gsk GlaxoSmithKline

**SPONSOR AGREEMENT**

**CLINICAL TRIAL**

**SUPPORT AGREEMENT FOR CLINICAL TRIAL (“Agreement”) made on 24th August, 2011**

BETWEEN

**GLAXOSMITHKLINE REPRESENTATIVE OFFICE IN HO CHI MINH CITY**, a representative office established based on the law of Vietnam under license No 41-001586 on 10th April, 2010 granted by Ho Chi Minh City Department of Industry and Trade with a head office based at the Metropolitan Building-Room 701, 235 Dong Khoi, District 1, Ho Chi Minh City is one party of the Contract; (called “GSK”)

and

**Binh Dan Hospital,** a state owned hospital which lawfully operates under the law of Vietnam, at No 371, Dien Bien Phu Street, Ward 4, District 3, Ho Chi Minh City, Vietnam; (called “Hospital”)

and

**PhD Doctor Nguyen Van An- Vice Dean of the Department of Urology A**, **Binh Dan Hospital,** ID No 020681991 issued on 27/9/2005 at Ho Chi Minh City police, Vietnam who resides at No 371, Dien Bien Phu Street, Ward 4, District 3, Ho Chi Minh City, Vietnam.

(mentioned in the role of principal researcher and project co-manager.)

and

**PhD Doctor Dao Quang Oanh-Dean of the Department of Urology B, Binh Dan Hospital,** ID No 020226928 issued on 7/2/2001 at Ho Chi Minh City police, Vietnam who resides at 371 Dien Bien Phu Street, Ward 4, District 3, Ho Chi Minh city, Vietnam

 (mentioned in the role of “Principal researcher and co-manager of the project)

**AT PRESENT**

**Considering that** GlaxoSmithKline Group is a pharmaceutical corporation in the field of researching, developing, producing and marketing many kinds of medicine for patients.

**Considering that** GSK conducted this study to evaluate the safety of the treatment by combining Dutasteride 0.5mg and Tamsulosin 0.4mg on men for the clinical diagnosis of benign prostate hyperplasia. This study was done on Vietnamese patients with a view to registering the product COMBODART/DUODART in Vietnam.

**Considering that** Binh Dan Hospital is the leading hospital for diagnosing, preventing and treating diseases of the urinary tract.

**Considering that GSK** wants to sign an Agreement with Binh Dan Hospital to sponsor a clinical study with the following theme:

***“Evaluating the safety of combining Dutasteride 0.5mg and Tamsulosin 0.4mg used once a each day for 6 months for patients with clinical diagnosis of benign prostate hyperplasia.”***

Therefore, the parties sign this Agreement with the following terms and conditions:

**1. DEFINITION**

* 1. The below words and phrases are construed as follows:

**“Clinical trial”** is the study sponsored by GSK and Binh Dan Hospital that was conducted at Binh Dan Hospital in the research program No 114785 and complies with all provisions and conditions in this Contract and regulations of Vietnamese law.

“Subjects in clinical trial” are people chosen to participate in the clinical trial under the regulations of Vietnamese law and the instructions of the Ministry of Health, Vietnam.

“**Information confidentiality**” under the provisions required for Binh Dan Hospital -Provision 7.2 and 13.9 and all information relating to the clinical study including the researched medical products and required provisions in parts of provision 7.2 and all information relating to the envisaged arrangement in this Contract.

“**ICH GCP**” is an international conference guiding good clinical practice with the consent of the 3 parties (CPMP/ICH/135/95) along with other requirements for good clinical practice as stated in Directive 2001/20/EC of the Parliament and European Council on 4th April, 2011 related to medical products used on humans in the guidelines of the European Commission published under this directive.

**“ Intellectual property rights”** include patients, trademarks, copyrights, rights to exploit information from the database, design rights and all sponsor forms or similar results to anything existing anywhere in the world, whether or not registered and including application to apply for any form.

“**The know-how”** is all technological information and other information that is not used publicly including, but not limited to, information relating to concepts, discoveries, data, designs, formulas, ideas, inventions, methods, models, procedures, the design to test and pilot, the test and pilot results, processes, technical features, laboratory facilities, clinical data, production data and other information in the file submitted to the authorities.

