The study listed may include approved and non-approved uses, formulations or treatment regimens. The results reported in any single study may not reflect the overall results obtained on studies of a product. Before prescribing any product mentioned in this Register, healthcare professionals should consult prescribing information for the product approved in their country.

Study No.: 106227 (TUBERCULOSIS-005), 106228 (TUBERCULOSIS-006 EXT:005 Y1), 108736 (TUBERCULOSIS-007 EXT: 005 Y2), 108738 (TUBERCULOSIS-008 EXT: 005 Y3)

Title: Observer-blinded, randomised, controlled, phase I/II study, to evaluate the safety, reactogenicity and immunogenicity of GSK Biologicals' candidate tuberculosis vaccines M72/AS01B and M72/AS02A when administered intramuscularly according to a vaccination schedule of 0, 1 month, to healthy PPD-negative adults aged 18 to 50 years.
M72/AS01B (TB 1): GlaxoSmithKline (GSK) Biologicals' candidate recombinant *Mycobacterium tuberculosis (M. tuberculosis*) vaccine, formulation 1.
M72/AS02A (TB 2): GSK Biologicals' candidate recombinant *M. tuberculosis* vaccine, formulation 2.
PPD: purified protein derivative

Rationale: The aim of the study was to assess the safety and immunogenicity of 2 doses of TB 1 or TB 2 vaccine in healthy purified protein derivative (PPD)-negative adults. In addition, two active comparators (GSK Biologicals' candidate, non-adjuvanted recombinant *M. tuberculosis* vaccine and the Mtb72F/AS02A vaccine) and an adjuvant alone control were evaluated alongside The study included an Active Vaccination Phase, up to Month 2, followed by a Follow-up Phase, up to the study end at Month 36. Safety and immunogenicity were assessed up until 1 month post-Dose 2 (Month 2) and 1 year after vaccination (Month 12/Year 1) for all vaccines, and up until 2 and 3 years (Months 24 & 36) for the TB 1 and TB 2 vaccines only..
Mtb72F/AS02A (TB 3): GSK Biologicals' candidate recombinant *M. tuberculosis* vaccine, formulation 3.
(TB 4): GSK Biologicals' candidate recombinant *M. tuberculosis* vaccine, non-adjuvanted.

Phase: I/II

Study Period:
106227 (TUBERCULOSIS-005): 13 November 2006 to 12 March 2007.
106228 (TUBERCULOSIS-006): 03 December 2007 to 25 January 2008.
108736 (TUBERCULOSIS-007): 02 December 2008 to 19 December 2008.
108738 (TUBERCULOSIS-008): 18 November 2009 to 01 December 2009.

Study Design: Observer-blinded, randomised (4:4:1:1:1), controlled study with 5 groups.
Note: Subjects were evaluated in an observer-blinded manner up to Subjects were evaluated in an observer-blinded manner up to ill Month 2, and then in an open manner up to the study end at Month 36.
For Years 2 and 3 follow-up periods, only the subjects in the groups receiving the TB 1 and TB 2 vaccines were considered.

Centres: 1 centre in Belgium.

Indication: Immunisation against *M. tuberculosis* infection in healthy adults between the ages of 18-50 years who never had *M. tuberculosis* infection or disease.

Treatment: The study groups were as follows:

- TB 1 Group: Subjects received 2 doses of TB 1 vaccine.
- TB 2 Group: Subjects received 2 doses of TB 2 vaccine.
- TB 3 Group: Subjects received 2 doses of the comparator TB 3 vaccine.
- TB 4 Group: Subjects received 2 doses of the comparator TB 4 vaccine.
- Control Group: Subjects received 2 doses of adjuvant alone.

All vaccines were administered intramuscularly in the deltoid muscle of the non-dominant arm at Month 0 and Month 1. No vaccine was administered during the follow-up period, when only blood samples were collected.

Objectives:

- To evaluate the safety of the TB 1 and TB 2 vaccines and the comparator vaccines (TB 3 and TB 4 vaccines, and adjuvant control) when given according to a 0, 1 month schedule in healthy PPD-negative adults aged 18 to 50 years.

Primary Outcome/Efficacy Variable:
Safety

- Occurrence, intensity and relationship to vaccination of solicited local and general symptoms during the 7-day follow-up period following vaccination (day of vaccination and 6 subsequent days) after each vaccine dose in each group.
- Occurrence, intensity and relationship to vaccination of unsolicited symptoms during the 30-day follow-up period following vaccination (day of vaccination and 29 subsequent days) after each vaccine dose in each group.
- Occurrence and relationship to vaccination of serious adverse events (SAEs) during the entire study period in each

group.
- Haematological and biochemical levels, at Days 0, 1, 7, 30, 31, 37 and 60 in each group.

Secondary Outcome/Efficacy Variable(s):

Immunogenicity

- Antibody titres to *M. tuberculosis* fusion proteins M72 and Mtb72F as measured by Enzyme-linked immunosorbent assay (ELISA) and measured at
  - Day 0, prior to Dose 2 (Month 1), 1 month post-Dose 2 (Month 2) and Year 1 (Month 12) in all groups.
  - Years 2 and 3 (Months 24 and 36) for the TB 1 and TB 2 groups.
- Antigen-specific cluster of differentiation 4/8 (CD4+/CD8+) T cells* expressing cytokines by flow cytometry using intracellular cytokine staining (ICS) on frozen peripheral blood mononuclear cell (PBMCs) and measured at (1) Day 0, prior to Dose 2 (Month 1), 1 month post-Dose 2 (Month 2) and Year 1 (Month 12) in all groups, and (2) at Years 2 and 3 (Months 24 and 36) for the TB 1 and TB 2 groups:
  - Frequency of antigen-specific CD4/CD8 T cells per 10^6 cells producing at least two different cytokines (interleukin-2 [IL-2] and/or interferon-γ [IFN-γ] and/or tumour necrosis factor-α [TNF-α] and/or cluster of differentiation 40-ligand [CD40-L]).£
  - Frequency of antigen-specific CD4/CD8 T cells per 10^6 cells producing at least CD40L and another signal molecule (IL-2 or IFN-γ or TNF-α).
  - Frequency of antigen-specific CD4/CD8 T cells per 10^6 cells producing at least IL-2 and another signal molecule (CD40L or IFN-γ or TNF-α).
  - Frequency of antigen-specific CD4/CD8 T cells per 10^6 cells producing at least TNF-α and another signal molecule (IL-2 or IFN-γ or CD40L).
  - Frequency of antigen-specific CD4/CD8 T cells per 10^6 cells producing at least IFN-γ and another signal molecule (CD40L or IL-2 or TNF-α).
- Frequency of cells expressing cytokines above cut-off measured at£*:
  - Day 0, prior to Dose 2 (Month 1), 1 month post-Dose 2 (Month 2) and Year 1 (Month 12) in all groups
  - Years 2 and 3 (Months 24 and 36) for the TB 1 and TB 2 groups.
- Concentration of IFN-γ produced in serum samples collected prior to vaccination and 1 day post vaccination in each group.
- Concentration of TNF-α produced in serum samples collected prior to vaccination, 1-2 hours post-vaccination and 1 day post-vaccination in each group.*

£ The cut-off value used for analysis of the frequency of cells expressing cytokines/immune markers was the 313 CD4+ T cells per million CD4+ T cells, i.e. the 95th percentile of the pre-vaccination level of cells expressing cytokines/immune markers.
* No vaccine induced responses were observed for CD8+ T cells and serum TNF-a, so no results are presented.

Statistical Methods:

The analyses were performed on the Total Vaccinated cohort and the According-To-Protocol (ATP) cohort for immunogenicity:

- The Total Vaccinated cohort included all subjects with at least one vaccine administration documented.
- The ATP cohort for immunogenicity included all evaluable subjects (i.e. those meeting all eligibility criteria, complying with the procedures defined in the protocol, with no elimination criteria during the study) for whom data concerning immunogenicity outcome measures were available.

Analysis of Immunogenicity

The analysis was performed on ATP cohort for immunogenicity.
For each group at each time point that a blood sample result was available, seropositivity* rates and geometric mean concentrations (GMCs) for M72, Mtb72F antibodies , serum IFN-γ and serum TNF-α levels were calculated with 95% confidence interval (CI).
Descriptive statistics of the frequency of M72-specific CD4/CD8+T cells and the percentage of responders for M72-specific CD4+T cells (expressing at least one or 2 different cytokines/activation markers using the 95th percentile of the pre-vaccination level as cut-off) were also tabulated.
*A seropositive subject was a subject whose antibody concentration was equal or higher than cut-off (2.8 EU/mL for M72 antibodies, 1.0 EU/mL for Mtb72F antibodies, 1pg/mL for IFN-γ antibodies, and 1.106 pg/mL for TNF-α antibodies).

Analysis of Safety

The analysis was based on the Total Vaccinated cohort.
The percentages of subjects reporting each individual solicited local and general symptoms, grade 3 and related (general) symptoms during the 7-day follow-up period after vaccination (Days 0-6) were tabulated with exact 95% CIs.
The percentage of subjects with at least one report of unsolicited adverse event (AE), classified by the Medical Dictionary for

Regulatory Activities (MedDRA) and reported within the 30-day after vaccination (Days 0-29), was tabulated. The same tabulation was performed for grade 3 unsolicited AEs and unsolicited AEs with relationship to vaccination. SAEs classified by MedDRA preferred terms were tabulated during the entire study period. Distribution of haematological and biochemical parameters with respect to normal laboratory ranges was tabulated at Days 0, 7, 30, 37 and 60 in each group. Descriptive statistics for Immunoglobulin E (IgE) and C-reactive protein (CRP) were measured in each group at Days 0, 1, 7, 30, 31, and 37.

Study Population: Healthy male or female subjects between, and including, 18 to 50 years of age at the time of first vaccination, who tested negative for the PPD test and had no evidence of pulmonary pathology as confirmed by chest X-ray. The subjects were seronegative for Human Immunodeficiency Virus 1 and 2 (HIV-1/2) antibodies, hepatitis B surface antigen (HBsAg) and hepatitis C virus (HCV) antibodies. Women were of non-childbearing potential, or if of childbearing potential, had to be abstinent or had to have used adequate contraceptive precautions for 30 days prior to vaccination and had to continue such precautions for the duration of the study. Written informed consent was obtained from the subject prior to any study procedure. During the Years 2 and 3 follow-up periods, only subjects who received TB 1 or TB 2 vaccines in the primary 106227 study were included.

