ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 06/27/2014

ClinicalTrials.gov ID: NCT00596102

Study Identification

Unique Protocol ID:	IC51-303
Brief Title:	Longterm Immunogenicity of the Japanese Encephalitis Vaccine IC51
Official Title:	Longterm Immunogenicity of the Japanese Encephalitis Vaccine IC51. An Uncontrolled Phase 3 Follow-up Study
Secondary IDs:	

Study Status

Record Verification:	June 2014
Overall Status:	Completed
Study Start:	October 2005
Primary Completion:	March 2011 [Actual]
Study Completion:	

Sponsor/Collaborators

Sponsor:	Valneva Austria GmbH
Responsible Party:	Sponsor
Collaborators:	

Oversight

FDA Regulated?:	Yes
Applicable Trial?:	Section 801 Clinical Trial? No Delayed Posting?

IND/IDE Protocol?:	Yes
IND/IDE Information:	Grantor: CBER IND/IDE Number: 8589 Serial Number: 0027 Has Expanded Access? No
Review Board:	Approval Status: Board Name: Board Affiliation: Phone: Email:
Data Monitoring?:	
Plan to Share Data?:	
Oversight Authorities:	United States: Food and Drug Administration

Study Description

Brief Summary:	The study investigates the long term safety and immunogenicity of the Japanese Encephalitis vaccine IC51 up to month 60.
Detailed Description:	

Conditions

Conditions:	Japanese Encephalitis
Keywords:	

Study Design

Study Type:	Observational
Observational Study Model:	Cohort
Time Perspective:	Other
Biospecimen Retention:	
Biospecimen Description:	
Enrollment:	3258 [Actual]
Number of Groups/Cohorts:	1

Groups and Interventions

Intervention Details:
Biological/Vaccine: Japanese Encephalitis purified inactivated vaccine
Japanese Encephalitis purified inactivated vaccine

Outcome Measures

[See Results Section.]

Eligibility

Study Population: Approximately 3,300 subjects having completed IC51, JE-VAX or placebo treatment in studies IC51-301 or IC51-302 will take part in the safety follow up, up to month 6 after 1st vaccination in the study IC51-301 (NCT00604708) or IC51-302 (NCT00605085). Only ~160 subjects, who have been treated with IC51 will take part in the immunogenicity and long-term analysis up to month 60.

Sampling Method: Non-Probability Sample

Minimum Age: 18 Years

Maximum Age:

Gender: Both

Accepts Healthy Volunteers?: Yes

Criteria: Inclusion Criteria:

- Healthy subjects at least 18 years of age
- Written informed consent obtained prior to study entry
- Subjects correctly included and having completed clinical studies IC51-301 (NCT00604708) and IC51-302 (NCT00605085) with at least one vaccination

Exclusion Criteria:

- Inability or unwillingness to provide informed consent and to abide the requirements of the study

Contacts/Locations

Study Officials: Evelyn Hatzenbichler, Ph.D.
Study Director
Intercell AG

Locations:

References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Recruitment Details	study participants were recruited from 44 study centers previously participating in study IC51-301 and IC51-302

Reporting Groups

	Description
IC51	no active treatment in study IC51-303, IC51 vaccinations were performed in preceeding study IC51-301 or IC51-302
JE-VAX	no active treatment in study IC51-303, vaccinations were performed in preceeding study IC51-301
Placebo	no treatment in study IC51-303, vaccinations were performed in preceeding study IC51-302

Up to Month 6

	IC51	JE-VAX	Placebo
Started	2283	338	637
Completed	2283	338	637
Not Completed	0	0	0

Up to Month 60

	IC51	JE-VAX	Placebo
Started	2283	338	637
Completed	102 [1]	0	0
Not Completed	2181	338	637

[1] long-term safety follow-up beyond Month 6 for a sub-set of subjects in "IC51" group only