**“Supervisor”** is one or many employees appointed by GSK to supervise the compliance with clinical trials according to regulations for good clinical practice ICH GCP and the regulations of the Ministry of Health of Vietnam and to verify data sources.

“**Party**” is GSK or Binh Dan Hospital or project co-managers and **“Parties**” are GSK and Binh Dan Hospital.

“**Research proposal**” describes the clinical trial and all additional amendments that parties agree from time to time. These additional amendments will be signed by the parties and become part of this Contract.

“**R&D Department**” is the Department or Division of Binh Dan Hospital that will represent Binh Dan Hospital and be responsible for the administrative procedures of the clinical trial.

“**Research profile”** is the profile kept by the project manager including materials specified in item 8 of ICH GCP (published CPMP/ICH/135/95).

“**The principal researcher and project co-manager**” is the legal representative for study carried out at the Hospital and sponsored by GSK, the head and coordinator of the clinical trial at the study site at the Hospital or any other person that all parties agree to replace at any time.

**“Result of clinical trial”** is the result of this clinical trial.

“**Staff of research team**” are people who implement this clinical trial at the study site under the direct instruction of the principal researcher/project co-manager and includes the principal researcher/project co-manager.

“**Specified time**” is the term set out in the attached Annex 2, but it can be adjusted with the agreement of parties and “specified time” means any time in such term.

“**Trial drug**” is the combination of Dutasteride 0.5mg and Tamsulosin 0.4mg produced by GlaxoSmithKline group as regulated in the research proposal.

“**Trial place**” Binh Dan Hospital

“**Force majeure events**” is related to any party of the parties, any circumstances beyond the reasonable control of such party including but not limited in any act of war or other actions of the armed forces, terrorism, riot, civil commotion, sabotage, vandalism, actions for limitation of the government or other public authorities, accidents, fire, flood, earthquake, other natural disasters or calamity (but not including strikes and closing door to pressure) provided that no situation or reason is considered beyond the reasonable control of a party if such situation or reason happens as a result of carelessness of such Party;

* + - 1. 1.2 All references in accordance with the provisions of law including reference to provisions as amended and adopted.
1. **PRINCIPAL RESEARCHER**
	1. 2.1 Binh Dan Hospital agrees, commits and ensure that PhD Doctor Nguyen Van An and PhD Doctor Dao Quang Oanh will take the role of principal researchers and project co-managers at the Hospital and that the main researchers and project co-managers will carry out their rights and obligations in accordance with regulations of this Agreement and the law of Vietnam.
	2. 2.2 Binh Dan Hospital found that the principal researchers and project co-managers have enough experience and the necessary expertise to do this clinical trial and found that the current principal researchers and project co-mangers have satisfied all conditions in Annex 6 of this Agreement.
	3. Binh Dan hospital will notify GSK immediately if PhD Nguyen Van An and PhD Dao Quang Oanh stop working for Binh Dan Hospital for any reason and will make all efforts to replace them with candidates that both GSK and the Binh Dan Hospital accept. If there is no candidate that two parties accept, GSK can terminate this Agreement pursuant to Provision 13.3 below
2. **RUNNING CLINICAL TRIAL**

GSK will notify Binh Dan Hospital, principal researchers and project co-managers of the full name and telephone number of the supervisor and the name of people who facilitate this contact. GSK will also give the principal researchers and project co-managers the phone number to contact in case of emergency to report any adverse event any time.

3.2 The Parties will comply with all relevant regulations and law applied to the clinical trial including, but not limited to, the regulations on clinical trials from the Ministry of Health of Vietnam and all instructions relating to medicine and clinical trials that are currently

 in effect including, but not limited to, ICH GCP, Helsinki Statement of the World Medical Association called “Ethics in medical research related to human subjects (Version 1996).

GSK will comply with all instructions for the period of validity and published by the British Pharmaceutical Industry Association related to clinical trials and in particular the instructions in [“ Compensation guidelines in clinical trial” (1991) or “Guidelines for medical testing with the participants of healthy people (1988)], note “Quotations related to guidelines issued at the locality, corresponding regulations referring to the compensation for the participants in clinical trial cited in Annex 3.

3.4 GSK must not violate (and ensure that the commitments in this Agreement do not violate ) the following actions:

3.4.1 Provide or ask to provide any employees of Binh Dan Hospital any gifts or compensation not regulated in this Agreement.