Number of Subjects:	TB 1 Group	TB 2 Group	TB 3 Group	TB 4 Group	Control Group
Planned, N	40	40	10	10	10
Randomised, N (Total Vaccinated cohort)	40	40	10	10	10
Completed at Day 60, n (%)	40 (100)	40 (100)	10 (100)	10 (100)	10 (100)
Completed at Year 1, n (%)	40 (100)	40 (100)	10 (100)	10 (100)	10 (100)
Completed at Year 2, n (%)	32 (80.0)	37 (92.5)	Not Applicable	Not Applicable	Not Applicable
Completed at Year 3, n (%)	28 (70.0)	31 (77.5)	Not Applicable	Not Applicable	Not Applicable
Total Number Subjects Withdrawn, n (%)	12 (30.0)	9 (22.5)	0 (0.0)	0 (0.0)	0 (0.0)
Withdrawn due to Adverse Events n (%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Withdrawn due to Lack of Efficacy n (%)	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Withdrawn for other reasons n (%)	12 (30.0)	9 (22.5)	0 (0.0)	0 (0.0)	0 (0.0)
Demographics	TB 1 Group	TB 2 Group	TB 3 Group	TB 4 Group	Control Group
N, (Total Vaccinated cohort)	40	40	10	10	10
Females: Males	24:16	23:17	9:1	4:6	7:3
Mean Age, years (SD)	25.0 (6.50)	26.4 (7.97)	28.5 (6.95)	24.8 (5.33)	25.9 (7.95)
White - caucasian/European heritage, n, (%)	38 (95.0)	39 (97.5)	10 (100)	10 (100)	10 (100)

Primary Efficacy Results: Percentage of subjects with solicited local symptoms reported during the 7-day (Days 0-6) post-vaccination period (Total Vaccinated cohort).

Symptom	Intensity	TB 1 Group					TB 2 Group				
					95% CI					95% CI	
		N	n	%	LL	UL	N	n	%	LL	UL
Dose 1											
Pain	Any	40	38	95.0	83.1	99.4	40	40	100	91.2	100
	Grade 3	40	7	17.5	7.3	32.8	40	5	12.5	4.2	26.8
Redness	Any	40	4	10.0	2.8	23.7	40	2	5.0	0.6	16.9
	> 50 mm	40	2	5.0	0.6	16.9	40	2	5.0	0.6	16.9
Swelling	Any	40	4	10.0	2.8	23.7	40	8	20.0	9.1	35.6
	> 50 mm	40	2	5.0	0.6	16.9	40	3	7.5	1.6	20.4
Dose 2											
Pain	Any	40	39	97.5	86.8	99.9	40	37	92.5	79.6	98.4
	Grade 3	40	7	17.5	7.3	32.8	40	4	10.0	2.8	23.7
Redness	Any	40	10	25.0	12.7	41.2	40	2	5.0	0.6	16.9
	> 50 mm	40	6	15.0	5.7	29.8	40	0	0.0	0.0	8.8
Swelling	Any	40	7	17.5	7.3	32.8	40	9	22.5	10.8	38.5
	> 50 mm	40	1	2.5	0.1	13.2	40	3	7.5	1.6	20.4
Across Doses											
Pain	Any	40	40	100	91.2	100	40	40	100	91.2	100
	Grade 3	40	13	32.5	18.6	49.1	40	6	15.0	5.7	29.8
Redness	Any	40	12	30.0	16.6	46.5	40	4	10.0	2.8	23.7
	> 50 mm	40	6	15.0	5.7	29.8	40	2	5.0	0.6	16.9

Swelling	Any		40	9	22.5	10.8	38.5	40	10	25.0	12.7	41.2				
	> 50 mm		40	3	7.5	1.6	20.4	40	4	10.0	2.8	23.7				
Symptom	Intensity	TB 3 Group					TB 4 Group					Control Group				
					95% CI					95% CI					95% CI	
		N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Dose 1																
Pain	Any	10	9	90.0	55.5	99.7	10	1	10.0	0.3	44.5	10	10	100	69.2	100
	Grade 3	10	4	40.0	12.2	73.8	10	0	0.0	0.0	30.8	10	1	10.0	0.3	44.5
Redness	Any	10	0	0.0	0.0	30.8	10	0	0.0	0.0	30.8	10	1	10.0	0.3	44.5
	> 50 mm	10	0	0.0	0.0	30.8	10	0	0.0	0.0	30.8	10	0	0.0	0.0	30.8
Swelling	Any	10	2	20.0	2.5	55.6	10	0	0.0	0.0	30.8	10	2	20.0	2.5	55.6
	> 50 mm	10	0	0.0	0.0	30.8	10	0	0.0	0.0	30.8	10	1	10.0	0.3	44.5
Dose 2																
Pain	Any	10	9	90.0	55.5	99.7	10	2	20.0	2.5	55.6	10	10	100	69.2	100
	Grade 3	10	2	20.0	2.5	55.6	10	0	0.0	0.0	30.8	10	0	0.0	0.0	30.8
Redness	Any	10	1	10.0	0.3	44.5	10	1	10.0	0.3	44.5	10	1	10.0	0.3	44.5
	> 50 mm	10	0	0.0	0.0	30.8	10	1	10.0	0.3	44.5	10	1	10.0	0.3	44.5
Swelling	Any	10	4	40.0	12.2	73.8	10	1	10.0	0.3	44.5	10	2	20.0	2.5	55.6
	> 50 mm	10	2	20.0	2.5	55.6	10	1	10.0	0.3	44.5	10	1	10.0	0.3	44.5
Across Doses																
Pain	Any	10	10	100	69.2	100	10	2	20.0	2.5	55.6	10	10	100	69.2	100
	Grade 3	10	4	40.0	12.2	73.8	10	0	0.0	0.0	30.8	10	1	10.0	0.3	44.5
Redness	Any	10	1	10.0	0.3	44.5	10	1	10.0	0.3	44.5	10	2	20.0	2.5	55.6
	> 50 mm	10	0	0.0	0.0	30.8	10	1	10.0	0.3	44.5	10	1	10.0	0.3	44.5
Swelling	Any	10	5	50.0	18.7	81.3	10	1	10.0	0.3	44.5	10	3	30.0	6.7	65.2
	> 50 mm	10	2	20.0	2.5	55.6	10	1	10.0	0.3	44.5	10	1	10.0	0.3	44.5

N = number of subjects with at least one administered dose
n (%) = number (percentage) of subjects reporting at least once the symptom
95%CI = exact 95% confidence interval; LL = lower limit, UL = upper limit
Any = occurrence of any local symptom regardless of intensity grade
Grade 3 Pain = pain that prevented normal activity

Primary Efficacy Results: Percentage of subjects with solicited general symptoms reported during the 7-day (Days 0-6) post-vaccination period (Total Vaccinated cohort).

Symptom	Intensity/ Relationship	TB 1 Group					TB 2 Group				
					95% CI					95% CI	
		N	n	%	LL	UL	N	n	%	LL	UL
Dose 1											
Fatigue	Any	40	27	67.5	50.9	81.4	40	21	52.5	36.1	68.5
	Grade 3	40	0	0.0	0.0	8.8	40	1	2.5	0.1	13.2
	Related	40	26	65.0	48.3	79.4	40	19	47.5	31.5	63.9
Fever (Axillary)	≥ 37.5 °C	40	5	12.5	4.2	26.8	40	2	5.0	0.6	16.9
	> 39.5°C	40	0	0.0	0.0	8.8	40	0	0.0	0.0	8.8
	Related	40	3	7.5	1.6	20.4	40	2	5.0	0.6	16.9
Gastro-intestinal symptoms	Any	40	9	22.5	10.8	38.5	40	7	17.5	7.3	32.8
	Grade 3	40	1	2.5	0.1	13.2	40	0	0.0	0.0	8.8
	Related	40	6	15.0	5.7	29.8	40	7	17.5	7.3	32.8
Headache	Any	40	19	47.5	31.5	63.9	40	12	30.0	16.6	46.5
	Grade 3	40	0	0.0	0.0	8.8	40	0	0.0	0.0	8.8
	Related	40	15	37.5	22.7	54.2	40	11	27.5	14.6	43.9
Dose 2											
Fatigue	Any	40	33	82.5	67.2	92.7	40	24	60.0	43.3	75.1
	Grade 3	40	4	10.0	2.8	23.7	40	2	5.0	0.6	16.9
	Related	40	33	82.5	67.2	92.7	40	23	57.5	40.9	73.0
Fever (Axillary)	≥ 37.5 °C	40	24	60.0	43.3	75.1	40	10	25.0	12.7	41.2

	> 39.5°C	40	0	0.0	0.0	8.8	40	0	0.0	0.0	8.8
	Related	40	24	60.0	43.3	75.1	40	10	25.0	12.7	41.2
Gastro-intestinal symptoms	Any	40	18	45.0	29.3	61.5	40	10	25.0	12.7	41.2
	Grade 3	40	2	5.0	0.6	16.9	40	2	5.0	0.6	16.9
	Related	40	17	42.5	27.0	59.1	40	8	20.0	9.1	35.6
Headache	Any	40	32	80.0	64.4	90.9	40	22	55.0	38.5	70.7
	Grade 3	40	8	20.0	9.1	35.6	40	2	5.0	0.6	16.9
	Related	40	32	80.0	64.4	90.9	40	19	47.5	31.5	63.9
Across Doses											
Fatigue	Any	40	36	90.0	76.3	97.2	40	29	72.5	56.1	85.4
	Grade 3	40	4	10.0	2.8	23.7	40	3	7.5	1.6	20.4
	Related	40	36	90.0	76.3	97.2	40	28	70.0	53.5	83.4
Fever (Axillary)	≥ 37.5 °C	40	25	62.5	45.8	77.3	40	10	25.0	12.7	41.2
	> 39.5°C	40	0	0.0	0.0	8.8	40	0	0.0	0.0	8.8
	Related	40	25	62.5	45.8	77.3	40	10	25.0	12.7	41.2
Gastro-intestinal symptoms	Any	40	23	57.5	40.9	73.0	40	10	25.0	12.7	41.2
	Grade 3	40	3	7.5	1.6	20.4	40	2	5.0	0.6	16.9
	Related	40	20	50.0	33.8	66.2	40	9	22.5	10.8	38.5
Headache	Any	40	33	82.5	67.2	92.7	40	27	67.5	50.9	81.4
	Grade 3	40	8	20.0	9.1	35.6	40	2	5.0	0.6	16.9
	Related	40	32	80.0	64.4	90.9	40	24	60.0	43.3	75.1