Baseline Characteristics

Reporting Groups

	Description
IC51	no active treatment in study IC51-303, IC51 vaccinations were performed in preceeding study IC51-301 or IC51-302
JE-VAX	no active treatment in study IC51-303, vaccinations were performed in preceeding study IC51-301
Placebo	no treatment in study IC51-303, vaccinations were performed in preceeding study IC51-302

Baseline Measures

	IC51	JE-VAX	Placebo	Total
Number of Participants	2283	338	637	3258
Age, Continuous [units: years] Mean (Standard Deviation)	35.3 (13.8)	42.3 (14.1)	33.5 (13.0)	35.6 (13.9)
Gender, Male/Female [units: participants]				
Female	1274	201	365	1840
Male	1009	137	272	1418
Race/Ethnicity, Customized [units: participants]				
Asian	38	1	16	55
Black or African American	101	35	25	161
Caucasian	2076	288	574	2938
Other	68	14	22	104

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Percentage of Subjects With Seroconversion Rate (SCR) ≥ 1:10 Anti-JEV Neutralizing Antibody Titer (PRNT)
Measure Description	first vaccination refers to 1st vaccine administration in studies IC51-301 or IC51-302
Time Frame	24 months after the first vaccination
Safety Issue?	No

Analysis Population Description

subjects enrolled into this study who planned to participate in the long-term immunogenicity part and received IC51 in the respective preceeding study

Reporting Groups

	Description
IC51	no active treatment in study IC51-303, IC51 vaccinations were performed in preceeding study IC51-301 or IC51-302

Measured Values

	IC51
Number of Participants Analyzed	181
Percentage of Subjects With Seroconversion Rate (SCR) ≥ 1:10 Anti-JEV Neutralizing Antibody Titer (PRNT) [units: percentage of subjects] Number (95% Confidence Interval)	81.8 (75.7 to 86.7)

2. Secondary Outcome Measure:

Measure Title	Percentage of Subjects With Seroconversion Rate (SCR) ≥ 1:10 Anti-JEV Neutralizing Antibody Titer (PRNT)
Measure Description	
Time Frame	6, 12, 36, 48 and 60 months after 1st vaccination
Safety Issue?	No

Outcome Measure Data Not Reported

3. Secondary Outcome Measure:

Measure Title	Geometric Mean Titers
Measure Description	
Time Frame	6, 12, 36, 48 and 60 months
Safety Issue?	No

Outcome Measure Data Not Reported

4. Secondary Outcome Measure:

Measure Title	Adverse Events
Measure Description	
Time Frame	6, 12, 24, 36, 48 and 60 months after 1st vaccination
Safety Issue?	No

Outcome Measure Data Not Reported

Reported Adverse Events

Time Frame	all participants across all treatment groups were followed-up until Month 6; a sub-group of the IC51 treatment arm was followed-up until Month 60
Additional Description	group "IC51 Month 6" includes the sub-set of study participants that later on is followed-up until Month 60 (group "IC51 Month 60")

Reporting Groups

	Description
IC51 Month 6	no active treatment in study IC51-303, IC51 vaccinations were performed in preceeding study IC51-301 or IC51-302; follow-up till Month 6
JE-VAX	no active treatment in study IC51-303, JE-VAX vaccinations were performed in preceeding study IC51-301 or IC51-302; follow-up till Month 6
Placebo	no active treatment in study IC51-303, Plarcebo vaccinations were performed in preceeding study IC51-301 or IC51-302; follow-up till Month 6
IC51 Month 60	no active treatment in study IC51-303, IC51 vaccinations were performed in preceeding study IC51-301 or IC51-302; follow-up till Month 60

Serious Adverse Events

	IC51 Month 6	JE-VAX	Placebo	IC51 Month 60
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	15/2283 (0.66%)	2/338 (0.59%)	7/637 (1.1%)	14/102 (13.73%)
Cardiac disorders				
Coronary Stenosis	0/2283 (0%)	0/338 (0%)	0/637 (0%)	1/102 (0.98%)
Gastrointestinal disorders				
Abdominal Pain	1/2283 (0.04%)	0/338 (0%)	1/637 (0.16%)	0/102 (0%)

