

# BMS 知情同意书 (ICF)

方案编号	AI447114
中心编号 (如适用):	0025
研究标题:	Daclatasvir 联合 Asunaprevir (Dual) 用于基因 1b 型慢性丙型肝炎病毒 (HCV) 感染初始受试者的 3 期临床研究
语言:	中文

## 研究医生

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陕西省西安市雁塔区雁塔西路272号

18991232860

## 1. 参加

我们正在考虑邀请您参加一项研究。我们将根据下面描述的筛选程序和其他合格性标准,判断您是否符合参加此项研究的条件。在您参加此项研究之前,让您理解此项研究所涉及的内容是十分重要的。请仔细阅读本信息,如果有任何问题,请您提出。独立伦理委员或机构审查委员会已经对此项研究的目的和拟进行的实施步骤进行了审查,并且给出了赞同的意见。

## 2. 研究目的

此项研究的目的是证明为期 24 周的 daclatasvir (DCV) 和 asunaprevir (ASV) 联合治疗慢性 HCV 基因型 1b 感染比历史对照 (即为期 48 周的聚乙二醇化干扰素 (pegIFN) 和利巴韦林 (RBV) 联合治疗) 更有效。

## 3. 大致参加者人数和您参加此项研究的预计持续时间

预计约有 200 名受试者将会参加此项研究,其中<中国><160 例>。即使您符合参加研究的全部标准,也有可能无法入选到此项研究中。如果您入选,您参加研究的时间预计为 48-60 周。(如下面第 5 节“随访”中所述,此后可能需要采集其他信息以进一步评价药物的安全性或有效性。)

## 4. 研究治疗

您有 75% 的机会接受为期 24 周的下列阳性药物治疗:

- 口服 DCV 片剂, 每日 1 次, 每次 60 mg;
- 和
- 口服 ASV 胶囊, 每日 2 次, 每次 100 mg;

或者



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### 密集 PK 亚研究:

还要求在更多的时间点采集 PK 血样。在这些时间点采集 PK 血样并非参加本项研究所必需的, 您可以选择不参加此部分研究。自愿参加此亚研究的受试者将被要求将第 2 周的门诊访视延长至全天。预计有 24 名受试者参加此部分的研究。

还将在您服用研究药物后 1、2、3、4 和 8 小时采集血样。如果您参加此部分研究, 将额外采集 20 mL 血样。

如果您同意参加此项研究的 PK 亚研究, 请在下面签字。

由各方同时签字 (即在同一天):

\_\_\_\_\_  
受试者的印刷体姓名

\_\_\_\_\_  
日期 (由受试者填写)

\_\_\_\_\_  
签名

\_\_\_\_\_  
获取知情同意的人员的印刷体姓名

\_\_\_\_\_  
日期

\_\_\_\_\_  
签名

对于精神上无行为能力的人或者文盲, 要求有公正见证人签字:

已经向研究参加者或他/她的法定代理人读了此份知情同意文件中的信息。我确信他/她理解所阅读和解释的内容, 并且自愿同意参加此项研究。受试者或其代理人已经在签名栏中签名或者留下了他/她的标记。

\_\_\_\_\_  
公正见证人印刷体姓名

\_\_\_\_\_  
日期 (由受试者填写)

\_\_\_\_\_  
签名

### 治疗后随访阶段:

当您结束或者完成研究治疗之后, 您将开始此项研究的最后一个阶段, 即随访阶段。在此阶段中, 您的研究医生将继续评价您的健康状况。例如, 需要知道您是否已经恢复、发生疾病或者发生了严重的不良事件。

治疗后随访阶段包括 3 次访视 (在研究治疗结束后 4、12 和 24 周进行), 要求您回到诊所/办公室进行这些访视。在这些门诊访视时, 将进行在其他研究访视时进行过的部分或全部评价, 包括简略体格检查、采血以及完成 2 个健康调查问卷。

工作人员将会询问您正在服用的治疗丙型肝炎的任何新的药物或治疗方法。如果您在随访阶段中开始服用任何新的抗 HCV 药物, 则在治疗后 4 周的随访访视完成之后, 您将结束此项研究。

此外, 在门诊随访第 8、16 和 20 周期间, 工作人员将会通过电话联系您, 确认您继续参加研究, 并采集您在家进行的妊娠试验的结果 (针对 WOCBP, 在随访访视第 8 周时), 并确认下次研究访视的日期。如果您在两次访视之间的联系方式发生了变化, 应告知工作人员。