Symptom	Intensity/ Relationship	TB 3 Group					TB 4 Group					Control Group				
					95% CI					95% CI					95% CI	
		N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Dose 1																
Fatigue	Any	10	6	60.0	26.2	87.8	10	2	20.0	2.5	55.6	10	3	30.0	6.7	65.2
	Grade 3	10	0	0.0	0.0	30.8	10	1	10.0	0.3	44.5	10	0	0.0	0.0	30.8
	Related	10	5	50.0	18.7	81.3	10	2	20.0	2.5	55.6	10	3	30.0	6.7	65.2
Fever (Axillary)	≥ 37.5 °C	10	1	10.0	0.3	44.5	10	0	0.0	0.0	30.8	10	1	10.0	0.3	44.5
	> 39.5°C	10	0	0.0	0.0	30.8	10	0	0.0	0.0	30.8	10	0	0.0	0.0	30.8
	Related	10	0	0.0	0.0	30.8	10	0	0.0	0.0	30.8	10	1	10.0	0.3	44.5
Gastro-intestinal symptoms	Any	10	3	30.0	6.7	65.2	10	2	20.0	2.5	55.6	10	1	10.0	0.3	44.5
	Grade 3	10	0	0.0	0.0	30.8	10	0	0.0	0.0	30.8	10	0	0.0	0.0	30.8
	Related	10	1	10.0	0.3	44.5	10	1	10.0	0.3	44.5	10	1	10.0	0.3	44.5
Headache	Any	10	9	90.0	55.5	99.7	10	2	20.0	2.5	55.6	10	3	30.0	6.7	65.2
	Grade 3	10	1	10.0	0.3	44.5	10	0	0.0	0.0	30.8	10	0	0.0	0.0	30.8
	Related	10	4	40.0	12.2	73.8	10	1	10.0	0.3	44.5	10	3	30.0	6.7	65.2
Dose 2																
Fatigue	Any	10	7	70.0	34.8	93.3	10	2	20.0	2.5	55.6	10	6	60.0	26.2	87.8
	Grade 3	10	0	0.0	0.0	30.8	10	0	0.0	0.0	30.8	10	1	10.0	0.3	44.5
	Related	10	7	70.0	34.8	93.3	10	1	10.0	0.3	44.5	10	4	40.0	12.2	73.8
Fever (Axillary)	≥ 37.5 °C	10	4	40.0	12.2	73.8	10	0	0.0	0.0	30.8	10	1	10.0	0.3	44.5
	> 39.5°C	10	0	0.0	0.0	30.8	10	0	0.0	0.0	30.8	10	1	10.0	0.3	44.5
	Related	10	4	40.0	12.2	73.8	10	0	0.0	0.0	30.8	10	0	0.0	0.0	30.8
Gastro-intestinal symptoms	Any	10	3	30.0	6.7	65.2	10	2	20.0	2.5	55.6	10	2	20.0	2.5	55.6
	Grade 3	10	0	0.0	0.0	30.8	10	1	10.0	0.3	44.5	10	0	0.0	0.0	30.8
	Related	10	3	30.0	6.7	65.2	10	1	10.0	0.3	44.5	10	1	10.0	0.3	44.5
Headache	Any	10	6	60.0	26.2	87.8	10	2	20.0	2.5	55.6	10	4	40.0	12.2	73.8
	Grade 3	10	0	0.0	0.0	30.8	10	0	0.0	0.0	30.8	10	1	10.0	0.3	44.5
	Related	10	6	60.0	26.2	87.8	10	1	10.0	0.3	44.5	10	3	30.0	6.7	65.2
Across Doses																
Fatigue	Any	10	8	80.0	44.4	97.5	10	3	30.0	6.7	65.2	10	6	60.0	26.2	87.8
	Grade 3	10	0	0.0	0.0	30.8	10	1	10.0	0.3	44.5	10	1	10.0	0.3	44.5
	Related	10	7	70.0	34.8	93.3	10	3	30.0	6.7	65.2	10	5	50.0	18.7	81.3

Fever (Axillary)	≥ 37.5 °C	10	4	40.0	12.2	73.8	10	0	0.0	0.0	30.8	10	1	10.0	0.3	44.5
	> 39.5°C	10	0	0.0	0.0	30.8	10	0	0.0	0.0	30.8	10	1	10.0	0.3	44.5
	Related	10	4	40.0	12.2	73.8	10	0	0.0	0.0	30.8	10	1	10.0	0.3	44.5
Gastro-intestinal symptoms	Any	10	5	50.0	18.7	81.3	10	2	20.0	2.5	55.6	10	2	20.0	2.5	55.6
	Grade 3	10	0	0.0	0.0	30.8	10	1	10.0	0.3	44.5	10	0	0.0	0.0	30.8
	Related	10	4	40.0	12.2	73.8	10	2	20.0	2.5	55.6	10	2	20.0	2.5	55.6
Headache	Any	10	9	90.0	55.5	99.7	10	3	30.0	6.7	65.2	10	5	50.0	18.7	81.3
	Grade 3	10	1	10.0	0.3	44.5	10	0	0.0	0.0	30.8	10	1	10.0	0.3	44.5
	Related	10	7	70.0	34.8	93.3	10	2	20.0	2.5	55.6	10	5	50.0	18.7	81.3

N = number of subjects with at least one administered dose
n (%) = number (percentage) of subjects reporting at least once the symptom
95% CI = exact 95% confidence interval; LL = lower limit, UL = upper limit
Any = occurrence of any general symptom regardless of intensity grade and relationship
Grade 3 = symptom that prevented normal activity
Related = general symptom assessed by the investigator as causally related to the study vaccination

Primary Efficacy Results: Distribution of haematological and biochemical parameters with respect to normal laboratory ranges (Total Vaccinated cohort).

Parameter	Timing	Parameters or Categories	TB 1 Group N = 40		TB 2 Group N = 40		TB 3 Group N = 10		TB 4 Group N = 10		Control Group N = 10	
			Value or n	%	Value or n	%	Value or n	%	Value or n	%	Value or n	%
Alanine amino-transferase	Screening	Inside	39	97.5	38	95.0	9	90.0	10	100	10	100
		Above	1	2.5	2	5.0	1	10.0	0	0.0	0	0.0
		Below	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 0	Inside	39	97.5	39	97.5	9	90.0	10	100	10	100
		Above	0	0.0	1	2.5	1	10.0	0	0.0	0	0.0
		Below	1	2.5	0	0.0	0	0.0	0	0.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 7	Inside	38	95.0	40	100	10	100	10	100	10	100
		Above	2	5.0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 30	Inside	40	100	39	97.5	10	100	10	100	10	100
		Above	0	0.0	1	2.5	0	0.0	0	0.0	0	0.0
		Below	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 37	Inside	39	97.5	39	97.5	10	100	10	100	10	100
		Above	1	2.5	1	2.5	0	0.0	0	0.0	0	0.0
		Below	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 60	Inside	39	97.5	39	97.5	10	100	10	100	10	100
		Above	0	0.0	1	2.5	0	0.0	0	0.0	0	0.0
		Below	1	2.5	0	0.0	0	0.0	0	0.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Aspartate amino-transferase	Screening	Inside	39	97.5	40	100	10	100	10	100	10	100
		Above	1	2.5	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 0	Inside	39	97.5	40	100	10	100	10	100	10	100
		Above	1	2.5	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 7	Inside	39	97.5	39	97.5	10	100	10	100	10	100

		Above	1	2.5	1	2.5	0	0.0	0	0.0	0	0.0
		Below	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 30	Inside	40	100	39	97.5	10	100	10	100	10	100
		Above	0	0.0	1	2.5	0	0.0	0	0.0	0	0.0
		Below	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 37	Inside	40	100	40	100	10	100	10	100	10	100
		Above	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 60	Inside	38	95.0	40	100	10	100	10	100	9	90.0
		Above	2	5.0	0	0.0	0	0.0	0	0.0	1	10.0
		Below	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Basophils	Screening	Inside	40	100	40	100	10	100	10	100	10	100
		Above	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 0	Inside	40	100	40	100	10	100	10	100	10	100
		Above	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 7	Inside	40	100	40	100	10	100	10	100	10	100
		Above	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 30	Inside	40	100	40	100	10	100	10	100	10	100
		Above	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 37	Inside	40	100	40	100	10	100	10	100	10	100
		Above	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 60	Inside	40	100	40	100	10	100	10	100	10	100
		Above	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Creatinine	Screening	Inside	39	97.5	39	97.5	9	90.0	10	100	10	100
		Above	1	2.5	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0.0	1	2.5	1	10.0	0	0.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 0	Inside	39	97.5	39	97.5	9	90.0	10	100	10	100
		Above	1	2.5	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0.0	1	2.5	1	10.0	0	0.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 7	Inside	37	92.5	39	97.5	10	100	10	100	9	90.0
		Above	2	5.0	0	0.0	0	0.0	0	0.0	1	10.0
		Below	1	2.5	1	2.5	0	0.0	0	0.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 30	Inside	40	100	38	95.0	9	90.0	10	100	10	100
		Above	0	0.0	1	2.5	0	0.0	0	0.0	0	0.0
		Below	0	0.0	1	2.5	1	10.0	0	0.0	0	0.0

