

11. EFFICACY RESULTS

Efficacy criteria were systolic and diastolic blood pressures. No primary efficacy criterion was defined as the main objective was to study the safety of S 90052/S 90652.

The results given hereafter correspond to the analyses defined in the statistical analysis plan.

Missing values were not replaced. The time since last treatment intake is presented in [Section 15.2.3](#).

Individual data are presented in [Appendix 16.2.7](#). Supportive information is given in [Section 15.2](#).

11.1. Evolution of blood pressures over time

11.1.1. SBP

Mean changes in SBP from baseline (inclusion visit before treatment intake) to D120, M24 and to the last value in the FAS are presented in [Table \(11.1.1\) 1](#).

In patients from **Subgroup A**, *i.e.* not previously treated for arterial hypertension, the mean SBP decreased by -8.8 ± 8.8 mmHg from inclusion to the end of short-term period (D120), and then remained stable during the extension period (M24 and last value).

In **Subgroup B**, the mean SBP tended to remain stable or slightly decreased from inclusion to D120, M24 and to the last value under treatment, consistently with the definition of the subgroup (hypertensive patients with BP controlled by their previous treatment). This result suggests that the control of BP was maintained under perindopril treatment.

In patients from **Subgroup C**, *i.e.* with previously treated uncontrolled arterial hypertension, the mean SBP decreased during the short-term period by -8.6 ± 15.8 mmHg and then remained stable during the extension period (last value).

In the FAS-24, the evolution of the mean SBP was close to that in the FAS:

- Regarding the change between baseline and D120, the mean SBP decreased by -8.8 ± 8.8 mmHg in Subgroup A, by -3.6 ± 12.1 mmHg in Subgroup B and by -8.6 ± 15.8 mmHg in Subgroup C.
- Regarding the change between baseline and M24, the mean SBP decreased by -7.2 ± 11.8 mmHg in Subgroup A, by -1.8 ± 14.6 mmHg in Subgroup B and by -13.0 ± 13.4 mmHg in Subgroup C.
- Regarding the change from baseline to the last value, the mean SBP decreased by -7.8 ± 10.7 mmHg in Subgroup A, and by -9.6 ± 13.0 mmHg in Subgroup C, while it remained stable in Subgroup B (1.4 ± 15.9 mmHg).

Table (11.1.1) 1 - Changes in SBP (mmHg) over time - FAS

		All (N = 61)	Subgroup A (N = 5)	Subgroup B (N = 51)	Subgroup C (N = 5)
INCLUSION		116.6 ± 13.6	124.0 ± 8.9	114.9 ± 13.6	126.8 ± 12.3
D120	n	59	5	49	5
	Mean ± SD	112.5 ± 14.7	115.2 ± 5.5	111.7 ± 14.9	118.2 ± 19.5
Change from inclusion	Mean ± SD	-3.4 ± 14.5	-8.8 ± 8.8	-2.3 ± 14.8	-8.6 ± 15.8
	E (SE)	-3.4 (1.89)	-8.8 (3.92)	-2.3 (2.12)	-8.6 (7.05)
	95% CI	[-7.1 ; 0.4]	[-19.7 ; 2.1]	[-6.5 ; 2.0]	[-28.2 ; 11.0]
M12	n	52	5	42	5
	Mean ± SD	111.9 ± 12.1	109.4 ± 6.2	111.2 ± 10.7	119.8 ± 23.5
Change from inclusion	Mean ± SD	-4.9 ± 13.8	-14.6 ± 11.8	-3.5 ± 13.3	-7.0 ± 18.2
M24	n	48	5	38	5
	Mean ± SD	113.5 ± 12.3	116.8 ± 4.6	113.0 ± 12.4	113.8 ± 17.9
Change from inclusion	Mean ± SD	-3.8 ± 14.3	-7.2 ± 11.8	-2.1 ± 14.5	-13.0 ± 13.4
Last value	n	61	5	51	5
	Mean ± SD	115.9 ± 13.3	116.2 ± 5.4	115.7 ± 14.3	117.2 ± 8.2
Change from inclusion	Mean ± SD	-0.8 ± 16.0	-7.8 ± 10.7	0.8 ± 16.4	-9.6 ± 13.0
	E (SE)	-0.8 (2.05)	-7.8 (4.77)	0.8 (2.29)	-9.6 (5.84)
	95% CI	[-4.8 ; 3.3]	[-21.0 ; 5.4]	[-3.8 ; 5.4]	[-25.8 ; 6.6]

Inclusion = B00A

As regards **Subgroups D and E**:

- In Subgroup D (N = 29, concomitant anti-hypertensive treatment started or modified after the first drug intake), the mean SBP slightly decreased from inclusion to the last value by -2.5 ± 16.9 mmHg.
- In patients from Subgroup E (N = 32, no concomitant anti-hypertensive treatment started or modified after the first drug intake), the mean SBP remained stable, with a mean change between baseline and the last value of 0.8 ± 15.2 mmHg.

Values of SBP at each visit and the changes from baseline to each visit, in the FAS (overall population and subgroups) are described in [Section 15.2.1.1.](#), together with results in the FAS-24.

11.1.2. DBP

Mean changes in DBP from baseline to D120, M24 and the last value during the study, in the FAS are presented in [Table \(11.1.2\) 1.](#)

In patients from **Subgroup A**, *i.e.* not previously treated for arterial hypertension, the mean DBP decreased by -13.6 ± 13.4 mmHg, from inclusion to D120 and then remained stable during the extension period (M24 and last value).

In **Subgroup B**, the mean DBP tended to remain stable from inclusion to D120, M24 and to the last value under treatment, consistently with the definition of the subgroup (hypertensive patients with BP controlled by their previous treatment).