ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 05/05/2014

ClinicalTrials.gov ID: NCT00776230

Study Identification

Unique Protocol ID:	IC51-314
Brief Title:	Immunogenicity of a Commercial Batch of JEV IC51 up to 24 Months Post Filling
Official Title:	Immunogenicity of a Commercial Batch of the Japanese Encephalitis Vaccine IC51 up to Twenty-four Months Post Filling. An Open-label, Multicenter, Phase 3 Study
Secondary IDs:	

Study Status

Record Verification:	May 2014
Overall Status:	Completed
Study Start:	September 2008
Primary Completion:	June 2010 [Actual]
Study Completion:	June 2010 [Actual]

Sponsor/Collaborators

Sponsor:	Valneva Austria GmbH
Responsible Party:	Sponsor
Collaborators:	

Oversight

FDA Regulated?:	No
IND/IDE Protocol?:	No

Review Board:	Approval Status: Approved Approval Number: EK-08-149-0908 / EK-14 370/08 Board Name: Ethics Committee City of Vienna / Ethics Committee Berlin Board Affiliation: Ethics Committee City of Vienna / Ethics Committee Berlin Phone: 0043 1 40 00 / 0049 30 9(0)12 Email: ethikkommission@m15.magwien.gv.at
Data Monitoring?:	No
Plan to Share Data?:	
Oversight Authorities:	Germany: Paul-Ehrlich-Institut Austria: Agency for Health and Food Safety

Study Description

Brief Summary:	The objective is to assess immunogenicity of a commercial IC51 batch at 3 different time points post filling (12, 18, 24 months) in terms of Geometric Mean Titers (GMT) for anti-JEV neutralizing antibodies at Day 56 after the first vaccination.
Detailed Description:	Open-label, multicenter, phase 3 study assessing immunogenicity at various time points throughout the shelf-life of a commercial batch of IC51 (Batch IC51/07F/008) The study population consists of male and female healthy subjects, aged at least 18 years. The study will be performed at 3 study centers in Germany and Austria. Three sequential cohorts, each containing 100 subjects, will be enrolled into the study at approximately 12, 18 and 24 months after filling of the commercial batch IC51/07F/008 of IC51

Conditions

Conditions:	Japanese Encephalitis
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Prevention
Study Phase:	Phase 3
Intervention Model:	Single Group Assignment
Number of Arms:	1
Masking:	Open Label
Allocation:	Non-Randomized
Endpoint Classification:	Efficacy Study

Enrollment: 304 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Active Comparator: IC51 6 mcg	Biological/Vaccine: IC51 6 mcg im. at day 0 and day 28 Other Names: • Japanese Encephalitis vaccine

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 18 Years

Maximum Age:

Gender: Both

Accepts Healthy Volunteers?: Yes

Criteria: Inclusion Criteria:

- Male and female healthy adults aged at least 18 years with written informed consent and either no childbearing potential or negative pregnancy test.

Exclusion Criteria:

- History of immunodeficiency or immunosuppressive therapy, known HIV infection, drug addiction including alcohol dependence, prior vaccination against JE

Contacts/Locations

Study Officials: Evelyn Hatzenbichler
Study Director
Intercell AG

Locations: Germany
Berliner Zentrum Reise- und Tropenmedizin
Berlin, Berlin, Germany, 10117

Universitätsklinikum Rostock
Rostock, Rostock, Germany, 18057

Austria
Zentrum für Reisemedizin
Vienna, Vienna, Austria, 1090

References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Reporting Groups

	Description
IC51 Cohort 1	vaccinations with IC51 6 mcg i.m. on Day 0 and Day 28; batch age: ~12 months after filling;
IC51 Cohort 2	vaccinations with IC51 6 mcg i.m. on Day 0 and Day 28; batch age: ~18 months after filling;
IC51 Cohort 3	vaccinations with IC51 6 mcg i.m. on Day 0 and Day 28; batch age: ~24 months after filling;

Overall Study

	IC51 Cohort 1	IC51 Cohort 2	IC51 Cohort 3
Started	99	103	102
Enrolled and Vaccinated at Day 0	98	103	102
Completed	96	100	97
Not Completed	3	3	5
Lost to Follow-up	2	1	5
Not vaccinated at Day 0	1	0	0
Withdrawal by Subject	0	1	0