		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 37	Inside	39	97.5	38	95.0	10	100	10	100	10	100
		Above	1	2.5	1	2.5	0	0.0	0	0.0	0	0.0
		Below	0	0.0	1	2.5	0	0.0	0	0.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 60	Inside	40	100	39	97.5	10	100	10	100	9	90.0
		Above	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0.0	1	2.5	0	0.0	0	0.0	1	10.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Eosinophils	Screening	Inside	37	92.5	38	95.0	10	100	10	100	10	100
		Above	3	7.5	2	5.0	0	0.0	0	0.0	0	0.0
		Below	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 0	Inside	37	92.5	40	100	10	100	10	100	10	100
		Above	3	7.5	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 7	Inside	39	97.5	39	97.5	10	100	10	100	10	100
		Above	1	2.5	1	2.5	0	0.0	0	0.0	0	0.0
		Below	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 30	Inside	38	95.0	38	95.0	10	100	10	100	10	100
		Above	2	5.0	2	5.0	0	0.0	0	0.0	0	0.0
		Below	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 37	Inside	39	97.5	38	95.0	10	100	10	100	10	100
		Above	1	2.5	2	5.0	0	0.0	0	0.0	0	0.0
		Below	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 60	Inside	38	95.0	38	95.0	10	100	10	100	10	100
		Above	2	5.0	2	5.0	0	0.0	0	0.0	0	0.0
		Below	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Haemoglobin	Screening	Inside	39	97.5	40	100	10	100	10	100	10	100
		Above	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	1	2.5	0	0.0	0	0.0	0	0.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 0	Inside	40	100	38	95.0	10	100	9	90.0	10	100
		Above	0	0.0	1	2.5	0	0.0	0	0.0	0	0.0
		Below	0	0.0	1	2.5	0	0.0	1	10.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 7	Inside	40	100	38	95.0	10	100	9	90.0	10	100
		Above	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0.0	2	5.0	0	0.0	1	10.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 30	Inside	38	95.0	39	97.5	10	100	9	90.0	10	100
		Above	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	2	5.0	1	2.5	0	0.0	1	10.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 37	Inside	38	95.0	39	97.5	10	100	9	90.0	10	100
		Above	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	2	5.0	1	2.5	0	0.0	1	10.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 60	Inside	39	97.5	40	100	10	100	9	90.0	10	100

		Above	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	1	2.5	0	0.0	0	0.0	1	10.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Haematocrite	Screening	Inside	38	95.0	37	92.5	10	100	9	90.0	10	100
		Above	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	2	5.0	3	7.5	0	0.0	1	10.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 0	Inside	37	92.5	37	92.5	10	100	9	90.0	10	100
		Above	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	3	7.5	3	7.5	0	0.0	1	10.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 7	Inside	39	97.5	36	90.0	10	100	9	90.0	10	100
		Above	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	1	2.5	4	10.0	0	0.0	1	10.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 30	Inside	38	95.0	40	100	10	100	10	100	10	100
		Above	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	2	5.0	0	0.0	0	0.0	0	0.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 37	Inside	37	92.5	37	92.5	10	100	9	90.0	10	100
		Above	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	3	7.5	3	7.5	0	0.0	1	10.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 60	Inside	38	95.0	36	90.0	10	100	9	90.0	10	100
		Above	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	2	5.0	4	10.0	0	0.0	1	10.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Lymphocytes	Screening	Inside	38	95.0	38	95.0	9	90.0	9	90.0	8	80.0
		Above	0	0.0	1	2.5	0	0.0	1	10.0	1	10.0
		Below	2	5.0	1	2.5	1	10.0	0	0.0	1	10.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 0	Inside	39	97.5	39	97.5	10	100	8	80.0	8	80.0
		Above	0	0.0	0	0.0	0	0.0	1	10.0	1	10.0
		Below	1	2.5	1	2.5	0	0.0	1	10.0	1	10.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 7	Inside	40	100	38	95.0	8	80.0	10	100	8	80.0
		Above	0	0.0	1	2.5	1	10.0	0	0.0	1	10.0
		Below	0	0.0	1	2.5	1	10.0	0	0.0	1	10.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 30	Inside	39	97.5	36	90.0	10	100	8	80.0	10	100
		Above	1	2.5	2	5.0	0	0.0	1	10.0	0	0.0
		Below	0	0.0	2	5.0	0	0.0	1	10.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 37	Inside	38	95.0	38	95.0	10	100	10	100	9	90.0
		Above	0	0.0	2	5.0	0	0.0	0	0.0	1	10.0
		Below	2	5.0	0	0.0	0	0.0	0	0.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 60	Inside	38	95.0	38	95.0	10	100	9	90.0	8	80.0
		Above	2	5.0	0	0.0	0	0.0	0	0.0	1	10.0
		Below	0	0.0	2	5.0	0	0.0	1	10.0	1	10.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Monocytes	Screening	Inside	28	70.0	31	77.5	8	80.0	7	70.0	7	70.0
		Above	12	30.0	9	22.5	2	20.0	3	30.0	3	30.0
		Below	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 0	Inside	29	72.5	32	80.0	8	80.0	6	60.0	6	60.0
		Above	10	25.0	8	20.0	1	10.0	4	40.0	4	40.0
		Below	1	2.5	0	0.0	1	10.0	0	0.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 7	Inside	29	72.5	33	82.5	7	70.0	9	90.0	8	80.0
		Above	11	27.5	7	17.5	3	30.0	1	10.0	2	20.0
		Below	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 30	Inside	33	82.5	29	72.5	7	70.0	8	80.0	6	60.0
		Above	7	17.5	11	27.5	3	30.0	2	20.0	4	40.0
		Below	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 37	Inside	30	75.0	35	87.5	9	90.0	7	70.0	7	70.0
		Above	8	20.0	4	10.0	1	10.0	3	30.0	3	30.0
		Below	2	5.0	1	2.5	0	0.0	0	0.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 60	Inside	29	72.5	35	87.5	8	80.0	9	90.0	7	70.0
		Above	11	27.5	5	12.5	2	20.0	1	10.0	3	30.0
		Below	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Neutrophils	Screening	Inside	38	95.0	40	100	9	90.0	10	100	9	90.0
		Above	1	2.5	0	0.0	1	10.0	0	0.0	0	0.0
		Below	1	2.5	0	0.0	0	0.0	0	0.0	1	10.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 0	Inside	38	95.0	38	95.0	9	90.0	9	90.0	9	90.0
		Above	1	2.5	1	2.5	1	10.0	0	0.0	0	0.0
		Below	1	2.5	1	2.5	0	0.0	1	10.0	1	10.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 7	Inside	40	100	39	97.5	7	70.0	10	100	8	80.0
		Above	0	0.0	1	2.5	1	10.0	0	0.0	1	10.0
		Below	0	0.0	0	0.0	2	20.0	0	0.0	1	10.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 30	Inside	39	97.5	39	97.5	10	100	9	90.0	10	100
		Above	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	1	2.5	1	2.5	0	0.0	1	10.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 37	Inside	38	95.0	38	95.0	10	100	10	100	9	90.0
		Above	2	5.0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0.0	2	5.0	0	0.0	0	0.0	1	10.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 60	Inside	39	97.5	36	90.0	10	100	10	100	8	80.0
		Above	0	0.0	2	5.0	0	0.0	0	0.0	1	10.0
		Below	1	2.5	2	5.0	0	0.0	0	0.0	1	10.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Platelets	Screening	Inside	39	97.5	39	97.5	10	100	9	90.0	10	100
		Above	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	1	2.5	1	2.5	0	0.0	1	10.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 0	Inside	38	95.0	39	97.5	10	100	9	90.0	10	100
		Above	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	2	5.0	1	2.5	0	0.0	1	10.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 7	Inside	40	100	39	97.5	10	100	9	90.0	10	100

		Above	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0.0	1	2.5	0	0.0	1	10.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 30	Inside	38	95.0	38	95.0	10	100	9	90.0	10	100
		Above	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	2	5.0	2	5.0	0	0.0	1	10.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 37	Inside	38	95.0	39	97.5	10	100	9	90.0	10	100
		Above	1	2.5	0	0.0	0	0.0	0	0.0	0	0.0
		Below	1	2.5	1	2.5	0	0.0	1	10.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 60	Inside	39	97.5	38	95.0	10	100	10	100	10	100
		Above	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	1	2.5	2	5.0	0	0.0	0	0.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Red blood cells	Screening	Inside	38	95.0	39	97.5	10	100	10	100	10	100
		Above	2	5.0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0.0	1	2.5	0	0.0	0	0.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 0	Inside	40	100	39	97.5	10	100	10	100	10	100
		Above	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0.0	1	2.5	0	0.0	0	0.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 7	Inside	40	100	39	97.5	10	100	10	100	10	100
		Above	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0.0	1	2.5	0	0.0	0	0.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 30	Inside	39	97.5	40	100	10	100	10	100	10	100
		Above	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	1	2.5	0	0.0	0	0.0	0	0.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 37	Inside	40	100	40	100	10	100	10	100	10	100
		Above	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 60	Inside	40	100	39	97.5	10	100	9	90.0	10	100
		Above	0	0.0	0	0.0	0	0.0	1	10.0	0	0.0
		Below	0	0.0	1	2.5	0	0.0	0	0.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
White blood cells	Screening	Inside	37	92.5	36	90.0	10	100	9	90.0	9	90.0
		Above	0	0.0	2	5.0	0	0.0	0	0.0	0	0.0
		Below	3	7.5	2	5.0	0	0.0	1	10.0	1	10.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 0	Inside	36	90.0	36	90.0	10	100	9	90.0	9	90.0
		Above	3	7.5	2	5.0	0	0.0	0	0.0	0	0.0
		Below	1	2.5	2	5.0	0	0.0	1	10.0	1	10.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 7	Inside	37	92.5	38	95.0	9	90.0	10	100	10	100
		Above	2	5.0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	1	2.5	2	5.0	1	10.0	0	0.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 30	Inside	38	95.0	37	92.5	10	100	9	90.0	9	90.0
		Above	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	2	5.0	3	7.5	0	0.0	1	10.0	1	10.0

		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 37	Inside	37	92.5	39	97.5	10	100	9	90.0	10	100
		Above	2	5.0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	1	2.5	1	2.5	0	0.0	1	10.0	0	0.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Day 60	Inside	38	95.0	37	92.5	9	90.0	9	90.0	9	90.0
		Above	0	0.0	1	2.5	0	0.0	0	0.0	0	0.0
		Below	2	5.0	2	5.0	1	10.0	1	10.0	1	10.0
		Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

