SYNOPSIS

Name of Sponsor/Company Sanofi Pasteur MSD S.N.C.	**Individual Study Table Referring to Part of the Dossier**	*(For National Authority Use only)*
Name of Finished Product REPEVAX® and REVAXIS®	Volume	
Name of Active Ingredient(s) REPEVAX®: diphtheria, tetanus, pertussis (acellular, component) and poliomyelitis (inactivated) vaccine (adsorbed, reduced antigen(s) content) REVAXIS®: diphtheria, tetanus and poliomyelitis (inactivated) vaccine (adsorbed, reduced antigen(s) content)	Page	

TITLE OF STUDY

An open-label, multicentre study to evaluate the immunogenicity and safety of one dose of a diphtheria, tetanus, acellular pertussis and poliomyelitis vaccine (REPEVAX®) followed by 2 doses of a diphtheria, tetanus and poliomyelitis vaccine (REVAXIS®) in subjects of 40 years of age or older without a previous diphtheria- and tetanus-containing booster within the last 20 years

Study Identification Number: RPV04C

EudraCT Number: 2010-023086-21

COORDINATING INVESTIGATORS

- France: Florence GALTIER, MD, Montpellier
- Germany: Rolf DOMINICUS, MD, Dülmen

STUDY CENTRE(S)

12 hospitals, practices, and site management organisations (6 in France and 6 in Germany)

PUBLICATION (REFERENCE)

Not applicable

STUDIED PERIOD	16 months	**PHASE OF DEVELOPMENT**
First Visit First Subject:	17 January 2011	Phase 3b
Last Visit Last Subject:	02 December 2011	
End of study:	24 May 2012 (serology results available)	

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OBJECTIVES

PRIMARY OBJECTIVES

- To demonstrate that 3 doses of a vaccine containing Td-IPV valences administered in a 0, 1, and 6-month schedule induced an acceptable immune response in terms of seroprotection rate (SPR) against diphtheria, tetanus and poliomyelitis type 1, 2, and 3, in subjects of 40 years of age or older with no diphtheria- and tetanus-containing booster within the last 20 years
- To evaluate the percentage of subjects with antibody concentration ≥5 EU/mL (Enzyme-linked immunosorbent assay [ELISA]) for each of the pertussis components (pertussis toxoid [PT], filamentous haemagglutinin [FHA], pertactin [PRN], and fimbriae types 2 & 3 [FIM2&3]) after 1 dose of REPEVAX® in these subjects.

SECONDARY OBJECTIVES

Secondary immunogenicity objectives:

- If the primary objective was achieved, to determine whether 1 or 2 doses of a vaccine containing Td-IPV valences induced an acceptable response in terms of SPR against diphtheria, tetanus, and poliomyelitis type 1, 2, and 3, in subjects of 40 years of age or older with no diphtheria- and tetanus-containing booster within the last 20 years
- To describe the immune responses to REPEVAX® in these subjects
- To describe the immune responses to REVAXIS® administered 1 and 6 months after the administration of REPEVAX® in these subjects (Dose 2 and Dose 3).

Secondary safety objective:

- To describe the safety of REPEVAX® and REVAXIS® in these subjects.

The secondary safety objective of this study was descriptive, thus no formal hypothesis was tested.

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METHODOLOGY

This was an open-label, single-arm, multi-centre study

Visit 1 Day 0	**Visit 2** Month 1	**Visit 3** Month 2	**Visit 4** Month 6	**Visit 5** Month 7
	28 to 35 days after Visit 1	28 to 35 days after Visit 2	22 to 30 weeks after Visit 1	28 to 35 days after Visit 4
Blood sample 1	Blood sample 2	Blood sample 3		Blood sample 4
Dose 1 **REPEVAX®**	**Dose 2** **REVAXIS®**		**Dose 3** **REVAXIS®**	

NUMBER OF SUBJECTS (PLANNED AND ANALYSED)

Planned: 335 subjects

Screened: 342 subjects (information consent form [ICF] signed)

Included: 336 subjects were included (vaccinated), 128 subjects (38.1%) in France and 208 subjects (61.9%) in Germany

Completed:

- 317 subjects (94.3%) completed the 3-dose schedule, 9 subjects (2.7%) received 1 dose of REPEVAX® and 1 dose of REVAXIS® and 10 subjects (3.0%) received only 1 dose of REPEVAX®.
- 316 subjects (94.0%) completed the study and 20 subjects (6.0%) were withdrawn: 8 subjects (2.4%) withdrew their consent, 5 subjects (1.5%) withdrew the study because of an AE (see safety results for further details), 3 subjects (0.9%) were withdrawn because of non-compliance with the protocol (after Dose 1, they found that they had received a diphtheria- or tetanus-containing within the last 20 years), 3 subjects (0.9%) were lost to follow-up, and 1 subject withdrew for another reason (i.e. due to 'heavy' reactions to vaccination, the investigator decided together with the subject to withdraw the subject).

