ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 10/31/2012

ClinicalTrials.gov ID: NCT00604708

Study Identification

Unique Protocol ID:	IC51-301
Brief Title:	Immunogenicity Study of the Japanese Encephalitis Vaccine IC51
Official Title:	Observer Blinded, Randomized Phase 3 Study to Investigate the Non-Inferiority of IC51 vs. JE-VAX as Vaccines for Japanese Encephalitis in Healthy Subjects
Secondary IDs:	

Study Status

Record Verification:	October 2012
Overall Status:	Completed
Study Start:	September 2005
Primary Completion:	September 2006 [Actual]
Study Completion:	September 2006 [Actual]

Sponsor/Collaborators

Sponsor:	Valneva Austria GmbH
Responsible Party:	Sponsor
Collaborators:	

Oversight

FDA Regulated?:	Yes
Applicable Trial?:	Section 801 Clinical Trial?

	Delayed Posting?
IND/IDE Protocol?:	Yes
IND/IDE Information:	Grantor: CBER IND/IDE Number: 8589 Serial Number: 0024 Has Expanded Access? No
Review Board:	Approval Status: Board Name: Board Affiliation: Phone: Email:
Data Monitoring?:	Yes
Plan to Share Data?:	
Oversight Authorities:	United States: Food and Drug Administration

Study Description

Brief Summary:	The objective is to demonstrate the non-inferiority of the Japanese Encephalitis vaccine IC51 compared to JE-VAX in healthy subjects aged > or = 18 years
Detailed Description:	

Conditions

Conditions:	Japanese Encephalitis
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Prevention
Study Phase:	Phase 3
Intervention Model:	Parallel Assignment
Number of Arms:	2
Masking:	Single Blind (Subject)
Allocation:	Randomized

Endpoint Classification: Efficacy Study

Enrollment: 867 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: IC51 6 mcg (microgram) i.m. (intramuscular) on Day0, 14 and 28	Biological/Vaccine: IC51 IC51 (JE-PIV), 6 mcg, i.m. injection, 2 vaccinations, days 0 and 28 Other Names: • Japanese Encephalitis purified inactivated vaccine
Active Comparator: JE-VAX given s.c. on Day 0, 7 and 28	Biological/Vaccine: JE-VAX JE-VAX, 1mL s.c. injection, 3 vaccinations, days 0, 7 and 28

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 18 Years

Maximum Age:

Gender: Both

Accepts Healthy Volunteers?: Yes

Criteria: Inclusion Criteria:

- At least 18 years of age
- Written informed consent obtained prior to study entry

Exclusion Criteria:

- History of clinical manifestation of any flavivirus infection
- History of vaccination against Japanese encephalitis (JE), Yellow fever and Dengue fever (an anti-JEV neutralizing antibody titer >= 1:10 at baseline is acceptable for inclusion, these subjects will be part of the safety population, but will not be analyzed for immunogenicity in the per-protocol analysis)
- Use of any other investigational or non-registered drug or vaccine in addition to the study vaccine during the study period or within 30 days preceding the first dose of study vaccine
- Immunodeficiency including post-organ-transplantation or immunosuppressive therapy
- A family history of congenital or hereditary immunodeficiency
- History of autoimmune disease
- Any acute infections within 4 weeks prior to enrollment

- Infection with HIV, Hepatitis B or Hepatitis C
- Pregnancy, lactation or unreliable contraception in female subjects

Contacts/Locations

Study Officials: Astrid Kaltenboeck, Ph.D.
Study Director
Intercell AG

Locations:

References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Reporting Groups

	Description
IC51	IC51
JE-VAX	JE-VAX

Overall Study

	IC51	JE-VAX
Started	430	437
Completed	399	397
Not Completed	31	40
Withdrawal by Subject	9	10
Protocol Violation	2	8

	IC51	JE-VAX
Lost to Follow-up	5	5
administrative reasons	9	11
Adverse Event	6	6

Baseline Characteristics

Reporting Groups

	Description
IC51	IC51
JE-VAX	JE-VAX

Baseline Measures

	IC51	JE-VAX	Total
Number of Participants	430	437	867
Age, Continuous [units: years] Mean (Standard Deviation)	41.6 (14.5)	41.1 (14.4)	41.3 (14.4)
Gender, Customized [1] [units: participants]			
Female	267	258	525
Male	161	177	338
Unknown	2	2	4
Region of Enrollment [units: participants]			
Europe	100	103	203
North America	330	334	664