N = number of subject analysed
n = number of subject in a given category
Value = value of the considered parameter
% = n / Number of subjects with available results x 100
Inside = within laboratory reference range
Above = above laboratory reference range
Below = below laboratory reference range
Day 0 = pre-vaccination
Day 7 = post-vaccination Dose 1 (Day 7)
Day 30 = post-vaccination Dose 1 (Day 30)
Day 37 = post-vaccination Dose 2 (Day 37)
Day 60 = post-vaccination Dose 2 (Day 60)

Primary Efficacy Results: C-reactive protein (mg/dL): Descriptive statistics (Total Vaccinated cohort)

Group	Timing	N	Mean	SD	Median
TB 1	PRE(D0)	40	0.37	0.75	0.10
	PI(D1)	40	1.75	1.61	1.45
	PI(D7)	40	0.35	0.43	0.20
	PI(D30)	40	0.21	0.26	0.10
	PII(D31)	40	1.78	1.04	1.65
	PII(D37)	40	0.44	0.43	0.30
TB 2	PRE(D0)	40	0.33	0.51	0.10
	PI(D1)	40	1.23	0.87	1.05
	PI(D7)	40	0.29	0.33	0.20
	PI(D30)	40	0.26	0.41	0.10
	PII(D31)	40	1.60	1.12	1.25
	PII(D37)	40	0.35	0.33	0.20
TB 3	PRE(D0)	10	0.19	0.18	0.15
	PI(D1)	10	0.82	0.41	0.70
	PI(D7)	10	0.37	0.39	0.20
	PI(D30)	10	0.16	0.14	0.10
	PII(D31)	10	1.32	0.94	1.15
	PII(D37)	10	0.26	0.16	0.20
TB 4	PRE(D0)	10	0.16	0.23	0.10
	PI(D1)	10	0.11	0.10	0.10
	PI(D7)	10	0.15	0.15	0.10
	PI(D30)	10	0.09	0.05	0.10
	PII(D31)	10	0.13	0.08	0.10
	PII(D37)	10	0.12	0.08	0.10
Control	PRE(D0)	10	0.24	0.16	0.30
	PI(D1)	10	1.23	0.79	1.10
	PI(D7)	10	0.23	0.17	0.15
	PI(D30)	10	0.42	0.67	0.20
	PII(D31)	10	1.05	0.83	0.75
	PII(D37)	10	0.39	0.55	0.25

N = number of subjects with available results
SD = standard deviation

PRE(D0) = pre-vaccination
PI(D1) = post-vaccination Dose 1 (Day 1)
PI(D7) = post-vaccination Dose 1 (Day 7)
PI(D30) = post-vaccination Dose 1 (Day 30)
PII(D31) = post-vaccination Dose 2 (Day 31)
PII(D37) = post-vaccination Dose 2 (Day 37)

Primary Efficacy Results: Immunoglobulin E (10^3 U/L): Descriptive statistics (Total Vaccinated cohort)

Group	Timing	N	Mean	SD	Median
TB 1	PRE(D0)	40	194.31	530.57	30.10
	PI(D1)	40	192.65	514.15	29.55
	PI(D7)	40	212.22	602.21	36.10
	PI(D30)	40	198.00	565.70	31.05
	PII(D31)	40	201.13	563.49	34.20
	PII(D37)	40	216.44	629.41	35.00
TB 2	PRE(D0)	40	152.88	281.28	61.55
	PI(D1)	40	155.94	284.14	61.90
	PI(D7)	40	155.74	293.44	65.50
	PI(D30)	40	150.73	285.87	58.60
	PII(D31)	40	154.74	292.89	64.10
	PII(D37)	40	160.63	301.88	60.35
TB 3	PRE(D0)	10	59.95	53.30	46.75
	PI(D1)	10	58.23	50.59	46.50
	PI(D7)	10	61.32	60.40	43.25
	PI(D30)	10	55.37	48.74	43.70
	PII(D31)	10	55.89	48.01	46.40
	PII(D37)	10	61.05	55.89	49.15
TB 4	PRE(D0)	10	35.51	24.16	39.55
	PI(D1)	10	35.81	25.30	41.05
	PI(D7)	10	35.97	25.97	38.00
	PI(D30)	10	33.43	22.61	38.10
	PII(D31)	10	34.36	23.29	39.05
	PII(D37)	10	33.98	22.69	40.85
Control	PRE(D0)	10	72.15	81.01	45.25
	PI(D1)	10	75.69	91.92	41.75
	PI(D7)	10	77.44	96.80	45.80
	PI(D30)	10	69.13	82.87	43.55
	PII(D31)	10	71.01	83.40	45.35
	PII(D37)	10	73.85	92.83	44.20

N = number of subjects with available results
SD = standard deviation
PRE(D0) = pre-vaccination
PI(D1) = post-vaccination Dose 1 (Day 1)
PI(D7) = post-vaccination Dose 1 (Day 7)
PI(D30) = post-vaccination Dose 1 (Day 30)
PII(D31) = post-vaccination Dose 2 (Day 31)
PII(D37) = post-vaccination Dose 2 (Day 37)

Primary Efficacy Results: Please refer to the safety section of the document for results for unsolicited AEs and SAEs.

Secondary Outcome Variable(s): Seropositivity* rates and GMCs for M72 antibodies (ATP cohort for immunogenicity)

			≥ 2.8 EU/mL				GMC (EU/mL)		
					95% CI			95% CI	
Group	Timing	N	n	%	LL	UL	value	LL	UL
TB 1	PRE(D0)	40	0	0.0	0.0	8.8	1.4	1.4	1.4
	PI(D30)	40	39	97.5	86.8	99.9	24.7	18.6	33.0
	PII(D60)	40	40	100	91.2	100	722.6	583.5	894.9
	PII(M12)	40	40	100	91.2	100	59.5	48.8	72.6

	PII(M24)	31	31	100	88.8	100	38.9	29.5	51.1
	PII(M36)	24	24	100	85.8	100	29.2	21.0	40.6
TB 2	PRE(D0)	40	0	0.0	0.0	8.8	1.4	1.4	1.4
	PI(D30)	40	38	95.0	83.1	99.4	10.4	7.8	13.8
	PII(D60)	39	39	100	91.0	100	470.8	394.0	562.5
	PII(M12)	40	40	100	91.2	100	42.5	34.2	52.6
	PII(M24)	37	37	100	90.5	100	21.6	17.0	27.6
	PII(M36)	29	29	100	88.1	100	19.3	14.0	26.6
TB 3	PRE(D0)	10	0	0.0	0.0	30.8	1.4	1.4	1.4
	PI(D30)	10	10	100	69.2	100	14.4	8.2	25.1
	PII(D60)	10	10	100	69.2	100	491.9	306.4	789.5
	PII(M12)	10	10	100	69.2	100	43.2	25.3	73.8
TB 4	PRE(D0)	10	0	0.0	0.0	30.8	1.4	1.4	1.4
	PI(D30)	10	1	10.0	0.3	44.5	1.8	1.0	3.0
	PII(D60)	10	5	50.0	18.7	81.3	5.3	1.5	18.2
	PII(M12)	10	4	40.0	12.2	73.8	2.7	1.3	5.7
Control	PRE(D0)	10	0	0.0	0.0	30.8	1.4	1.4	1.4
	PI(D30)	10	0	0.0	0.0	30.8	1.4	1.4	1.4
	PII(D60)	10	0	0.0	0.0	30.8	1.4	1.4	1.4
	PII(M12)	10	0	0.0	0.0	30.8	1.4	1.4	1.4

* A seropositive subject was defined as a subject with M72 antibody concentration ≥ the cut-off value of 2.8 EU/mL.
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n (%) = number (percentage) of subjects with concentration within the specified range
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PRE(D0) = pre-vaccination (Day 0)
PI(D30) = post-vaccination Dose 1 (Day 30)
PII(D60) = post-vaccination Dose 2 (Day 60)
PII(M12) = post-vaccination Dose 2 (Month 12)
PII(M24) = post-vaccination Dose 2 (Month 24)
PII(M36) = post-vaccination Dose 2 (Month 36)

Secondary Outcome Variable(s): Seropositivity* rates and GMCs for Mtb72F antibodies (ATP cohort for immunogenicity)

			≥ 1.0 EU/mL				GMC (EU/mL)		
					95% CI			95% CI	
Group	Timing	N	N	%	LL	UL	value	LL	UL
TB 1	PRE(D0)	40	1	2.5	0.1	13.2	0.5	0.5	0.5
	PI(D30)	40	40	100	91.2	100	27.6	20.8	36.8
	PII(D60)	40	40	100	91.2	100	731.6	589.0	908.8
	PII(M12)	40	40	100	91.2	100	44.7	36.2	55.2
TB 2	PRE (D0)	40	0	0.0	0.0	8.8	0.5	0.5	0.5
	PI(D30)	40	40	100	91.2	100	11.5	8.7	15.1
	PII(D60)	39	39	100	91.0	100	473.1	398.0	562.4
	PII(M12)	40	40	100	91.2	100	30.1	24.4	37.1
TB 3	PRE(D0)	10	0	0.0	0.0	30.8	0.5	0.5	0.5
	PI(D30)	10	10	100	69.2	100	16.0	9.3	27.8
	PII(D60)	10	10	100	69.2	100	512.1	314.6	833.6
	PII(M12)	10	10	100	69.2	100	31.6	19.3	51.7
TB 4	PRE(D0)	10	0	0.0	0.0	30.8	0.5	0.5	0.5
	PI(D30)	10	3	30.0	6.7	65.2	0.8	0.4	1.9
	PII(D60)	10	5	50.0	18.7	81.3	3.2	0.7	15.5
	PII(M12)	10	4	40.0	12.2	73.8	1.4	0.5	3.8
Control	PRE(D0)	10	0	0.0	0.0	30.8	0.5	0.5	0.5
	PI(D30)	10	0	0.0	0.0	30.8	0.5	0.5	0.5
	PII(D60)	10	0	0.0	0.0	30.8	0.5	0.5	0.5

	PII(M12)	10	0	0.0	0.0	30.8	0.5	0.5	0.5

* A seropositive subject was defined as a subject with Mtb72F antibody concentration ≥ the cut-off value of 1.0 EU/mL.
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n (%) = number (percentage) of subjects with concentration within the specified range
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PRE(D0) = Pre-vaccination (Day 0)
PII(D30) = Post-vaccination dose II (Day 30)
PII(D60) = Post-vaccination dose II (Day 60)
PII(M12) = Post-vaccination dose II (Month 12)