Analysed: Please, refer to Table 1.

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Table 1. Analysis Sets of Subjects

Vaccinated		Full Analysis Set	
- Dose 1 (REPEVAX®)	336 (100%)	- Full Analysis Set Post-Dose 1 (FAS1)	330 (98.2%)
- Dose 2 (REVAXIS®)	326 (97.0%)	- Full Analysis Set Post-Dose 2 (FAS2)	325 (96.7%)
- Dose 3 (REVAXIS®)	317 (94.3%)	- Full Analysis Set Post-Dose 3 (FAS3)	316 (94.0%)
		Per Protocol Set	
		- Per Protocol Set Post-Dose 1 (PPS1)	318 (94.6%)
		- Per Protocol Set Post-Dose 2 (PPS2)	297 (88.4%)
		- Per Protocol Set Post-Dose 3 (PPS3)	291 (86.6%)
		Safety Set	
		- Safety Set Post-Dose 1 (SS1)	334 (99.4%)
		- Safety Set Post-Dose 2 (SS2)	325 (96.7%)
		- Safety Set Post-Dose 3 (SS3)	316 (94.0%)

Percentages are calculated based on the number of included subjects

DIAGNOSIS AND MAIN CRITERIA FOR INCLUSION

Adults aged ≥40 years at Visit 1, having not received a booster dose of diphtheria- and tetanus-containing vaccine within the last 20 years before Visit 1, and no medical condition or treatment that could affect the immune system.

TEST VACCINES, DOSE AND MODE OF ADMINISTRATION, BATCH NUMBER

REPEVAX® (Tdap-IPV): diphtheria, tetanus, pertussis (acellular, component), and poliomyelitis (inactivated) vaccine (adsorbed, reduced antigen(s) content)

- Presentation and mode of administration: suspension for injection in a prefilled syringe
- Route of administration: intramuscular
- Dose: 0.5 mL
- Storage: +2°C to +8°C
- Batch number: E1142-3 (expiry date: 30 June 2012)

REVAXIS® (Td-IPV): diphtheria, tetanus, and poliomyelitis (inactivated) Vaccine (adsorbed, reduced antigen(s) content).

- Presentation and mode of administration: suspension for injection in a prefilled syringe
- Route of administration: intramuscular
- Dose: 0.5 mL
- Storage: +2°C to +8°C
- Batch number: E0630-1 (expiry date: 30 June 2012)

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REFERENCE VACCINE, DOSE AND MODE OF ADMINISTRATION, BATCH NUMBER

Not applicable.

DURATION OF FOLLOW-UP

The total follow-up was of about 7 months for each subject.

CRITERIA FOR EVALUATION

IMMUNOGENICITY

Primary endpoints

- **After Dose 3:**
  - Post-vaccination SPR for diphtheria defined as the percentage of subjects with antibody concentration ≥0.1 IU/mL (SNA)
  - Post-vaccination SPR for tetanus defined as the percentage of subjects with antibody concentration ≥0.1 IU/mL (ELISA)
  - Post-vaccination SPR for poliomyelitis type 1, 2, and 3 defined as the percentage of subjects with antibody titre ≥8 (1/dilution [dil]) (SNA).
- **After Dose 1:**
  - Post-vaccination percentage of subjects with antibody concentration ≥5 EU/mL (ELISA) for each of the pertussis components (PT, FHA, PRN, and FIM2&3).