3.4.2 Pay or agree to pay any commissions to any employee of Binh Dan Hospital whether related to this agreement or any other agreement of Binh Dan Hospital or not.

3.5 If GSK or any employee of GSK violate any acts mentioned in provision 3.4, in addition to any measures available under the regulations of this Agreement, Binh Dan Hospital has the right to terminate this Agreement immediately.

3.6 If there is any conflict between the research proposal and the other provisions in this Agreement, the provisions of the research proposal will be given priority for execution, except conflicts relating to article 6,9 and/or 10 of this Agreement that such provisions will be used to replace if the relevant parts in the research proposal do not mention exactly the applied provisions.

**4. RESPONSIBILITIES OF PARTIES**

4.1 Binh Dan Hospital, principal researchers and project co-manager will be responsible for achieving and keeping all the approvals and agreements allowed by the Board of Ethics and or/other state agencies in the local research for the implementation of this clinical trial in accordance with regulations of Vietnamese law. Binh Dan Hospital, principal researchers and project co-managers will always fully inform GSK of the progress of handing in the dossier to the Board of Ethics and later, upon request, will provide GSK with all material and information relating to handing in the dossier. Binh Dan Hospital, principal researchers and project co-managers must not change anything in the research proposal that the Board of Ethics requires without prior consent in writing from GSK.

4.2 Parties must carry out this clinical trial to comply with:

(i) The research proposal, a summary of the proposal attached in Annex 1 of this Agreement;

(ii) Provisions and conditions in this Agreement;

(iii) Circulation permits of the research medicine, or if possible, the certificate of clinical trial or other documents according to Vietnamese law;

(iv) Provisions and conditions approved by the Ministry of Health, Ho Chi Minh City Department of Health or state authorities.

(v) Provisions and conditions approved by the Board of Ethics of the Ministry of Health; and

(vi)Regulations of Vietnamese law including, but not limited to, regulations regarding research and clinical trial.

And Binh Dan Hospital commit, ensure and agree not to use any of the research medicine used for the clinical trials or any clinical intervention as suggested in the outline for the clinical trials bing be carried out until Binh Dan Hospital gain sufficient agreements and approvals of the authorized agencies and the Board of Trustees according to Vietnam laws.

4.3 GSK will provide principal researchers and project co-managers copies of materials specified in section (i) and (iii) of the provision 4.2 above (if any) and principal researchers and project co-managers must keep these documents with the approval of the Board of Ethics in the hospital research profile.

4.4 The principal researchers and project co-managers will inform GSK immediately if there is any financial benefit or interest between the main researchers and project co-managers and GSK with the form as described in item (f) of Annex 6 below and obligations stated in such regulations, GSK will notify principal researchers and project co-manager at the hospital in writing of the date of completion of this clinical trial.

4.5 Binh Dan Hospital and the main researchers and project co-managers are not allowed to use any research drug for any purpose other than this clinical trial. At the termination or expiration of this Agreement, all unused research drug must be destroyed in accordance with Vietnamese law.

4.6 Binh Dan hospital will choose 90 people to participate in this clinical trial and Binh Dan Hospital and the main researchers and project co-managers must perform this clinical trial on time as agreed in the provisions of this Agreement.

4.7 When this clinical trial is finished (including finishing early or for other reasons), the principal researchers and project co-managers will write a report about this clinical trial, where the details of method, results and result analysis will be stated clearly and conclusions will be properly drawn.

4.8 During the effective term of this Agreement, both Binh Dan Hospital and the principal researchers and project co-managers are not allowed to conduct any other trials that may adversely affect the ability of Binh Dan Hospital in the implementation of the obligations in this Agreement.

4.9 Binh Dan Hospital, the principal researchers and project co-managers acknowledge the receipt of “Anti-corruption guidance of a third party” which is attached in Part A below and agree to comply with its obligations under this Agreement in accordance with the principles in it.

4.10 Binh Dan Hospital, the main researchers and project co-managers must comply fully with all laws and regulations including but not limited to the Anti-corruption Law of Vietnam

4.11 Binh Dan Hospital, the principal researchers and project co-managers declare and ensure that, except as disclosed in writing: (1) the Hospital, the principal researchers and project co-managers don’t have any rights that directly or indirectly conflict with the performance of this contract properly and morally; and (2) the Hospital, the principal researchers and project co-managers will maintain an independent relationship with any third parties (including Government officials) that the hospital is in transactions with on behalf of GSK.