Secondary Outcome Variable(s): Descriptive statistics of the frequency of M72-specific CD4+ T-cells (per million cells) expressing at least two different cytokines/activation markers (ATP cohort for immunogenicity)

Group	Timing	N	Mean	SD	MIN	Q1	Median	Q3	MAX
TB 1	PRE(D0)	40	109.6	105.3	1	17.5	90.5	149.0	375
	PI(D30)	40	1118.6	746.6	181	629.0	955.5	1395.0	4316
	PII(D60)	39	3236.7	1944.5	954	2029.0	2641.0	4080.0	10887
	PII(M12)	39	1557.3	1210.3	470	940.0	1282.0	1613.0	6959
	PII(M24)	31	1910.23	1621.27	440	1000.0	1506.0	2200.0	8160
	PII(M36)	24	1507.04	943.57	374	1013.5	1313.0	1886.5	5107
TB 2	PRE(D0)	40	90.9	108.6	1	1.0	65.5	121.5	521
	PI(D30)	40	591.0	369.3	2	351.0	484.0	873.0	1851
	PII(D60)	39	1835.0	929.6	519	1206.0	1589.0	2241.0	4321
	PII(M12)	39	872.2	558.0	238	492.0	769.0	1161.0	3128
	PII(M24)	37	1017.32	720.95	253	520.0	826.0	1293.0	3320
	PII(M36)	26	691.77	619.68	133	373.0	507.0	800.0	3147
TB 3	PRE(D0)	10	74.6	80.6	1.0	1.0	58.0	131.0	223.0
	PI(D30)	10	843.9	600.5	157.0	515.0	745.5	818.0	2077.0
	PII(D60)	10	1992.0	525.8	1201.0	1451.0	2082.5	2403.0	2810.0
	PII(M12)	9	704.3	396.7	236.0	504.0	642.0	758.0	1383.0
TB 4	PRE(D0)	10	108.1	88.0	1.0	1.0	134.5	186.0	210.0
	PI(D30)	10	427.1	831.5	1.0	4.0	173.0	323.0	2736.0
	PII(D60)	10	494.7	695.0	1.0	80.0	278.0	514.0	2315.0
	PII(M12)	10	378.7	657.9	1.0	1.0	153.5	226.0	2091.0
Control	PRE(D0)	10	92.0	124.9	1.0	1.0	45.0	107.0	352.0
	PI(D30)	10	96.0	71.9	1.0	30.0	95.5	160.0	197.0
	PII(D60)	10	83.1	98.0	1.0	1.0	43.0	139.0	279.0
	PII(M12)	10	104.9	105.4	1.0	1.0	82.0	165.0	315.0

N = number of subjects with available results
SD = standard deviation
Q1/Q3 = 1st / 3rd quartile
MIN/MAX = Minimum/Maximum
PRE(D0) = pre-vaccination (Day 0)
PI(D30) = post-vaccination Dose 1 (Day 30)
PII(D60) = post-vaccination Dose 2 (Day 60)
PII(M12) = post-vaccination Dose 2 (Month 12)
PII(M24) = post-vaccination Dose 2 (Month 24)
PII(M36) = post-vaccination Dose 2 (Month 36)

Secondary Outcome Variable(s): Descriptive statistics of the frequency of M72-specific CD4+ T-cells (per million cells) expressing CD40-L and at least another cytokine/activation marker (ATP cohort for immunogenicity)

Group	Timing	N	Mean	SD	MIN	Q1	Median	Q3	MAX
TB 1	PRE(D0)	40	96.3	94.7	1.0	27.5	63.0	146.5	334.0
	PI(D30)	40	993.0	587.5	143.0	505.5	883.0	1282.0	2744.0
	PII(D60)	39	2928.3	1842.9	666.0	1877.0	2333.0	3605.0	10055.0
	PII(M12)	39	1474.8	1068.0	470.0	881.0	1234.0	1562.0	5904.0
	PII(M24)	31	1834.84	1586.14	440	973.0	1467.0	1920.0	8053

	PII(M36)	24	1447.96	929.99	387	900.0	1106.5	1846.5	4973
TB 2	PRE(D0)	40	79.2	94.6	1.0	1.5	50.0	129.5	462.0
	PI(D30)	40	515.1	341.5	42.0	281.0	420.5	782.0	1631.0
	PII(D60)	39	1683.6	900.6	334.0	1077.0	1466.0	2167.0	3637.0
	PII(M12)	39	830.9	543.4	185.0	474.0	718.0	1074.0	3109.0
	PII(M24)	37	994.59	710.09	240	520.0	800.0	1293.0	3306
	PII(M36)	26	678.00	613.90	147	373.0	493.5	773.0	3147
TB 3	PRE(D0)	10	89.1	80.3	1.0	1.0	90.0	156.0	198.0
	PI(D30)	10	811.5	601.1	157.0	435.0	715.0	818.0	2026.0
	PII(D60)	10	1886.5	517.8	1156.0	1413.0	1997.5	2208.0	2647.0
	PII(M12)	9	677.3	413.3	129.0	496.0	597.0	694.0	1341.0
TB 4	PRE(D0)	10	85.3	85.6	1.0	1.0	81.5	143.0	229.0
	PI(D30)	10	329.1	578.6	1.0	3.0	158.5	263.0	1905.0
	PII(D60)	10	399.8	521.7	1.0	102.0	238.0	418.0	1712.0
	PII(M12)	10	376.6	659.0	1.0	1.0	137.0	253.0	2091.0
Control	PRE(D0)	10	83.4	121.0	1.0	1.0	37.0	89.0	355.0
	PI(D30)	10	83.7	77.0	1.0	28.0	56.5	137.0	219.0
	PII(D60)	10	67.4	79.1	1.0	1.0	29.0	127.0	204.0
	PII(M12)	10	101.2	102.0	1.0	1.0	77.5	166.0	315.0

N = number of subjects with available results
SD = standard deviation
Q1/Q3 = 1st / 3rd quartile
MIN/MAX = Minimum/Maximum
PRE(D0) = pre-vaccination (Day 0)
PI(D30) = post-vaccination Dose 1 (Day 30)
PII(D60) = post-vaccination Dose 2 (Day 60)
PII(M12) = post-vaccination Dose 2 (Month 12)
PII(M24) = post-vaccination Dose 2 (Month 24)
PII(M36) = post-vaccination Dose 2 (Month 36)

Secondary Outcome Variable(s): Descriptive statistics of the frequency of M72-specific CD4+ T-cells (per million cells) expressing TNF-α and at least another cytokine/activation marker (ATP cohort for immunogenicity)

Group	Timing	N	Mean	SD	MIN	Q1	Median	Q3	MAX
TB 1	PRE(D0)	40	80.9	81.9	1.0	2.5	65.0	121.0	343.0
	PI(D30)	40	594.9	539.7	29.0	330.0	466.0	684.5	3280.0
	PII(D60)	39	1605.6	1109.0	314.0	954.0	1394.0	1964.0	5924.0
	PII(M12)	39	742.9	679.4	108.0	377.0	545.0	821.0	4023.0
	PII(M24)	31	936.39	895.58	160	426.0	574.0	1226.0	4520
	PII(M36)	24	965.42	758.23	227	593.5	833.5	1170.0	4174
TB 2	PRE(D0)	40	67.9	98.7	1.0	1.0	33.5	79.5	524.0
	PI(D30)	40	290.6	213.6	1.0	104.0	250.0	410.0	859.0
	PII(D60)	39	892.9	502.7	218.0	512.0	744.0	1293.0	2716.0
	PII(M12)	39	407.9	304.2	10.0	221.0	321.0	515.0	1543.0
	PII(M24)	37	455.57	343.21	80	227.0	307.0	560.0	1334
	PII(M36)	26	410.23	349.05	26	214.0	293.0	454.0	1747
TB 3	PRE(D0)	10	43.3	47.0	1.0	1.0	45.0	63.0	149.0
	PI(D30)	10	372.6	293.0	1.0	243.0	291.5	465.0	1098.0
	PII(D60)	10	922.9	312.8	410.0	727.0	863.0	1133.0	1401.0
	PII(M12)	9	394.8	323.7	105.0	166.0	314.0	434.0	999.0
TB 4	PRE(D0)	10	83.7	103.1	1.0	1.0	34.0	204.0	265.0
	PI(D30)	10	259.5	584.3	1.0	2.0	59.0	219.0	1905.0
	PII(D60)	10	245.3	463.2	1.0	1.0	110.5	225.0	1528.0
	PII(M12)	10	234.0	460.8	1.0	4.0	50.0	140.0	1484.0
Control	PRE(D0)	10	62.1	77.3	1.0	1.0	40.5	97.0	209.0
	PI(D30)	10	84.3	65.0	1.0	35.0	82.0	113.0	225.0
	PII(D60)	10	64.4	90.5	1.0	1.0	15.5	111.0	278.0

	PII(M12)	10	51.2	90.7	1.0	1.0	1.0	76.0	256.0

N = number of subjects in the subsets with available results
SD = standard deviation
Q1/Q3 = 1st / 3rd quartile
MIN/MAX = Minimum/Maximum
PRE(D0) = pre-vaccination (Day 0)
PI(D30) = post-vaccination Dose 1 (Day 30)
PII(D60) = post-vaccination Dose 2 (Day 60)
PII(M12) = post-vaccination Dose 2 (Month 12)
PII(M24) = post-vaccination Dose 2 (Month 24)
PII(M36) = post-vaccination Dose 2 (Month 36)

Secondary Outcome Variable(s): Descriptive statistics of the frequency of M72-specific CD4+ T-cells (per million cells) expressing IL-2 and at least another cytokine/activation marker (ATP cohort for immunogenicity)