Secondary endpoints

- **After Dose 1:**
  - Geometric mean of antibody concentrations (GMCs) (EU/mL) and the geometric mean of individual post/pre-antibody concentration ratios (GMCRs) to pertussis components (PT, FHA, PRN and FIM2&3).
- **After Dose 1 and Dose 2:**
  - Post-vaccination SPR for diphtheria, tetanus, and poliomyelitis type 1, 2, and 3
- **After each of the 3 doses:**
  - Post-vaccination GMC to diphtheria
  - Post-vaccination GMC to tetanus
  - Post-vaccination GMT to poliomyelitis type 1, 2, and 3
  - Post-vaccination percentage of subjects with antibody concentration ≥0.01 IU/mL for diphtheria
  - Post-vaccination percentage of subjects with antibody concentration ≥0.01 IU/mL for tetanus.

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SAFETY *(secondary endpoints only)*

The safety endpoints were the percentage of subjects with the following adverse events (AEs):

- **From Day 0 to Day 7 after each of the 3 doses:**
  - Solicited injection-site adverse reactions (ISRs): erythema, swelling, and pain
  - Solicited systemic AEs: fever (body temperature ≥38.0°C), headache, malaise, and myalgia
- **From Day 0 to Day 28 after each of the 3 doses:** Unsolicited ISRs and systemic AEs
- **From Visit 1 to the last visit of the enrolled subjects:** Serious adverse events (SAEs).

STATISTICAL METHODS

IMMUNOGENICITY

Primary objectives

Immunogenicity was evaluated using a Full Analysis Set (main analysis) and a Per Protocol Set (supportive analysis). The post-Dose 3 SPR (and 2-sided 95% confidence interval [CI]) was calculated for diphtheria, tetanus, and poliomyelitis type 1, 2, and 3. It was considered as acceptable if the lower bounds of the 2-sided 95%CI of the post-vaccination seroprotection rate were greater than 95% for diphtheria, tetanus, and poliomyelitis type 1, 2, and 3. The post-Dose 1 percentage of subjects (and 2-sided 95% CI) with antibody concentration ≥5 EU/mL (ELISA) was calculated for each of the pertussis components (PT, FHA, PRN and FIM2&3).

The success of the study required that the primary objective was achieved for diphtheria, tetanus, and poliomyelitis type 1, 2, and 3.

Secondary objectives

The post-Dose 1 and post-Dose 2 SPRs were considered as acceptable if the lower bounds of the 2-sided 95%CI of the post-vaccination SPRs were greater than 95% for diphtheria, tetanus, and poliomyelitis type 1, 2, and 3.

Descriptive summaries following each dose (with 2-sided 95%CI) including reverse cumulative distribution curves (RCDC) were provided.

SAFETY

Descriptive safety profile after each vaccination.

SUMMARY – CONCLUSIONS

DEMOGRAPHY

The mean age (range) of the 336 included subjects was 60.2 years (40; 89) and 55.1% were women. Their mean weight was 79.2 kg (43; 152).

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IMMUNOGENICITY RESULTS (refer to Table 2)

Table 2: Post-Dose 1, 2 and 3 Antibody Response Rate to Diphtheria, Tetanus and Poliomyelitis Type 1, 2, and 3 - Full Analysis

	Pre-vaccination	Dose 1 – REPEVAX® (N=330)	Dose 2 - REVAXIS® (N=325)	Dose 3 - REVAXIS® (N=316)
Diphtheria antibody				
≥0.1 IU/mL	147 (44.5%)	272 (82.4%)	294 (90.5%)	299 (94.6%)
95% CI (≥0.1 IU/mL)	[39.1%; 50.1%]	[77.9%; 86.4%]	[86.7%; 93.4%]	[91.5%; 96.8%]
≥0.01 IU/mL	239 (72.4%)	306 (92.7%)	312 (96.0%)	316 (100%)
95% CI (≥0.01 IU/mL)	[67.3%; 77.2%]	[89.4%; 95.3%]	[93.3%; 97.9%]	[98.8%; 100%]
Tetanus antibody				
≥0.1 IU/mL	268 (81.2%)	325 (98.5%)	325 (100%)	316 (100%)
95% CI (≥0.1 IU/mL)	[76.6%; 85.3%]	[96.5%; 99.5%]	[98.9%; 100%]	[98.8%; 100%]
≥0.01 IU/mL	305 (92.4%)	329 (99.7%)	325 (100%)	316 (100%)
95% CI (≥0.01 IU/mL)	[89.0%; 95.0%]	[98.3%; 100%]	[98.9%; 100%]	[98.8%; 100%]
Poliomyelitis type 1 antibody				
≥8 (1/dil)	308 (93.3%)	328 (99.4%)	325 (100%)	316 (100%)
95% CI (≥8 (1/dil)	[90.1%; 95.8%]	[97.8%; 99.9%]	[98.9%; 100%]	[98.8%; 100%]
Poliomyelitis type 2 antibody				
≥8 (1/dil)	315 (95.5%)	330 (100%)	325 (100%)	316 (100%)
95% CI (≥8 (1/dil)	[92.6%; 97.4%]	[98.9%; 100%]	[98.9%; 100%]	[98.8%; 100%]
Poliomyelitis type 3 antibody				
≥8 (1/dil)	294 (89.1%)	326 (98.8%)	324 (99.7%)	316 (100%)
95% CI (≥8 (1/dil)	[85.2%; 92.2%]	[96.9%; 99.7%]	[98.3%; 100%]	[98.8%; 100%]