4.12 Binh Dan Hospital ensures that all transactions under this Agreement are recorded correctly and accurately on every important aspect of the Hospital’s records and books and each document which is the basis of the entries in the books and records mentioned above must be complete and accurate in all aspects. The Hospital must maintain a system of internal accounting controls reasonably built to make sure that no item is not included in the book.

4.13 Binh Dan Hospital, the principal researchers and project co-managers agree that GSK may disclose sufficiently information regarding potential violations of the provisions of this Agreement at any time and for any reason for any authorized state agencies and the unit of the agencies and for anyone that GSK determines honestly has a legitimate need to know

4.14 Not depending on any provisions of this Agreement, the Hospital, principal researchers and project co-managers agree that GSK has the right to disclose and inform any third party about any information regarding payments and sponsorship under this Agreement including the name and address of the Hospital, the principal researchers and project co-managers and the value of any payments and/or sponsorships that the Hospital, the principal researchers and project co-managers received relating to this Agreement (“Disclosed information”). Particularly, the Hospital, the principal researchers and project co-managers agree that GSK may popularize the disclosed information on the computer system and/or web controlled by GSK and/or any entity of GlaxoSmithKline Corporation.

**5. KEEPING AND ACCESSING RECORDS**

5.1 Binh Dan Hospital will establish and keep records related to this clinical trial at the request of the research proposal and in accordance with current legislation or the applicable guideline.

5.2 Binh Dan Hospital approved supervisors and any authorized representative of GSK may access the records of the participants to supervise and verify the original data. Such access must be arranged at a time convenient for both parties and with reasonable notice. GSK will immediately alert the Board of Directors of the Hospital about any serious problems (as assessed by supervisors) regarding the conduct of this clinical trial. In the case that GSK believes that there is something wrong in this clinical trial, Binh Dan Hospital, the principal researchers and project co-managers must greatly support any investigation of whatever is wrong with the study and this investigation will be undertaken by GSK or representatives appointed by GSK. When concluded, GSK and the Board of Directors of Binh Dan Hospital must consider the conduct of this clinical trial at the research site, and such consideration will take place over a period of three (3) months of the end of each research activity at the research site.

5.3 If any government agencies or authority in Vietnam notifies Binh Dan Hospital of an inspection of the Binh Dan Hospital for records, facilities, equipment or processes or claims related to this clinical trial, Binh Dan Hospital must notify GSK immediately and allow GSK to be present during the inspection and/or sue claim or participate in any response on the inspection and/or claim and provide GSK the copy of any minutes of the authorities and the response to Binh Dan Hospital proposals.

5.4 Binh Dan Hospital will comply with the regulations of Provision 5 until the end of the agreement.

**6. LEGAL RESPONSIBILITY AND COMPENSATION FOR LOSSES**

6.1 In the event of any claim or anyone suing Binh Dan Hospital for personal injury by the research subjects, GSK will compensate Binh Dan Hospital, servers, departments and employees of Binh Dan Hospital according to the provisions stated in the attached Annex 4.

6.2 GSK will pay Binh Dan Hospital, its departments, servers and employees about complaints, lawsuits, costs, and expenses (including reasonable legal fees) for losses of property due to negligence by GSK or violation of the obligations of GSK under this Agreement

6.3 Binh Dan Hospital will compensate GSK, GSK’s servers, departments, employees for loss or property loss or body injure (including death) due to negligence of Binh Dan Hospital or violation of obligations of Binh Dan Hospital under this Agreement except damage or loss due to the negligence of GSK, GSK’s servers, departments and employees or violation of obligations of GSK under this Agreement.

6.4 There is no case where each party will have legal responsibility for other party in this Agreement related to faults (including errors and violation of responsibilities as prescribed by law) or other arising problems to any degree or causes for any losses of profit, business, reputation, contracts, income or other predictable provisions of savings, or special, indirect losses or consequence of such losses under any form which directly or indirectly arise from the fault of each party. There is no content in this provision affecting the responsibility of each party relating to death or personal injury caused by negligence of such party or server, departments and employees of such party.

