time to first loss of $PASI_{50}$ response – observed, FAS

	Analysed N	Time to loss of $PASI_{50}$ [days] Median (Q1,Q3)	BI 655066 vs. Stelara®[1]		
			Hazard ratio	95% CI	p-value
BI 18 mg	43	253 (192, 337)	2.0786	1.2, 3.7	0.0009
BI 90 mg	41	NC (NC, NC)	0.1825	0.1, 0.5	0.0002
BI 180 mg	42	NC (NC, NC)	0.1864	0.1, 0.5	0.0003
BI 90 mg + 180 mg	83	NC (NC, NC)	0.1844	0.1, 0.4	<0.0001
Stelara®	40	338 (224, NC)	–	–	–

CI: confidence interval; NC: not calculated; FAS: full analysis set

[1] P-values, hazard ratios, and CIs are calculated from a stratified log-rank test. Results are obtained from fitting a separate Kaplan Meier model for each treatment.

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Efficacy Results (cont.):

PASI reduction

By Week 12, the near-maximum mean percent reduction from baseline in PASI was achieved in all treatment groups. The mean observed reduction in PASI at Week 12 was -79.7% (SD 19.5) in the BI 18 mg group, -93.4% (SD 7.7) in the BI 90 mg group, -90.7% (SD 23.1) in the BI 180 mg group, and -82.1% (SD 19.5) in the Stelara® group.

Static physicians global assessment

The proportion of patients who achieved sPGA clear or almost clear at Week 12 was comparable between the 2 higher doses of BI 655066 (BI 90 mg and BI 180 mg). A greater proportion of patients in these treatment groups achieved sPGA clear or almost clear than did in the BI 18 mg and Stelara® treatment groups. The proportion of patients that achieved sPGA clear or almost clear at Week 12 was similar in the BI 18 mg group and the Stelara® group. The proportion of patients that achieved sPGA clear or almost clear was significantly higher in the pooled BI 90 mg + 180 mg group than in the Stelara® group. The analysis of the achievement of sPGA clear or almost clear at Week 12 is presented in Table 7.

Table 7 Achievement of sPGA clear or almost clear at Week 12, Cochran-Mantel-Haenszel risk difference estimates – LOCF, FAS

	Analysed N	Achieved sPGA clear or almost clear N (%)	BI 655066 vs. Stelara®		
			Estimated difference[1]	95% CI	p-value
BI 18 mg	43	27 (62.8)	-4.6	-24.3, 15.1	0.6459
BI 90 mg	41	37 (90.2)	21.2	4.5, 37.9	0.0126
BI 180 mg	42	38 (90.5)	20.9	4.3, 37.4	0.0136
BI 90 mg + 180 mg	83	75 (90.4)	21.2	5.7, 36.6	0.0072
Stelara®	40	27 (67.5)	–	–	–

CI: confidence interval; LOCF: last observation carried forward; FAS: full analysis set
[1] Cochran-Mantel-Haenszel risk difference estimates stratified by the randomisation factors weight (≤100 kg vs. >100 kg) and prior exposure to TNF antagonists with discontinuation due to lack of efficacy (<2 vs. ≥2). A positive difference favours BI 655066 over Stelara®.

Safety Results:

All 166 randomised patients were treated with study medication and were thus all included in the analysis set for safety.

The frequency of patients reported with ≥1 AE decreased with increasing dose of BI 655066 (BI 18 mg: 35 patients, 81.4%; BI 90 mg: 33 patients,

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Safety Results (cont.):

80.5%; BI 180 mg: 29 patients, 69.0%). In the Stelara® group, the frequency was similar to the BI 180 mg group (29 patients, 72.5%). Most AEs were of mild or moderate intensity, while AEs of severe intensity were reported for ≤10% of patients per treatment group (BI 18 mg: 9.3%; BI 90 mg: 7.3%; BI 180 mg: 2.4%; Stelara®: 10.0%). Only 1 AE of severe intensity was assessed by the investigator as drug related: severe bronchitis reported in the Stelara® group. There was only 1 AE of life-threatening intensity (Rheumatology Common Toxicity Criteria grade): an abnormal liver function test in the BI 90 mg group. The AE was not considered by the investigator to be serious or drug related.

In total, 3 AEs were reported that led to premature discontinuation of the patient: 1 patient each in the BI 18 mg (allergy to arthropod bite), BI 90 mg (pyelonephritis), and Stelara® (psoriasis) treatment groups. All 3 AEs occurred during the follow-up period of the trial.

In general, the proportion of patients reported with drug-related AEs was low. The overall frequency of AEs assessed by the investigator as drug related was highest in the BI 90 mg group, and lowest in the BI 180 mg group (BI 18 mg: 7 patients, 16.3%; BI 90 mg: 10 patients, 24.4%; BI 180 mg: 6 patients, 14.3%; Stelara®: 8 patients, 20.0%). The most frequently reported AE assessed by the investigator as being drug related was nasopharyngitis (BI 18 mg: 1 patient, 2.3%; BI 90 mg: 3 patients, 7.3%; BI 180 mg: 2 patients, 4.8%; Stelara®: 0 patients).

There were no deaths in this trial.

In general, SAEs were not reported at a high frequency in this trial (8.4% of patients overall). While the frequency of SAEs was slightly higher in the BI 18 mg (5 patients, 11.6%) and BI 90 mg (6 patients, 14.6%) groups than in the Stelara® group (3 patients, 7.5%), there were no SAEs reported in the BI 180 mg group. The only SAE to be reported for >1 patient was basal cell carcinoma (1 patient each in the BI 18 mg and BI 90 mg groups – only the event in the BI 90 mg group was assessed by the investigator as drug related); none of the SAEs were reported for >1 patient in a given treatment group.

No protocol-specified AESIs (hepatic injury defined by particular alterations of liver parameters) were reported during the trial.

There were no clinically relevant changes or findings in the clinical-laboratory evaluation of safety.

There were no clinically relevant changes from baseline in vital signs

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Safety Results (cont.):	(systolic and diastolic blood pressure, heart rate, breathing rate, and temperature).
Conclusions:	In patients with moderate to severe chronic plaque-type psoriasis, the pooled analysis of BI 90 mg + 180 mg was superior to treatment with Stelara® in terms of the proportion of patients that achieved a ≥90% reduction from baseline PASI score ($PASI_{90}$) at Week 12; the effect was maintained over time and was still present at Week 48. In addition, the proportion of patients that achieved $PASI_{75}$, $PASI_{100}$, and sPGA clear or almost clear at Week 12 was significantly higher for the pooled analysis of BI 90 mg + 180 mg than in the Stelara® treatment group; this treatment difference also persisted over time. Overall, BI 655066 was safe and well tolerated. In summary, the benefit-risk profile of BI 655066, administered subcutaneously in 18 mg, 90 mg, and 180 mg dose regimens, was favourable in patients with moderate to severe chronic plaque-type psoriasis.