FAS1 was used for Dose 1, FAS2 for Dose 2 and FAS3 for Dose 3

Primary objectives

Post-Dose 3 SPR for diphtheria was 94.6% [91.5; 96.8]. Consequently, the primary objective of the study was not met as the lower bound of the 95% CI of the diphtheria SPR was ≤95%. Post-Dose 3 SPR for tetanus and poliomyelitis type 1, 2, and 3 was 100% [98.8; 100%].

Post-Dose 1 percentage of subjects with antibody concentration ≥5 EU/mL against the pertussis components contained in the study vaccine was 96.3% [93.6; 98.1] (for PT), 100% [98.9; 100] (for FHA), 99.4% [97.8; 99.9] (for PRN), and 95.8% [93.0; 97.7] (for FIM2&3).

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Secondary objectives

On the Full Analysis Sets, post-Dose 1 and Dose 2 SPR for diphtheria was 82.4% [77.9; 86.4] and 90.5% [86.7; 93.4], respectively. Post-Dose 1 and Dose 2 SPR was 98.5% [96.5; 99.5] and 100% [98.9; 100] for tetanus, 99.4% [97.8; 99.9] and 100% [98.9; 100] for poliomyelitis type 1, 100% [98.9; 100] and 100% [98.9; 100] for poliomyelitis type 2, and 98.8% [96.9; 99.7] and 99.7% [98.3; 100] for poliomyelitis type 3. Post-Dose 1, Dose 2, and Dose 3 percentages of subjects with anti-diphtheria concentration ≥0.01 IU/mL were 92.7% [89.4; 95.3], 96.0% [93.3; 97.9] and 100% [98.8; 100], respectively.

Results obtained on the Per Protocol Set (supportive analysis) were similar to the ones obtained on the Full Analysis Set (main analysis).

SAFETY RESULTS (refer to Table 3)

Within 28 days after Dose 1, 65.3% of subjects reported at least 1 AE, and 62.0% reported AEs considered by the investigator as vaccine-related. 53.6% of subjects reported at least 1 ISR, and 52.7% reported solicited ISRs between Day 0 and Day 7: pain (50.6%), erythema (10.2%) and swelling (8.7%). 41.6% of subjects reported at least 1 systemic AE, 34.4% reported at least 1 systemic AE considered by the investigator as vaccine-related, and 33.5% reported solicited systemic AEs between Day 0 and Day 7: myalgia (19.8%), headache (18.9%), malaise (11.1%) and pyrexia (0.9%). No subject was withdrawn from the study due to an AE occurring after Dose 1.

Within 28 days after Dose 2 and Dose 3, 48.3% and 50.3% of subjects, respectively, reported at least 1 AE, and 43.4% and 47.8% reported AEs considered by the investigator as vaccine-related. 35.4% and 41.5% of subjects reported at least 1 ISR, 35.4% and 41.5% of subjects also reported solicited ISRs between Day 0 and Day 7: pain (34.5% and 39.9%), erythema (5.5% and 7.9%) and swelling (4.3% and 6.3%). 30.8% and 28.5% of subjects reported at least 1 systemic AE after Dose 2 and Dose 3, respectively, 23.4% reported at least 1 systemic AE considered by the investigator as vaccine-related after each of these doses, and 24.9% and 25.0% reported solicited systemic AEs between Day 0 and Day 7: myalgia (17.2% and 15.5%), headache (12.0% and 13.6%), malaise (4.6% and 6.0%) and pyrexia (0.3% and 2.2%).