	IC51 Cohort 1	IC51 Cohort 2	IC51 Cohort 3
Subject missed Visit 4	0	1	0

Baseline Characteristics

Reporting Groups

	Description
IC51 Cohort 1	vaccinations with IC51 6 mcg i.m. on Day 0 and Day 28; batch age: ~12 months after filling;
IC51 Cohort 2	vaccinations with IC51 6 mcg i.m. on Day 0 and Day 28; batch age: ~18 months after filling;
IC51 Cohort 3	vaccinations with IC51 6 mcg i.m. on Day 0 and Day 28; batch age: ~24 months after filling;

Baseline Measures

	IC51 Cohort 1	IC51 Cohort 2	IC51 Cohort 3	Total
Number of Participants	98	103	102	303
Age, Continuous [units: years] Mean (Standard Deviation)	27.3 (7.6)	28.6 (10.7)	31.6 (10.7)	29.2 (10.0)
Gender, Male/Female [units: participants]				
Female	61	55	51	167
Male	37	48	51	136
Race/Ethnicity, Customized [units: participants]				
Caucasian/ White	93	98	102	293
Asian	5	5	0	10
Black or African American	0	0	0	0
Other	0	0	0	0

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Primary: 1. Geometric Mean Titers (GMT) at Day 56
Measure Description	

Time Frame	see above
Safety Issue?	No

Analysis Population Description

Intention To Treat Population, i.e., all subjects entered into the study who received at least one dose of study medication

Reporting Groups

	Description
IC51 Cohort 1	vaccinations with IC51 6 mcg i.m. on Day 0 and Day 28; batch age: ~12 months after filling;
IC51 Cohort 2	vaccinations with IC51 6 mcg i.m. on Day 0 and Day 28; batch age: ~18 months after filling;
IC51 Cohort 3	vaccinations with IC51 6 mcg i.m. on Day 0 and Day 28; batch age: ~24 months after filling;

Measured Values

	IC51 Cohort 1	IC51 Cohort 2	IC51 Cohort 3
Number of Participants Analyzed	98	103	102
Primary: 1. Geometric Mean Titers (GMT) at Day 56 [units: Geometric Mean Titer - Estimate] Geometric Mean (95% Confidence Interval)	100.1 (78.9 to 127.0)	84.7 (66.3 to 108.2)	68.1 (54.4 to 85.4)

2. Secondary Outcome Measure:

Measure Title	Secondary: 1. Seroconversion Rate 2. GMTs Day 28, Month 6 and Month 12 3. Treatment Emergent Adverse Events 4. Systemic and Local Tolerability
Measure Description	
Time Frame	see above
Safety Issue?	Yes

Outcome Measure Data Not Reported

Reported Adverse Events

Time Frame	up to Day 56
Additional Description	[Not specified]

Reporting Groups

	Description
IC51 Cohort 1	
IC51 Cohort 2	
IC51 Cohort 3	

Serious Adverse Events

	IC51 Cohort 1	IC51 Cohort 2	IC51 Cohort 3
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	2/98 (2.04%)	1/103 (0.97%)	0/102 (0%)
Infections and infestations			
Subcutaneous abscess	1/98 (1.02%)	0/103 (0%)	0/102 (0%)
Reproductive system and breast disorders			
Endometrial hyperplasia	1/98 (1.02%)	0/103 (0%)	0/102 (0%)
Vascular disorders			
Hypertension	0/98 (0%)	1/103 (0.97%)	0/102 (0%)

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 1%

	IC51 Cohort 1	IC51 Cohort 2	IC51 Cohort 3
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	66/98 (67.35%)	58/103 (56.31%)	61/102 (59.8%)
Blood and lymphatic system disorders			
Lymphadenopathy	0/98 (0%)	2/103 (1.94%)	0/102 (0%)
Cardiac disorders			
Tachycardia	1/98 (1.02%)	0/103 (0%)	0/102 (0%)
Ear and labyrinth disorders			
Vertigo	2/98 (2.04%)	1/103 (0.97%)	2/102 (1.96%)
Eye disorders			
Ocular Hyperaemia	1/98 (1.02%)	0/103 (0%)	0/102 (0%)