	IC51 Month 6	JE-VAX	Placebo	IC51 Month 60
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Abdominal Pain Lower	1/2283 (0.04%)	0/338 (0%)	0/637 (0%)	0/102 (0%)
Appendix Disorder	1/2283 (0.04%)	0/338 (0%)	0/637 (0%)	0/102 (0%)
Vomiting	0/2283 (0%)	1/338 (0.3%)	0/637 (0%)	0/102 (0%)
Infections and infestations				
Abscess Soft Tissue	0/2283 (0%)	0/338 (0%)	0/637 (0%)	1/102 (0.98%)
Appendiceal Abscess	1/2283 (0.04%)	0/338 (0%)	0/637 (0%)	0/102 (0%)
Appendicitis	0/2283 (0%)	0/338 (0%)	1/637 (0.16%)	0/102 (0%)
Diverticulitis	1/2283 (0.04%)	0/338 (0%)	0/637 (0%)	0/102 (0%)
Endometritis	0/2283 (0%)	0/338 (0%)	0/637 (0%)	1/102 (0.98%)
Pneumonia	0/2283 (0%)	0/338 (0%)	1/637 (0.16%)	0/102 (0%)
Pyelonephritis	1/2283 (0.04%)	0/338 (0%)	0/637 (0%)	0/102 (0%)
Sepsis	0/2283 (0%)	0/338 (0%)	1/637 (0.16%)	0/102 (0%)
Tonsillitis	0/2283 (0%)	0/338 (0%)	0/637 (0%)	1/102 (0.98%)
Injury, poisoning and procedural complications				
Head Injury	1/2283 (0.04%)	0/338 (0%)	0/637 (0%)	0/102 (0%)
Joint Ligament Rupture	1/2283 (0.04%)	0/338 (0%)	0/637 (0%)	0/102 (0%)
Lower Limb Fracture	0/2283 (0%)	0/338 (0%)	0/637 (0%)	2/102 (1.96%)
Tibia Fructure	1/2283 (0.04%)	0/338 (0%)	0/637 (0%)	0/102 (0%)
Investigations				
Smear Cervix Abnormal	0/2283 (0%)	0/338 (0%)	0/637 (0%)	1/102 (0.98%)
Musculoskeletal and connective tissue disorders				
Rhabdomyolysis	0/2283 (0%)	0/338 (0%)	1/637 (0.16%)	0/102 (0%)
Shoulder Pain	0/2283 (0%)	0/338 (0%)	0/637 (0%)	2/102 (1.96%)
Synovial Cyst	0/2283 (0%)	0/338 (0%)	1/637 (0.16%)	0/102 (0%)
Toe Deformity	0/2283 (0%)	0/338 (0%)	0/637 (0%)	1/102 (0.98%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				

	IC51 Month 6	JE-VAX	Placebo	IC51 Month 60
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Adenocarinoma Pancreas	1/2283 (0.04%)	0/338 (0%)	0/637 (0%)	0/102 (0%)
Breast Cancer	1/2283 (0.04%)	0/338 (0%)	0/637 (0%)	0/102 (0%)
Lung Adenocarcinoma Metastatic	1/2283 (0.04%)	0/338 (0%)	0/637 (0%)	0/102 (0%)
Prostate Cancer	0/2283 (0%)	0/338 (0%)	0/637 (0%)	1/102 (0.98%)
Nervous system disorders				
Central Nervous System Inflammation	1/2283 (0.04%)	0/338 (0%)	0/637 (0%)	0/102 (0%)
Post Herpetic Neuralgia	0/2283 (0%)	0/338 (0%)	0/637 (0%)	1/102 (0.98%)
Pregnancy, puerperium and perinatal conditions				
Ectopic Pregnancy	1/2283 (0.04%)	0/338 (0%)	0/637 (0%)	0/102 (0%)
Renal and urinary disorders				
Nephrolithiasis	1/2283 (0.04%)	0/338 (0%)	0/637 (0%)	0/102 (0%)
Urethral Stricture	0/2283 (0%)	0/338 (0%)	0/637 (0%)	1/102 (0.98%)
Reproductive system and breast disorders				
Ovarian Cyst	0/2283 (0%)	0/338 (0%)	1/637 (0.16%)	0/102 (0%)
Respiratory, thoracic and mediastinal disorders				
Mediastinal Mass	1/2283 (0.04%)	0/338 (0%)	0/637 (0%)	0/102 (0%)
Nasal Septum Deviation	0/2283 (0%)	0/338 (0%)	0/637 (0%)	1/102 (0.98%)
Social circumstances				
Blood Donor	0/2283 (0%)	0/338 (0%)	0/637 (0%)	1/102 (0.98%)
Surgical and medical procedures				
Meniscus Operation	0/2283 (0%)	0/338 (0%)	1/637 (0.16%)	0/102 (0%)
Tonsillectomy	0/2283 (0%)	1/338 (0.3%)	0/637 (0%)	1/102 (0.98%)

