Clinical Trial Details (PDF Generation Date :- Thu, 21 Jan 2021 04:25:22 GMT)

CTRI Number	CTRI/2016/09/007289 [Registered on: 19/09/2016] - **Trial Registered Prospectively**
Last Modified On	16/10/2017
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Vaccine
Study Design	Randomized, Parallel Group, Active Controlled Trial
Public Title of Study	Phase 1 Clinical study to test the safety of Plasmodium Vivax (Malaria) Vaccine in Healthy Volunteers.
Scientific Title of Study	A Phase-I,randomised, controlled, dose escalating, single blind clinical trial to evaluate the safety and immunogenicity of PvDBPII vaccine (Plasmodium vivax Duffy Binding Protein Region II) formulated with adjuvant GLA-SE in healthy Indian male subjects

Secondary IDs if Any

Secondary ID	Identifier
MVD/vivax/1/15/02/01 Version 01 Dated 24 July 2015	Protocol Number

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
Name	Dr Anil K
Designation	Head Human Pharmacology Unit
Affiliation	Syngene International Limited
Address	Syngene International Limited, Human Pharmacology Unit(HPU), Tower 1, Semicon Park Electronics City Phase II Bangalore-560100 Bangalore KARNATAKA 560100 India
Phone	9845519111
Fax	9128082820
Email	anil.dr@Syngeneintl.com

Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	Dr Kavita Singh
Designation	Program Director
Affiliation	International Centre for Genetic Engineering and Biotechnology
Address	Multi Vaccines Development Program International Centre for Genetic Engineering and Biotechnology Campus Aruna Asaf Ali Marg Delhi New Delhi DELHI 110067 India
Phone	
Fax	
Email	kavita.singh@mvdp.org.in

Details Contact Person (Public Query)

Details Contact Person (Public Query)	
Name	Dr Anand Eswaraiah MD
Designation	Head Regulatory Affairs
Affiliation	Syngene International Limited
Address	Syngene International Limited Clinical Development Tower 1 Semicon Park Electronics City Phase II Bangalore 560100 80 2808 2728 99456 22776 Bangalore

	KARNATAKA 560100 India
Phone	9945622776
Fax	918028082685
Email	anand.eswaraiah@syngeneintl.com

Source of Monetary or Material Support

Source of Monetary or Material Support
> Biotechnology Industry Research Assistance Council (BIRAC)(A Government of India Enterprise) 1st Floor, MTNL Building, 9, CGO Complex, Lodhi Road, New Delhi-110003

Primary Sponsor

Primary Sponsor Details	
Name	International Centre for Genetic Engineering and Biotechnology
Address	International Centre for Genetic Engineering and Biotechnology (ICGEB)campus Aruna Asaf Ali Marg, New Delhi-110 067 India
Type of Sponsor	Research institution

Details of Secondary Sponsor

Name	Address
Multi Vaccines Development Program	Multi Vaccines Development Program International Center for Genetic Engineering and Biotechnology(ICGEB) Campus Aruna Asaf Ali Marg, New Delhi-110 067 India Tel:91 1126741331/32 Fax:91 1126741384

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr Anil K MBBS MD Medicine	Human Pharmacology Unit Syngene Clinical Development	Syngene International Limited Clinical Development Human Pharmacology Unit Tower 1 Ground Floor Semicon Park Electronics City Phase 2 Hosur Road Bangalore 560100 INDIA Bangalore KARNATAKA	9845519111 9128082820 anil.dr@Syngeneintl.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Sri Venkateshwara Hospital Ethics Committee	Approved	24/08/2016	No

Regulatory Clearance Status from DCGI

Status	Date
Approved/Obtained	08/07/2016

Health Condition / Problems Studied

Health Type	Condition
Healthy Human Volunteers	Healthy Male subjects

Intervention / Comparator Agent

Type	Name	Details
Intervention	PvDBPII	10, 25, 50µg single dose cohort study,Study duration upto 180 days for the Assessment of the safety and reactogenicity of above said three different IM doses of maleria vaccine

		candidate.
Comparator Agent	Hepatitis B	IM injection of Hepatitis B single dose as a comparator.Study duration of 180 days.

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	45.00 Year(s)
Gender	Male
Details	1.A Male between the ages of 18 to 45 years (both inclusive) (age at informed consent). 2.Willing and having the capacity to provide voluntary free informed consent for participation evidenced by signing of the IRB/IEC approved informed consent 3. Subject is in good general health and is free from clinically significant health problems as determined by medical history, physical examination and clinical laboratory evaluation. 4. Willing to be available for the duration of the study, contactable by phone. 5. Capable and willing to complete and return subject diary cards, and to attend all follow-up visits, including unscheduled visits. 6. Willing to undergo HIV test 7. Must agree to use one of the following medically-acceptable birth control measures throughout the duration of the study (birth control counselling and measures will be provided by clinical trial site as required) Double barrier method (e.g. condom with spermicidal jelly) OR Subjects must be surgically sterile (undergone vasectomy) 8. Willing to take Intramuscular injection.