Group	Timing	N	Mean	SD	MIN	Q1	Median	Q3	MAX
TB 1	PRE(D0)	40	68.2	74.1	1.0	2.0	41.5	107.5	289.0
	PI(D30)	40	978.8	664.7	102.0	494.5	886.5	1359.0	3557.0
	PII(D60)	39	2884.7	1824.9	931.0	1809.0	2325.0	3338.0	9986.0
	PII(M12)	39	1450.4	1184.2	442.0	803.0	1212.0	1530.0	6711.0
	PII(M24)	31	1753.90	1570.30	426	906.0	1320.0	1800.0	7907
	PII(M36)	24	1355.29	881.17	347	799.5	1087.0	1727.0	4653
TB 2	PRE(D0)	40	63.2	71.8	1.0	1.5	44.5	101.0	348.0
	PI(D30)	40	536.8	329.8	1.0	297.0	451.5	762.0	1696.0
	PII(D60)	39	1690.6	878.7	432.0	1096.0	1489.0	2107.0	4106.0
	PII(M12)	39	811.6	528.6	212.0	437.0	650.0	1054.0	3078.0
	PII(M24)	37	949.65	687.69	226	520.0	787.0	1174.0	3226
	PII(M36)	26	636.88	606.35	80	307.0	479.5	693.0	3040
TB 3	PRE(D0)	10	72.2	77.3	1.0	1.0	41.0	156.0	173.0
	PI(D30)	10	810.9	569.8	197.0	446.0	732.0	831.0	1923.0
	PII(D60)	10	1764.0	509.3	946.0	1304.0	1729.5	2130.0	2627.0
	PII(M12)	9	626.3	311.4	216.0	443.0	569.0	672.0	1152.0
TB 4	PRE(D0)	10	75.8	72.0	1.0	1.0	50.5	153.0	168.0
	PI(D30)	10	368.3	773.6	1.0	1.0	141.0	254.0	2541.0
	PII(D60)	10	409.5	604.3	1.0	95.0	223.5	450.0	2038.0
	PII(M12)	10	319.8	604.1	1.0	1.0	98.0	212.0	1924.0
Control	PRE(D0)	10	65.4	71.8	1.0	1.0	54.0	74.0	222.0
	PI(D30)	10	53.8	39.3	1.0	16.0	62.0	80.0	111.0
	PII(D60)	10	68.5	80.5	1.0	1.0	29.0	138.0	242.0
	PII(M12)	10	77.0	77.7	1.0	14.0	77.5	110.0	255.0

N = number of subjects in the subsets with available results
SD = standard deviation
Q1/Q3 = 1st / 3rd quartile
MIN/MAX = Minimum/Maximum
PRE(D0) = pre-vaccination (Day 0)
PI(D30) = post-vaccination Dose 1 (Day 30)
PII(D60) = post-vaccination Dose 2 (Day 60)
PII(M12) = post-vaccination Dose 2 (Month 12)
PII(M24) = post-vaccination Dose 2 (Month 24)
PII(M36) = post-vaccination Dose 2 (Month 36)

Secondary Outcome Variable(s): Descriptive statistics of the frequency of M72-specific CD4+ T-cells (per million cells) expressing IFN-γ and at least another cytokine/activation marker (ATP cohort for immunogenicity)

Group	Timing	N	Mean	SD	MIN	Q1	Median	Q3	MAX
TB 1	PRE(D0)	40	63.1	77.9	1.0	1.0	34.5	94.5	341.0
	PI(D30)	40	375.9	563.0	1.0	91.5	168.5	479.5	3281.0
	PII(D60)	39	967.5	840.7	176.0	370.0	820.0	1277.0	4912.0
	PII(M12)	39	421.3	478.5	72.0	164.0	317.0	471.0	2950.0

	PII(M24)	31	648.48	649.58	120	226.0	387.0	894.0	3026
	PII(M36)	24	497.08	471.94	67	152.5	373.0	700.0	2239
TB 2	PRE(D0)	40	49.5	62.5	1.0	1.0	34.5	70.0	248.0
	PI(D30)	40	146.2	157.8	1.0	41.0	112.0	197.0	739.0
	PII(D60)	39	337.8	317.2	1.0	84.0	275.0	502.0	1712.0
	PII(M12)	39	142.6	157.6	1.0	57.0	109.0	160.0	861.0
	PII(M24)	37	222.03	139.36	1	134.0	200.0	254.0	747
	PII(M36)	26	136.81	100.37	1	66.0	106.5	187.0	347
TB 3	PRE(D0)	10	54.4	51.3	1.0	21.0	35.0	100.0	149.0
	PI(D30)	10	135.0	102.0	1.0	97.0	107.0	188.0	367.0
	PII(D60)	10	394.1	306.5	78.0	148.0	335.0	529.0	1085.0
	PII(M12)	9	162.8	147.5	1.0	59.0	120.0	224.0	466.0
TB 4	PRE(D0)	10	51.3	47.7	1.0	1.0	46.5	75.0	153.0
	PI(D30)	10	181.9	420.5	1.0	1.0	33.0	138.0	1365.0
	PII(D60)	10	155.0	246.8	30.0	42.0	58.0	109.0	833.0
	PII(M12)	10	163.1	364.6	1.0	1.0	27.5	88.0	1183.0
Control	PRE(D0)	10	62.1	50.9	1.0	22.0	57.0	82.0	150.0
	PI(D30)	10	54.2	36.3	1.0	22.0	62.5	80.0	108.0
	PII(D60)	10	33.6	54.3	1.0	1.0	1.0	33.0	137.0
	PII(M12)	10	62.7	72.8	1.0	1.0	41.5	72.0	197.0

N = number of subjects in the subsets with available results
SD = standard deviation
Q1/Q3 = 1st / 3rd quartile
MIN/MAX = Minimum/Maximum
PRE(D0) = pre-vaccination (Day 0)
PI(D30) = post-vaccination Dose 1 (Day 30)
PII(D60) = post-vaccination Dose 2 (Day 60)
PII(M12) = post-vaccination Dose 2 (Month 12)
PII(M24) = post-vaccination Dose 2 (Month 24)
PII(M36) = post-vaccination Dose 2 (Month 36)

Secondary Outcome Variable(s): Percentage of responders of M72-specific CD4+ T-cells secreting at least two different cytokines/activation markers (ATP cohort for immunogenicity)

Group	Timing	Responder				
		N	n	%	95% CI	
					LL	UL
TB 1	PRE(D0)	40	3	7.5	1.6	20.4
	PI(D30)	40	38	95.0	83.1	99.4
	PII(D60)	39	39	100	91.0	100
	PII(M12)	39	39	100	91.0	100
	PII(M24)	31	31	100	88.8	100
	PII(M36)	24	24	100	85.8	100
TB 2	PRE(D0)	40	2	5.0	0.6	16.9
	PI(D30)	40	33	82.5	67.2	92.7
	PII(D60)	39	39	100	91.0	100
	PII(M12)	39	35	89.7	75.8	97.1
	PII(M24)	37	36	97.3	85.8	99.9
	PII(M36)	26	23	88.5	69.8	97.6
TB 3	PRE(D0)	10	0	0	0.0	30.8
	PI(D30)	10	9	90.0	55.5	99.7
	PII(D60)	10	10	100	69.2	100
	PII(M12)	9	8	88.9	51.8	99.7
TB 4	PRE(D0)	10	0	0	0.0	30.8
	PI(D30)	10	3	30.0	6.7	65.2
	PII(D60)	10	5	50.0	18.7	81.3
	PII(M12)	10	2	20.0	2.5	55.6

Control	PRE(D0)	10	1	10.0	0.3	44.5
	PI(D30)	10	0	0	0.0	30.8
	PII(D60)	10	0	0	0.0	30.8
	PII(M12)	10	1	10.0	0.3	44.5

N = number of subjects with available results
n (%) = number (percentage) of responders using the 95% percentile of the pre-vaccination frequency of CD4+ T cells as responder threshold. A subject with a post-vaccination frequency higher than 313 was counted as a responder.
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PRE(D0) = pre-vaccination (Day 0)
PI(D30) = post-vaccination Dose 1 (Day 30)
PII(D60) = post-vaccination Dose 2 (Day 60)
PII(M12) = post-vaccination Dose 2 (Month 12)
PII(M24) = Post-vaccination Dose 2 (Month 24)
PII(M36) = Post-vaccination Dose 2 (Month 36)

Secondary Outcome Variable(s): Seropositivity* rates and GMCs for serum IFN-γ (ATP cohort for immunogenicity)

Group	Timing	≥ 1 pg/mL					GMC (pg/mL)		
		N	n	%	95% CI		Value	95% CI	
					LL	UL		LL	UL
TB 1	PRE(D0)	40	3	7.5	1.6	20.4	0.6	0.5	0.6
	PI(D1)	40	31	77.5	61.5	89.2	4.5	2.8	7.1
	PI(D30)	40	3	7.5	1.6	20.4	0.6	0.5	0.7
	PII(D31)	39	39	100	91.0	100	77.2	57.8	103.0
TB 2	PRE(D0)	40	3	7.5	1.6	20.4	0.6	0.5	0.6
	PI(D1)	40	12	30.0	16.6	46.5	1.0	0.7	1.5
	PI(D30)	40	4	10.0	2.8	23.7	0.6	0.5	0.7
	PII(D31)	39	36	92.3	79.1	98.4	20.1	13.2	30.4
TB 3	PRE(D0)	10	1	10.0	0.3	44.5	0.6	0.4	0.9
	PI(D1)	10	6	60.0	26.2	87.8	2.2	0.7	6.6
	PI(D30)	10	1	10.0	0.3	44.5	0.6	0.4	1.0
	PII(D31)	10	9	90.0	55.5	99.7	23.4	7.4	73.6
TB 4	PRE(D0)	10	3	30.0	6.7	65.2	1.0	0.4	2.2
	PI(D1)	10	1	10.0	0.3	44.5	0.7	0.3	1.3
	PI(D30)	10	3	30.0	6.7	65.2	1.1	0.4	2.7
	PII(D31)	10	4	40.0	12.2	73.8	1.4	0.5	3.8
Control	PRE(D0)	10	3	30.0	6.7	65.2	1.0	0.4	2.7
	PI(D1)	10	5	50.0	18.7	81.3	3.3	0.8	14.2
	PI(D30)	10	2	20.0	2.5	55.6	1.1	0.3	3.5
	PII(D31)	10	7	70.0	34.8	93.3	4.1	1.2	14.7