6.5 For the purpose of compensation in provision 6.2 and 6.3 above, the term “departments” will include, but not be limited to any person who provides services to Binh Dan Hospital (provision 6.2) or to SGK (Provision 6.3)-under a service contract or other mode of agreement.

6.6 Upon request, GSK will provide Binh Dan Hospital with a copy of the policy or other evidence relating to insurance and other evidence that the insurance contract is still valid. The provisions about any kinds of insurance or the level of insurance will not mitigate GSK from liability under this Agreement.

6.8 GSK’s insurance will not relieve the obligations of Binh Dan Hospital and parts in the clinical trial in maintenance of insurance policies according to the laws of Binh Dan Hospital. Binh Dan Hospital commits that it has and will maintain in effect an insurance contract in accordance with the law on the implementation of clinical studies and that such insurance coverage will include payments for any mistakes, errors or negligence by Binh Dan Hospital or employees of Binh Dan Hospital. Upon request, Binh Dan Hospital will provide a certificate of insurance for GSK to prove that the insurance is valid.

**7. PRIVACY**

**7.1 Medical privacy**

The parties agree to comply with the medical privacy principles relating to medical research subjects participating in clinical trials. Binh Dan Hospital must not disclose personal data to GSK unless this is required directly or indirectly in order to achieve the requirements in the proposal and for monitoring and reporting adverse events. GSK will not be allowed to disclose the resume of participants in clinical trial to third parties without the written consent of the subjects in the clinical trial, except for the case of complying with the requirements of regulations about privacy of personal data.

**7.2 Information Confidentiality**

7.2.1 Binh Dan Hospital, the principal researchers and project co-managers must ensure that only officials and employees directly related to the implementation this Agreement will be allowed to access confidential information and each party commits not to disclose confidential information to any third party except as required by the authorities and the law. They will not use confidential information for any purpose other than the purposes specified in this Agreement without the prior written consent of the other parties.

7.2.2 If one party visits the leaders of the other party, the visiting party commit that any new information about other trials which the visiting party know about as a result of the visit must be kept secret and not be disclosed to a third party or used by the visiting party in any form without the prior written consent of the other party.

7.2.3 The responsibility for information security stated in this 7.2 provision does not apply to the confidential information when:

(i) it is announced or widely known in public without fault of the receiving party,

(ii) the receiving party had the information before the date of signing this Agreement and is not obliged to secure it.

(iii) the receiving party deployed the information independently and is not obliged to secure it,

(iv) the receiving party had the information from a third party and is not obliged to secure it.

7.3 Provision 7 must continue to apply after the expiry or termination of this Agreement.

**8. ADVERTISING**

8.1 GSK will not use the name of Binh Dan Hospital or the name of any of member of Binh Dan Hospital when announcing the result, advertising or popularizing the news without the prior written approval of an authorized representative of Binh Dan Hospital. Therefore, Binh Dan Hospital will have a written approval for the use and publication of GSK in the name of Binh Dan Hospital, the principal researchers and project co-managers in one or more advertisements which are globally registered provided in provision 9.3. Binh Dan Hospital will not use GSK or the name of any employees of GSK when announcing without the written approval of GSK.

**9. ANNOUNCING RESEARCH RESULTS**

9.1 GSK know that Binh Dan Hospital, the principal researchers and project co-managers want the scientific results of this clinical trial to be published and disseminated properly. GSK agrees that the employees of Binh Dan Hospital can use the results of this research in scientific reports presented at conferences, seminars, professional conferences in the country or region and published in journals, theses or dissertations or other forms or methods and the results of this clinical trial as in provision 9.2 mentioned in this research proposal and must confirm the regulation stated in this Research.

9.2 When this clinical trial has finished, Binh Dan Hospital can analyze the data from this clinical trial to announce the results. Such data must be presented for GSK to comment and discussion before publishing. To ensure GSK can give comments and propose a satisfactory opinion, materials for announcing should be sent to GSK to consider at least sixty (60) days (or the time fixed in the proposal if longer) before handing the profile to the Board of publishing to consider and announce or popularize the results.

9.2.1 Binh Dan Hospital agrees that all reasonable comments from GSK on the published draft must be included in the main distribution by Binh Dan Hospital.