[1] overall number of baseline participants equals ITT Population (= All subjects randomized, N = 867) Demographic data are provided for the Safety Population: N = 863

Outcome Measures

1. Primary Outcome Measure:

Measure Title	SCR (Seroconversion Rate)of IC51 Compared to JE-VAX at Day 56
Measure Description	SCR: anti-JEV neutralizing antibody titer ≥1:10
Time Frame	Day 56
Safety Issue?	No

Analysis Population Description

Per Protocol Population: all randomized subjects without any protocol deviations as defined in the Statistical Analysis Plan

Reporting Groups

	Description
IC51	IC51
JE-VAX	JE-VAX

Measured Values

	IC51	JE-VAX
Number of Participants Analyzed	365	370
SCR (Seroconversion Rate)of IC51 Compared to JE-VAX at Day 56 [units: percentage of participants]	96.4	93.6

2. Primary Outcome Measure:

Measure Title	GMT (Geometric Mean Titer) of IC51 Compared to JE-VAX at Day 56
Measure Description	GMT: geometric mean of PRNT50
Time Frame	Day 56
Safety Issue?	No

Analysis Population Description

PP Population: All randomized subjects without any major protocol deviations as assessed during a Data Review Meeting. Subjects who were randomized incorrectly or took the wrong study medications were also excluded.

Reporting Groups

	Description
IC51	IC51
JE-VAX	JE-VAX

Measured Values

	IC51	JE-VAX
Number of Participants Analyzed	361	364
GMT (Geometric Mean Titer) of IC51 Compared to JE-VAX at Day 56 [units: titers] Geometric Mean (Standard Deviation)	243.6 (1163.1)	102 (221)

3. Secondary Outcome Measure:

Measure Title	Safety and Adverse Events
Measure Description	
Time Frame	until Day 56
Safety Issue?	Yes

Outcome Measure Data Not Reported

4. Secondary Outcome Measure:

Measure Title	Immunogenicity at Day 28
Measure Description	
Time Frame	Day 28
Safety Issue?	No

Outcome Measure Data Not Reported

5. Secondary Outcome Measure:

Measure Title	Immunogenicity at Day 56 for North America vs. Europe
Measure Description	
Time Frame	Day 56

Safety Issue?	No

Outcome Measure Data Not Reported

6. Secondary Outcome Measure:

Measure Title	Immunogenicity at Day 56 for Subjects Older vs. Younger Than 50 Years of Age
Measure Description	
Time Frame	Day 56
Safety Issue?	No

Outcome Measure Data Not Reported

Reported Adverse Events

Time Frame	[Not specified]
Additional Description	numbers provided for safety population (N= 863)

Reporting Groups

	Description
IC51	IC51
JE-VAX	JE-VAX

Serious Adverse Events

	IC51		JE-VAX	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Total	1/428 (0.23%)		0/435 (0%)	
Cardiac disorders				
Myocardial Infarction	1/428 (0.23%)	1	0/435 (0%)	0

Other Adverse Events

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

	IC51		JE-VAX	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Total	217/428 (50.7%)		213/435 (48.97%)	
Gastrointestinal disorders				
Diarrhoea	7/428 (1.64%)		9/435 (2.07%)	
Nausea	29/428 (6.78%)		39/435 (8.97%)	
General disorders				
Fatigue	54/428 (12.62%)		48/435 (11.03%)	
Influenza like Ilness	54/428 (12.62%)		55/435 (12.64%)	
Pyrexia	24/428 (5.61%)		21/435 (4.83%)	
Infections and infestations				
Nasopharyngitis	26/428 (6.07%)		33/435 (7.59%)	
Musculoskeletal and connective tissue disorders				
Myalgia	88/428 (20.56%)		69/435 (15.86%)	
Nervous system disorders				
Headache	113/428 (26.4%)		125/435 (28.74%)	
Respiratory, thoracic and mediastinal disorders				
Cough	10/428 (2.34%)		11/435 (2.53%)	
Pharyngolaryngeal Pain	12/428 (2.8%)		5/435 (1.15%)	

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:

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