Five subjects were withdrawn from the study due to an AE occurring after Dose 2 and none was withdrawn due to an AE occurring after Dose 3. Within the 5 AEs leading to premature discontinuation after Dose 2, none was considered by the investigator as vaccine-related: 3 were serious AEs (THYROID NEOPLASM [Investigator's term: thyroid nodule; clinical description: Class III multinodular goitre], CEREBROVASCULAR ACCIDENT and ALCOHOLISM) and 2 were non-serious AE (DIVERTICULUM [Investigator's term: diverticulosis] and NODULE [Investigator's term: inflammatory nodule right foot]). Only 1 AE leading to withdrawal (DIVERTICULUM) occurred less than 1 month after vaccination.

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Eight subjects reported 1 SAE, none of these SAEs was considered by the investigator as vaccine-related: 2 SAEs occurred after Dose 1 (SUPRAVENTRICULAR TACHYCARDIA and MANIA [Investigator's term: manic episode], 4 after Dose 2 (SICK SINUS SYNDROME, THYROID NEOPLASM, CEREBROVASCULAR ACCIDENT and ALCOHOLISM) and 2 after Dose 3 (FEMORAL NECK FRACTURE and CEROBROVASCULAR ACCIDENT).

Table 3: Global Summary of Safety - Safety Set

	Dose 1 - REPEVAX® (N=334) n (%)	**Dose 2 - REVAXIS® (N=325) n (%)**	**Dose 3 - REVAXIS® (N=316) n (%)**
Adverse event (AE) (Day 0 – Day 28)	218 (65.3)	157 (48.3)	159 (50.3)
Vaccine-related AE (Day 0 – Day 28)	207 (62.0)	141 (43.4)	151 (47.8)
Injection-site adverse reaction (ISR) (Day 0 – Day 28)	179 (53.6)	115 (35.4)	131 (41.5)
Solicited ISR (Day 0 – Day 7)	176 (52.7)	115 (35.4)	131 (41.5)
Injection site erythema	*34 (10.2)*	*18 (5.5)*	*25 (7.9)*
Injection site pain	*169 (50.6)*	*112 (34.5)*	*126 (39.9)*
Injection site swelling	*29 (8.7)*	*14 (4.3)*	*20 (6.3)*
Unsolicited ISR (Day 0 – Day 28)	14 (4.2)	4 (1.2)	4 (1.3)
Systemic AE (Day 0 – Day 28)	139 (41.6)	100 (30.8)	90 (28.5)
Solicited systemic AE (Day 0 – Day 7)	112 (33.5)	81 (24.9)	79 (25.0)
Headache	*63 (18.9)*	*39 (12.0)*	*43 (13.6)*
Malaise	*37 (11.1)*	*15 (4.6)*	*19 (6.0)*
Myalgia	*66 (19.8)*	*56 (17.2)*	*49 (15.5)*
Pyrexia	*3 (0.9)*	*1 (0.3)*	*7 (2.2)*
Unsolicited systemic AE (Day 0 – Day 28)	48 (14.4)	34 (10.5)	23 (7.3)
Vaccine-related systemic AE (Day 0 – Day 28)	115 (34.4)	76 (23.4)	74 (23.4)
Serious AE from vaccination to next visit	2 (0.6)	4 (1.2)	2 (0.6)
Vaccine-related serious AE	0	0	0
Withdrawal due to AE following vaccination	0	5 (1.5%)	0

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CONCLUSION

In this study performed in subjects of 40 years of age or more who did not receive a diphtheria- and tetanus-containing vaccine within the last 20 years,

- 3 doses of diphtheria-containing vaccine provided full protection in 94.6% of subjects (concentration measured by seroneutralisation assay ≥0.1 UI/mL) and basic clinical immunity against disease (concentration measured by seroneutralisation assay ≥0.01 UI/mL) in all subjects,
- 2 doses of tetanus-containing vaccine provided protection to all subjects, and
- 1 dose of poliomyelitis-containing vaccine provided protection in ≥98.8% of subjects.

The safety profile of the 3-dose regimen used in this study, REPEVAX® (Tdap-IPV) followed by 2 doses of REVAXIS® (Td-IPV) 1 and 6 months later, was well tolerated and in accordance to the Summary of Product Characteristics of either vaccine.

DATE OF REPORT 06 December 2012