9.2.2 In considering the published draft, pursuant to provision 9.2 above, GSK has the right to make reasonable requests to Binh Dan Hospital to ask for slow publishing within six (6) months from the first day of handing in the profile to GSK so that GSK can protect information ownership and Binh Dan Hospital should approve the request.

9.3 Binh Dan Hospital, the principal researchers and project co-managers agree that GSK may present at seminars, national, regional or global professional conferences, and announce in journals, theses or dissertations or other selected forms, the outline summary, methodology and results of this clinical trial; and especially Binh Dan Hospital, the principal researchers and project co-managers agree to comply with the process of GSK on publishing and announcing the results of the trials sponsored by GSK. GSK can announce the result of the trial to the public by placing the summary of the trial results on the website of GSK or GlaxoSmithKline Corporation before or after the result is announced in the journal or other forms. Besides, Binh Dan Hospital, the principal researchers and project co-manager agree that GSK can announce at any time the names of the principal researchers and project co-managers, the details relating to Binh Dan Hospital and/or the details of Binh Dan Hospital that the principal researchers and project co-managers are members of global publishing registration.

**10. INTELLECTUAL PROPERTY**

10.1 All intellectual property and know-how is held by Binh Dan Hospital or licensed before and after the date of signing this Agreement, in addition, any intellectual rights and know- how gained from this clinical trial are the property of Binh Dan Hospital and will become the property of Binh Dan Hospital.

10.2 All intellectual property and know-how held by Binh Dan Hospital or licensed to GSK before and after the date of signing this Agreement, in addition to any intellectual rights and know- how gained from this clinical trial, are the property of GSK and will be the property of GSK.

10.3 All rights of intellectual property and know-how gained from this clinical trial will be awarded to GSK and exclusively licensed to GSK or companies designated by GSK under Articles 10.4 and 10.5 below.

10.4 In this way, Binh Dan Hospital will transfer its intellectual property rights and know-how gained from this clinical trial to GSK or the company appointed by GSK at the expense and at the request of GSK; Binh Dan Hospital, the principal researchers and project co-managers must conduct legal procedures and perform all necessary actions when GSK requires reasonably to transfer fully and validly all intellectual property and know-how gained from this clinical trial to GSK or the company appointed by GSK.

10.5 Binh Dan Hospital and the principal researchers and project co-managers must disclose immediately to GSK all and any know-how according to the spirit of this Agreement and commit not to use the know-how for any purpose other than the purpose of this Agreement without the written approval of GSK; such consent must not be withheld without any proper reason. In this way, Binh Dan Hospital will transfer to GSK an exclusive license which is worldwide, irrevocable and paid enough royalties for know-how due to exploit the know-how for any purpose.

**11. AGREEMENT ON FUNDING**

11.1 GSK will pay for the funding of this clinical trial for Binh Dan Hospital as specified in Annex 5 hereto.

11.2 Binh Dan Hospital is responsible for providing receipts and/or legal receipts for all payments made by GSK in accordance with the administrative procedures of the Ministry of Health.

All payments must be made in accordance with the schedule regulated in Annex 5 after Binh Dan Hospital submits a valid bill/invoice or value-added tax invoice (if any) to GSK.

11.3 The process of payment will be based on the progress of the study based on the real work done.

11.4 Binh Dan Hospital will be responsible for paying any taxes, charges and fees relating to and/or arising from this Agreement.

**12. DURATION OF THE CONTRACT**

This Agreement will come into effect from the date the parties sign the agreement and will remain in force until the completion of this clinical trial, when the Study Site is closed and the responsibilities of the parties are complete under the contract, except for terminating early in accordance with the terms and conditions of this agreement.

**13. TERMINATING THE CONTRACT BEFORE EXPIRY**

13.1 Both GSK and Binh Dan Hospital (non violating) can terminate this agreement immediately at any time if the other party (the violator):

13.1.1 Violates any of the following responsibilities (including but not ensuring the progress without reasonable reason) and not fixing errors if capable of fixing them, repairing within twenty (28) days from the date of written notice from the non violating party showing errors and fix requirements;

13.1.2 Declared to have no ability to pay or a manager or a takeover is specified of all or any part of the property of that party, or stop threatening, stop working

13.2 A party may terminate this Agreement upon notice to other party and the termination of this Agreement will take effect immediately if there is reasonable opinion that this clinical trial should be discontinued because the health benefits to the research participants related to this clinical trial. \*\*\*\* health risks?