	IC51 Cohort 1	IC51 Cohort 2	IC51 Cohort 3
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Gastrointestinal disorders			
Abdominal Pain Upper	1/98 (1.02%)	0/103 (0%)	0/102 (0%)
Dental Caries	1/98 (1.02%)	0/103 (0%)	0/102 (0%)
Diarrhoea	0/98 (0%)	0/103 (0%)	3/102 (2.94%)
Dry Mouth	0/98 (0%)	2/103 (1.94%)	0/102 (0%)
Enteritis	1/98 (1.02%)	0/103 (0%)	0/102 (0%)
Nausea	5/98 (5.1%)	5/103 (4.85%)	7/102 (6.86%)
Toothache	1/98 (1.02%)	0/103 (0%)	1/102 (0.98%)
General disorders			
Asthenia	1/98 (1.02%)	0/103 (0%)	0/102 (0%)
Fatigue	3/98 (3.06%)	20/103 (19.42%)	10/102 (9.8%)
Influenza Like Illness	13/98 (13.27%)	10/103 (9.71%)	15/102 (14.71%)
Injection Site Erythema	1/98 (1.02%)	0/103 (0%)	0/102 (0%)
Pyrexia	0/98 (0%)	2/103 (1.94%)	1/102 (0.98%)
Infections and infestations			
Cystitis	1/98 (1.02%)	2/103 (1.94%)	0/102 (0%)
Gastroenteritis	3/98 (3.06%)	0/103 (0%)	2/102 (1.96%)
Nasopharyngitis	11/98 (11.22%)	7/103 (6.8%)	7/102 (6.86%)
Rhinitis	5/98 (5.1%)	1/103 (0.97%)	2/102 (1.96%)
Sinusitis	1/98 (1.02%)	1/103 (0.97%)	1/102 (0.98%)
Subcutaneous Abscess	1/98 (1.02%)	0/103 (0%)	0/102 (0%)
Tonsillitis	0/98 (0%)	2/103 (1.94%)	0/102 (0%)
Urinary Tract Infection	2/98 (2.04%)	0/103 (0%)	2/102 (1.96%)
Investigations			
Hepatic Enzyme Increased	1/98 (1.02%)	0/103 (0%)	0/102 (0%)
Iron Deficiency	0/98 (0%)	2/103 (1.94%)	0/102 (0%)

	IC51 Cohort 1	IC51 Cohort 2	IC51 Cohort 3
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Musculoskeletal and connective tissue disorders			
Arthralgia	1/98 (1.02%)	0/103 (0%)	0/102 (0%)
Back Pain	2/98 (2.04%)	0/103 (0%)	0/102 (0%)
Muscle Spasms	1/98 (1.02%)	0/103 (0%)	0/102 (0%)
Myalgia	7/98 (7.14%)	9/103 (8.74%)	9/102 (8.82%)
Rotator Cuff Syndrome	1/98 (1.02%)	0/103 (0%)	0/102 (0%)
Nervous system disorders			
Disturbance In Attention	1/98 (1.02%)	1/103 (0.97%)	0/102 (0%)
Dizziness	1/98 (1.02%)	3/103 (2.91%)	2/102 (1.96%)
Headache	26/98 (26.53%)	24/103 (23.3%)	32/102 (31.37%)
Paraesthesia	1/98 (1.02%)	0/103 (0%)	0/102 (0%)
Renal and urinary disorders			
Dysuria	1/98 (1.02%)	0/103 (0%)	0/102 (0%)
Reproductive system and breast disorders			
Endometrial Hyperplasia	1/98 (1.02%)	0/103 (0%)	0/102 (0%)
Endometriosis	1/98 (1.02%)	0/103 (0%)	0/102 (0%)
Menorrhagia	1/98 (1.02%)	0/103 (0%)	0/102 (0%)
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal Pain	3/98 (3.06%)	3/103 (2.91%)	2/102 (1.96%)
Skin and subcutaneous tissue disorders			
Pruritus	0/98 (0%)	2/103 (1.94%)	0/102 (0%)
Rash	0/98 (0%)	0/103 (0%)	2/102 (1.96%)

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

Results Point of Contact:

Name/Official Title: Katrin Dubischar-Kastner
Organization: Valneva Austria GmbH
Phone: +43120620 Ext: 0
Email: info@valneva.com