* A seropositive subject was defined as a subject with serum IFN-γ concentration ≥ the cut-off value of 1 pg/mL.
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with pre-vaccination results available
n (%) = number (percentage) of subjects with concentration within the specified range
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PRE(D0) = pre-vaccination (Day 0)
PI(D1) = post-vaccination Dose 1 (Day 1)
PI(D30) = post-vaccination Dose 2 (Day 30)
PII(D31) = post-vaccination Dose 2 (Day 31)

Safety Results: Number (%) of subjects with unsolicited AEs within the 30-day (Days 0-29) post vaccination period (Total Vaccinated cohort)

Most frequent adverse events - On-Therapy (occurring within Days 0-29 following vaccination)	TB 1 Group N = 40	TB 2 Group N = 40	TB 3 Group N = 10	TB 4 Group N = 10	Control Group N = 10
Subjects with any AE(s), n (%)	37 (92.5)	33 (82.5)	10 (100)	7 (70.0)	7 (70.0)
Subjects with Grade 3 AE(s), n (%)	12 (30.0)	7 (17.5)	4 (40.0)	2 (20.0)	1 (10.0)
Subjects with related AE(s), n (%)	31 (77.5)	21 (52.5)	8 (80.0)	2 (20.0)	4 (40.0)

Nasopharyngitis	11 (27.5)	8 (20.0)	3 (30.0)	3 (30.0)	6 (60.0)
Headache	8 (20.0)	5 (12.5)	2 (20.0)	1 (10.0)	3 (30.0)
Influenza like illness	10 (25.0)	4 (10.0)	3 (30.0)	-	1 (10.0)
Malaise	9 (22.5)	4 (10.0)	2 (20.0)	-	1 (10.0)
Myalgia	9 (22.5)	-	2 (20.0)	-	1 (10.0)
Pharyngolaryngeal pain	-	5 (12.5)	1 (10.0)	-	-
Feeling of body temperature change	-	4 (10.0)	1 (10.0)	1 (10.0)	1 (10.0)
Gastroenteritis	-	4 (10.0)	-	-	-
Hyperhidrosis	-	4 (10.0)	-	-	1 (10.0)
Musculoskeletal stiffness	-	4 (10.0)	1 (10.0)	-	-
Abdominal pain	-	-	-	-	2 (20.0)
Injection site paraesthesia	-	-	2 (20.0)	-	-
Nausea	-	-	-	1 (10.0)	2 (20.0)
Vomiting	-	-	-	-	2 (20.0)
Dizziness	-	-	1 (10.0)	-	-
Injection site movement impairment	-	-	1 (10.0)	-	-
Insomnia	-	-	1 (10.0)	-	-
Deafness unilateral	-	-	1 (10.0)	-	-
Dyspepsia	-	-	1 (10.0)	1 (10.0)	-
Gastritis	-	-	1 (10.0)	-	-
Injection site haematoma	-	-	1 (10.0)	-	-
Gastroenteritis viral	-	-	1 (10.0)	-	-
Genital candidiasis	-	-	1 (10.0)	-	-
Sinusitis	-	-	1 (10.0)	-	-
Upper respiratory tract infection	-	-	1 (10.0)	-	-
Facial bones fracture	-	-	1 (10.0)	-	-
Traumatic haematoma	-	-	1 (10.0)	-	-
Neck pain	-	-	-	1 (10.0)	-
Erythema	-	-	-	1 (10.0)	-
Herpes simplex	-	-	-	1 (10.0)	-
Infection	-	-	-	1 (10.0)	-
Wrist fracture	-	-	-	1 (10.0)	-
Fatigue	-	-	-	-	1 (10.0)
Constipation	-	-	-	-	1 (10.0)
Toothache	-	-	-	-	1 (10.0)
Pyrexia	-	-	-	-	1 (10.0)
Lethargy	-	-	-	-	1 (10.0)

Grade 3 = event that prevented normal activities
Related = event assessed by the investigator as causally related to the study vaccination
As there were more than 3 groups:

Counting rule applied for the TB 1 and TB 2 groups:

- As there were more than 30 subjects per treatment group, only the 5 most frequent events in each treatment group are to be listed.
- - = Implies that the adverse event was not reported in the particular group or that the adverse event was reported in the particular group but did not fall within the pre-defined counting rule of 5 most frequent events for that group.

Counting rule applied for the TB 3, TB 4 and Control groups:

- As there were less than 30 subjects per treatment group, display any AE that occurs in the group.
- - = Implies that adverse event was not reported in the particular group.

Safety Results: Number (%) of subjects with SAE(s) during the Active Vaccination Phase (Total Vaccinated cohort)

Serious adverse event, n (%) [n considered by the investigator to be related to study medication

All SAEs	TB 1 Group N = 40	TB 2 Group N = 40	TB 3 Group N = 10	TB 4 Group N = 10	Control Group N = 10
Subjects with any SAE(s), n (%) [n	0 (0.0) [0]	0 (0.0) [0]	1 (10.0) [0]	0 (0.0) [0]	0 (0.0) [0]

assessed by the investigator as related]					
Facial bones fracture	0 (0.0) [0]	0 (0.0) [0]	1 (10.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Fatal SAEs	TB 1 Group N = 40	TB 2 Group N = 40	TB 3 Group N = 10	TB 4 Group N = 10	Control Group N = 10
Subjects with fatal SAE(s), n (%) [n assessed by the investigator as related]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Safety Results: Number (%) of subjects with SAE(s) reported after the Active Vaccination Phase up to Year 1 (Month 12) (Total Vaccinated cohort)					
Serious adverse event, n (%) [n considered by the investigator to be related to study medication					
All SAEs	TB 1 Group N = 40	TB 2 Group N = 40	TB 3 Group N = 10	TB 4 Group N = 10	Control Group N = 10
Subjects with any SAE(s), n (%) [n assessed by the investigator as related]	2 (5.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (10.0) [0]
Tonsillitis	1 (2.5) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Dyspnoea	1 (2.5) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Ventricular septal defect*	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (10.0) [0]
Fatal SAEs	TB 1 Group N = 40	TB 2 Group N = 40	TB 3 Group N = 10	TB 4 Group N = 10	Control Group N = 10
Subjects with any SAE(s), n (%) [n assessed by the investigator as related]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
* This SAE was reported for the child of the subject.					
Safety Results: Number (%) of subjects with SAE(s) reported after Year 1 (Month 12) up to Year 2 (Month 24) (Total Vaccinated cohort)*					
Serious adverse event, n (%) [n considered by the investigator to be related to study medication					

All SAEs	TB 1 Group N = 32	TB 2 Group N = 37
Subjects with any SAE(s), n (%) [n assessed by the investigator as related]	0 (0.0) [0]	0 (0.0) [0]
Fatal SAEs	TB 1 Group N = 32	TB 2 Group N = 37
Subjects with any SAE(s), n (%) [n assessed by the investigator as related]	0 (0.0) [0]	0 (0.0) [0]
* Follow-up during Year 2 and Year 3 continued only for the TB 1 and TB 2 groups.		
Safety Results: Number (%) of subjects with SAE(s) reported after Year 2 (Month 24) to Year 3 (Month 36) (Total Vaccinated cohort)		
Serious adverse event, n (%) [n considered by the investigator to be related to study medication		
All SAEs	TB 1 Group N = 28	TB 2 Group N = 31
Subjects with any SAE(s), n (%) [n assessed by the investigator as related]	0 (0.0) [0]	0 (0.0) [0]
Fatal SAEs	TB 1 Group N = 28	TB 2 Group N = 31
Subjects with any SAE(s), n (%) [n assessed by the investigator as related]	0 (0.0) [0]	0 (0.0) [0]
* Follow-up during Year 2 and Year 3 continued only for the TB 1 and TB 2 groups.		

Conclusion:

During the 7-day follow-up period after each vaccination, across doses, pain at the site of injection was the most commonly reported solicited local symptom in all groups (40 (100%) subjects in the TB 1 Group, 40 (100%) subjects in the TB 2 Group, 10 (100%) subjects in the TB 3 Group, 2 (20.0%) subjects in the TB 4 Group, and 10 (100%) subjects in the Control Group). The most frequently reported solicited general symptoms were fatigue in the TB 1, TB 2 and Control groups (reported for, respectively, 36 (90.0%), 29 (72.5%) and 6 (60.0%) subjects in TB 1, TB 2 and Control groups), headache in the TB 3 Group (9 (90.0%) subjects) and, in the TB 4 Group, fatigue and headache (both reported for 3 (30.0%) subjects). At Day 60 after vaccination, at least 72.5 % of subjects in the TB 1 Group, 87.5 % of subjects in the TB 2 Group, 80.0 % of subjects in the TB 3 Group, 90.0 % of subjects in the TB 4 Group and 70.0 % of subjects in the Control Group had biochemical and

haematological levels within laboratory reference ranges.
During the 30-day follow-up period after each vaccination, at least one unsolicited AE was reported for 37 (92.5%) subjects in the TB 1 Group, 33 (82.5%) subjects in the TB 2 Group, 10 (100%) subjects in the TB 3 Group and 7 (70.0%) subjects in the TB 4 and Control groups. During that same period, B the following sentence "or additon bject.. not overlap and CTRS documents in the safety section have to include data reprotin12 (30.0%) subjects in the TB 1 Group, 7 (17.5%) subjects in the TB 2 Group, 4 (40.0%) subjects in the TB 3 Group, 2 (20.0%) subjects in the TB 4 Group and 1 (10.0%) subject in the Control Group reported at least one Grade 3 unsolicited AE, and 31 (77.5%) subjects in the TB 1 Group, 21 (52.5%) subjects in the TB 2 Group, 8 (80.0%) subjects in the TB 3 Group, 2 (20.0%) subjects in the TB 4 Group and 4 (40.0%) subjects in the Control Group reported at least one unsolicited AE assessed by the investigators as causally related to the vaccination.
Up to Year 1, 1 (2.5%) subject in theTB 3 Group reported an SAE, which was not assessed by the investigator as causally related to the study vaccination. At Year 1, SAEs were reported for 2 (5.0%) subjects in the TB 1 Group and 1 (10.0%) subject in the Control Group. All these SAEs were assessed by the investigators as not causally related to the vaccination. No SAEs were reported in the TB 1 and TB 2 groups during the Year 2 and Year 3 follow-up period. No fatal SAEs were reported during the entire study and follow-up period.

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