 13.3 GSK may terminate this Agreement upon notice to Binh Dan Hospital if PhD Doctor Nguyen Van An and PhD Doctor Dao Quang Oanh no longer work (for any reason) as principal researchers and project co-managers and cannot find a replacement approved by Binh Dan Hospital and GSK.

13.4 GSK may terminate this Agreement upon written notice given to Binh Dan Hospital in cases of violation of Binh Dan Hospital and/or the principal researchers and project co-managers of any provisions of this Agreement.

13.5 In the event that this Agreement is terminated prior to expiry, and if it is required by current regulations, the principal researchers and project co-managers must immediately notify Binh Dan Hospital, Review Board / Board of Ethics (“IEC/IRB”) and provide reason(s) for the suspension or termination before terminating this clinical trial.

13.6 In the event this Agreement is terminated before expiry, if GSK has made the payment to Binh Dan Hospital for work which has not been completed, Binh Dan Hospital will refund this money to GSK within 20 days from the date this Agreement is terminated.

13.7 At the closing of the research site after this contract is terminated or expired, Binh Dan Hospital must immediately transfer to GSK all confidential information and unused materials which were provided to Binh Dan Hospital under this Agreement.

13.8 The termination of this Agreement will be without prejudice to the rights and obligations of the parties in this Agreement.

**14. ANNOUNCEMENT**

Any announcement under this Agreement must be made in writing, signed by related parties of this contract and moved manually by regular or registered mail. Announcements to GSK should be sent to:

Representative office of GlaxoSmithKline Pte Ltd at Ho Chi Minh City

Metropolitan Building, Room 701

235 Dong Khoi, District 1

Ho Chi Minh City, Vietnam.

Announcements to Binh Dan Hospital should be sent to:

**DR. NGUYEN CHI HUNG-Director of the hospital**

Binh Dan Hospital

371 Dien Bien Phu, Ward 4, District 3

Ho Chi Minh City, Vietnam

Tel: (84-8) 38394747

Fax: (84-8) 38391315

**15. FORCE MAJEURE CASES**

15.1 Depending on compliance article 15.2, neither party is liable to the other party for any delay or fails to perform its obligations under this Agreement arising from any force majeure cases.

15.2 In the event either party delays or impedes the implementation of its obligations, it will:

a. Send a notice in writing of the delay or interference to the other party as soon as possible and reasonably specify that start date and the range of the delay or impediment, the reason for delay or hindrance and estimated time of such delay or hindrance;

b. Use all reasonable efforts to mitigate the impact of the delay or hindrance to the implementation of its obligations under this Agreement; and

c. Recover the implementation of its obligations as soon as reasonably possible after eliminating the reason for the delay or hindrance.

15.3 If one of the parties is hindered in performing its obligations by a force majeure event within 60 (sixty) days or more continuously and cumulatively in one year (“the affected party”), the other party may terminate this Agreement immediately by sending written notice to the affected party.

**16. SOLVING DISPUTE**

16.1 If any party believes that there is a dispute between the parties arising out of or relating to this Agreement, including but not limited to any dispute or claim or issue outside the contract related to the existence, validity or termination of this Agreement (“Dispute”), such party may send a written notice to the other party to state details of the dispute and the reasons why the notifying party believes the dispute has arisen (“Notice of dispute”). When sending the notice of dispute, the dispute will be made:

a. First time to the representatives of each party whose daily responsibility is managing issues related to this Agreement, and these representatives will meet and try to solve the dispute (each representative will act appropriately and with goodwill) within 5 (five) working days of sending the “notice” of dispute” (“meeting of authorized representatives”); and

b. If the Conflict cannot be resolved according to provision 16.1 (a) it will be resolved by the authorized representative of GSK and the hospital (called “the authorized representative”) and these people will meet each other and try to resolve conflict (each of them acts in a suitable way and willingly) within 05 (five) working days of sending the announcement about the conflict (“the meeting of the authorized representatives”)

16.2 If the conflict cannot be resolved within 05 (five) working days of the meeting of the authorized representatives, the conflict will be presented and resolved generally by the Center for International Arbitration of Vietnam to the Chamber of Commerce and Industry of Vietnam (“VIAC”) according to Arbitration Rules of VIAC (“VIAC Rules”). Parties agree that:

a. The number of the arbitrators will be three. Each party recommends one arbitrator and the two recommended arbitrators will recommend the third party;

b. Legal location or place for arbitration is in Ho Chi Minh City, Vietnam;

c. The language used in the sentencing by the arbitrator is Vietnamese; and

d. Adjusting low for this Agreement are defined in Article 17.9.