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 2%

	IC51 Month 6	JE-VAX	Placebo	IC51 Month 60
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	78/2283 (3.42%)	16/338 (4.73%)	31/637 (4.87%)	54/102 (52.94%)
Endocrine disorders				
Hypothyroidism	0/2283 (0%)	2/338 (0.59%)	0/637 (0%)	3/102 (2.94%)
Gastrointestinal disorders				
Diarrhoea	10/2283 (0.44%)	0/338 (0%)	3/637 (0.47%)	3/102 (2.94%)
Infections and infestations				
Acute Tonsillitis	6/2283 (0.26%)	4/338 (1.18%)	1/637 (0.16%)	3/102 (2.94%)
Bronchitis	13/2283 (0.57%)	2/338 (0.59%)	4/637 (0.63%)	6/102 (5.88%)
Cystitis	11/2283 (0.48%)	0/338 (0%)	3/637 (0.47%)	7/102 (6.86%)
Herpes Simplex	3/2283 (0.13%)	0/338 (0%)	1/637 (0.16%)	3/102 (2.94%)
Nasopharyngitis	78/2283 (3.42%)	16/338 (4.73%)	31/637 (4.87%)	19/102 (18.63%)
Pneumonia	4/2283 (0.18%)	0/338 (0%)	2/637 (0.31%)	3/102 (2.94%)
Pyelonephritis	1/2283 (0.04%)	0/338 (0%)	0/637 (0%)	3/102 (2.94%)
Tonsillitis	6/2283 (0.26%)	0/338 (0%)	0/637 (0%)	2/102 (1.96%)
Urinary Tract Infection	17/2283 (0.74%)	2/338 (0.59%)	6/637 (0.94%)	4/102 (3.92%)
Injury, poisoning and procedural complications				
Upper Limb Fracture	0/2283 (0%)	0/338 (0%)	0/637 (0%)	3/102 (2.94%)
Musculoskeletal and connective tissue disorders				
Arthralgia	6/2283 (0.26%)	0/338 (0%)	3/637 (0.47%)	4/102 (3.92%)
Back Pain	13/2283 (0.57%)	1/338 (0.3%)	3/637 (0.47%)	3/102 (2.94%)
Shoulder Pain	6/2283 (0.26%)	0/338 (0%)	3/637 (0.47%)	3/102 (2.94%)
Nervous system disorders				
Headache	42/2283 (1.84%)	1/338 (0.3%)	7/637 (1.1%)	4/102 (3.92%)
Psychiatric disorders				
Depression	5/2283 (0.22%)	2/338 (0.59%)	0/637 (0%)	4/102 (3.92%)

	IC51 Month 6	JE-VAX	Placebo	IC51 Month 60
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Surgical and medical procedures				
Dental Implantation	1/2283 (0.04%)	0/338 (0%)	0/637 (0%)	3/102 (2.94%)

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: +43 1 20620 Ext: 0
Email: info@valneva.com