Exclusion Criteria

Exclusion Criteria	
Details	1. Any past history of malaria 2. Simultaneous participation in any other intervention clinical trial at the CRO 3. Subject with evidence of previous exposure to vivax malaria parasite as determined by presence of IgG antibodies against PvDBPII (ELISA). 4. Has prior history of immunisation with Hepatitis B vaccine. 5. History of receipt of any other candidate malaria vaccine. 6. History of allergic reactions,hypersensitivity or anaphylaxis to immunizations, to any of the components of the study vaccines (including adjuvant or peptide) or of serious allergic reactions that required hospitalisation or emergency medical care. 7. Use of an investigational or non-registered drug or vaccine within thirty (30) days prior to enrolment or expects to receive such an agent during the study period. 8. Administration of any vaccination or gamma globulin during the three-month period prior to the first Immunization or planned use during the study. 9. Chronic administration (defined as more than 14 days) of immuno-suppressants or other immune-modifying drugs or cytotoxic therapies(chemotherapy or radiotherapy) within six months prior to the first Immunization. This includes any dose level of oral steroids or inhaled steroids, but not topical steroids. 10. Received a blood transfusion within the past 3 months 11. Evidence of any acute or chronic illness (including cardiovascular, pulmonary, neurological, hepatic, rheumatic,haematological, immunological, metabolic, or renal disorders), as determined by history or clinical examination or laboratory screening.

	12. History of splenectomy 13. Has a history of autoimmune disease (including inflammatory bowel disease,haemolytic anaemia, autoimmune hepatitis, rheumatoid arthritis, lupus, etc.) or connective tissue disease. 14. Subject has clinically Significant laboratory abnormalities, which will include haematology, biochemistry, urinalysis, at the time of screening as determined by the Investigator. 15. Clinical or laboratory presence of Hepatitis B, C or HIV infection or Syphilis. 16. Subject with an abnormal 12-lead ECG at screening associated with relevant clinical symptoms/signs suggestive of cardiac pathology (including conduction disturbances). 17. Subject with an abnormal Chest X-Ray associated with relevant clinical symptoms/signs of respiratory pathology at screening/ anytime in the past 6 months. 18. Subject gives a history of social, occupational and/ or family problems due to illicit alcohol or drug abuse (to be determined by Urine Drug Screen) within the past 12 months. 19. Has any other condition that, in the opinion of the Principal Investigator, may jeopardise the safety and rights of the volunteer, may interfere with the capacity to provide free and willing informed consent or render the subject unable to comply with the requirements of the study protocol.

Method of Generating Random Sequence	Computer generated randomization
Method of Concealment	Not Applicable
Blinding/Masking	Participant Blinded

Primary Outcome

Outcome	Timepoints
Assessment of the safety and reactogenicity of three different doses of malaria vaccine candidate.	Immediate reactogenicity: within 1st hrs after each Immunization, • Local and systemic Solicited AE(s): From 1hrs post Immunization till day 7 after each immunization • Local and systemic Unsolicited AE(s):From 1hrs post Immunization till Day 26 days after each Immunization •SAE:From the signing of ICD till the last follow-up visil. • Lab Safety: AEs related to clinical laboratory investigations (bood and urine)monitored at day 7 after each immunisation and at the end of the visit.

Secondary Outcome

Outcome	Timepoints
• Humoral immune response against PvDBPII by IgG ELISA • Test recognition of native antigen in late stage P.vivax schizonts by Immunofluorescence assay (IFA). • ability of Anti-PvDBPIi antibodies to block the interaction between PvDBPil and Duffy antigen receptor chemokine (DARC) by ELISA based Binding Inhibition Assay (BIA) • Subclasses of IgG (lgG1, IgG2, IgG3, IgG4) by ELISA	Thrice during the trial period (Day 0, Day 84 and Day 180 of participation)

Target Sample Size	**Total Sample Size=**36 **Sample Size from India=**36 **Final Enrollment numbers achieved (Total)=**36 **Final Enrollment numbers achieved (India)=**36
Phase of Trial	Phase 1
Date of First Enrollment (India)	12/10/2016
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**1 **Months=**0 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Completed
Publication Details	None yet
Brief Summary	This is a Phase I, randomized, controlled, dose-escalating, single-blind clinical trial for assessment of safety and immunogenicity of the malaria vaccine candidate, PvDBPII formulated with GLA-SE adjuvant (PvDBPII/GLA-SE). The study involves administration of investigational vaccine PvDBPII/GLA-SE in three dose-escalating cohorts corresponding to three dosages of 10, 25 and 50 µg of PvDBPII with constant dosage of adjuvant GLA-SE (5µg). The dose escalating design will allow study of safety (Immediate reactogenicity within the first hour after each Immunization, Solicited AEs occurring from one hour post Immunization till day 7, unsolicited AEs from one hour post Immunization till Day 28 days, SAE’s from the signing of ICD till the last follow-up visit and Laboratory safety during conduct of study) and immunogenicity of different doses of PvDBPII/GLA-SE. The control vaccine to be used is Hepatitis B. In each cohort, 12 subjects will be enrolled. Following a 3:1 randomization scheme nine subjects will receive PvDBPII/GLA-SE while three subjects will receive Hepatitis-B vaccine. Therefore in total for this Phase I study thirty six malaria naïve healthy adults will be enrolled as subjects: twenty seven subjects will receive PvDBPII/GLA-SE (9 subjects in each cohort) and 9 subjects will receive Hepatitis B vaccine (3 subjects in each cohort).Randomization and blinding will control for possible biases during study conduct. This study will be completed when all subjects in all the three Study cohorts successfully complete the protocol defined visits and assessments. An independent Data Safety Monitoring Board (DSMB) will maintain a safety oversight for the study and will advise on dose escalation to the next higher cohort after reviewing the 7 day safety data post first Immunization for all 12 subjects of the previous cohort. Thus, enrolment for each new cohort would have a delay of about 21 days from previous cohort so as to allow for safety data assessed by DSMB. The volunteers will be enrolled in a Single center (Human Pharmacology unit of Syngene International Limited, Bengaluru, India). Study population will include healthy Indian male subjects between 18 to 45 years of age (both inclusive). The Subjects will be recruited from the healthy volunteer database of the study site. The recruitment in the three study cohorts will begin sequentially but the study periods after initiation may

overlap.