17. **GENERAL PROVISION**

17.1 The hospital declares, ensures and commits with GSK that:

(a) The hospital has capability and has been implementing all necessary actions to allow for the signing and implementing of this agreement consistent with the terms of this Agreement and in the extent of the knowledge, the signing of this agreement will not conflict with any obligations that the hospital must comply with any contracts which the hospital signed before;

(b) The Hospital holds all approvals, authorizations, registrations, agreements, certificates, licenses, permits or exemptions required from each of the competent state agency which are necessary to perform their obligations specified in this agreement relating to the receiving and using of funding payments under the provisions of this Agreement in accordance with the law of Vietnam and will pay all due fees relating to the above approval that do not violate any of the conditions specified in this Agreement as such violations can cause a serious adverse impact on the ability to perform the obligations of the hospital specified in the Agreement.

(c) The Hospital has provided the necessary reports to competent state agencies in accordance with the provisions and laws of Vietnam related to receiving and using payments, funding; and

(d) There is not and will not be any misleading, infringing or falsities regarding the use of such funding payment under this Agreement which may affect the reputation of GSK and other companies in the \*\*\*\*\*\*\*WHAT?

17.2 At any time, by written notice addressed to the Hospital, GSK has the right to transfer or otherwise transfer any of its rights and obligations under this Agreement or one part or all parts of this Agreement to any company in the GlaxoSmithKline Corporation or any inheriting party with respect to the ownership of the whole or part of the activities of GSK.

17.3 This Agreement covers the entire agreement between parties regarding the subject of the Contract and replaces all previous contracts, agreements and oral or written between the parties relating to this subject.

17.4 Nothing in this Agreement will create or be deemed to have created a new partnership, joint venture or any other relationship between the parties outside the contractual relationship expressly provided in this Agreement.

17.5 The failure of one party in performing or delaying the rights or sanctions regulated in this Agreement or law does not constitute a waiver of such rights or sanctions (or any other rights or fine) and also not preventing or limiting the implementation of the rights or such fine. In addition, a single service or the party of any right or sanction above does not prevent or restrict the implementation of such rights or sanctions (or any other right or sanction)

17.6 If any provisions in this Agreement are invalid or considered to be invalid or unenforceable in whole or in part by the decision of any court or other competent authority, the Agreement will continue to be valid for other provisions and the remainder of the affected provisions.

17.7 This Agreement can only be adjusted when there is a written approval signed by the legally authorized representatives of parties.

17.8 This Agreement may be signed in many copies, but will not take effect until each party has signed in at least one copy. Each copy will constitute an original copy of this Agreement and all parties will together constitute a single document.

17.9 This Agreement and any dispute or claim arising from or relating to this Agreement or the subject of this Agreement (including claims and any non-contractual claims or disputes) will be adjusted and explained under the law of Vietnam.

17.10 This Agreement is made in 06 (six) copies in Vietnamese, each party keeps 03 (three) Vietnamese copies.

**On behalf of and represent**

**REPRESENTATIVE OFFICE OF GLAXOSMITHKLINE PTE. LTD at Ho Chi Minh city**

***24th August, 2011***

Signed and sealed

**BINH DAN HOSPITAL, HO CHI MINH CITY**

**371 Dien Bien Phu, Ward 4, District 3, Ho Chi Minh City, Vietnam**

***24th, August, 2011***

**Signed and sealed**

**Dr Nguyen Chi Hung**

*Director of the hospital*

Signed Signed

**PH.D DOCTOR NGUYEN VAN AN PhD DOCTOR DAO QUANG OANH**

Vice Dean of Department of Urology A Dean of Department of Urology B

Principal researcher Principal researcher