如果您是一名 WOCBP, 无论您接受了多少周的治疗, 您必须在治疗后第 4 周和第 8 周随访访视时进行妊娠试验。在随访第 8 周末安排诊室访视, 所以此次妊娠试验将在您的家中进行。将为您提供妊娠日志, 用于记录随访第 8 周时的妊娠试验结果。在预定的下次定期访视期间, 您需要将此结果带到办公室, 或者研究医生或研究护士将会



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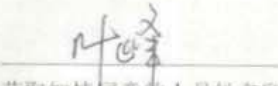

### 18. 签名

我已经阅读并理解了此知情同意书中提供的信息。我有机会提出问题，而且我提出的问题均得到了答复。

- 我确认已经收到提供了研究医生联系方式的患者警示卡。我同意在任何时间随身携带此卡片。
- 我将收到一份已经签署姓名和日期的知情同意书副本。
- 请选择一项：
  - ☒ 我同意研究医生告知我的诊治医生我正在参加此项研究。
  - ☐ 我不愿意研究医生告知我的诊治医生我正在参加此项研究。

### • 我自愿接受参加此项研究

由各方同时签名（即在同一天）：

	2015.9.24	
<受试者/患者>姓名印刷体	日期（由受试者填写）	签名
	2015.9.24	
获取知情同意的人员姓名印刷体	日期	签名

分发：原件由研究医生保留，签名后的复印件提供给受试者/患者



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对于精神残障或文盲，应根据研究/受试者人群的需要提供下列附加签名：

- 在无法获得成年受试者/患者同意的情况下，要求法定代理人的签名：

\_\_\_\_\_  
受试者/患者法定代理人的姓名

\_\_\_\_\_  
日期（由受试者/患者的法定  
代理人填写）      签名

\_\_\_\_\_  
注明与受试者/患者的关系

无行为能力的个人可能在任何特定时间明确拒绝参加或者要求退出临床试验。研究医生必须尊重该要求。

- 如果参加者（或者法定监护人，若适用）不能阅读此知情同意书，则要求有公正见证人的签名。

已经向研究参加者或他/她的法定代理人读了此份知情同意文件中的信息。我确信他/她理解所阅读和解释的内容，并且自愿同意参加此项研究。受试者或其代理人已经在签名栏中签名或者留下了他/她的标记。

\_\_\_\_\_  
公正见证人姓名

\_\_\_\_\_  
日期（由公正见证人填写）      签名



## **Appendix 1.5: List and Description of Investigators for Study AI447114**

Protocol AI447114  
18 page(s) excluding cover page

Appendix 1.5 List and Description of Investigators for Study AI447114				
Site No	Principal or Sub Investigator Name or Responsible Medical Personnel	Study Center and Address	Enrolled	Randomized
AI447-114-0002*	<p><b>Yeon, Jong Eun, MD, PhD</b></p> <p>Byun, Kwan Soo, MD Kang, Seong Hee, MD, MS Kim, Ji-Hoon, MD, PhD Kim, Tae Suk, MD, MS Lee, Young-Sun, MD, PhD Yoo, Yang Jae, MD</p> <p>(P) +82226266630 (F) +8228386591</p> <p>Email: jeyyeon@hotmail.com</p>	<p>Korea University Guro Hospital(Office) 148, gurodong-ro, Guro-gu, Seoul, 08308 Korea, Republic of</p> <p>Korea University Guro Hospital(Pt Tx Ctr - Hosp/Med Ctr) 148, gurodong-ro, Guro-gu, Seoul, 08308 Korea, Republic of</p> <p>Korea University Guro Hospital(Office)(Previous) 148 Gurodong-ro, Guro-gu Seoul, 152-703 Korea, Republic of</p> <p>Korea University Guro Hospital(Pt Tx Ctr - Hosp/Med Ctr)(Previous) 148 Gurodong-ro, Guro-gu Seoul, 152-703 Korea, Republic of</p>	4	4

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<b>Site No</b>	<b>Principal or Sub Investigator Name or Responsible Medical Personnel</b>	<b>Study Center and Address</b>	<b>Enrolled</b>	<b>Randomized</b>
AI447-114-0003*	<p><b>Yang, Yongfeng, DR</b></p> <p>Wang, Huali, MD</p> <p>(P) +8613951990210 (F) +862583626313</p> <p>Email: yyf1997@163.com</p>	<p>The 2nd Hospital Of Nanjing(Office) 1-1 Zhongfu Road Nanjing, JIANGSU 210003 China</p> <p>The 2nd Hospital Of Nanjing(Pt Tx Ctr - Hosp/Med Ctr) 1F Clinical Research office, Outpatient Building No.1 Zhongfu Road Nanjing, Jiangsu 210003 China</p> <p>The 2nd Hospital Of Nanjing(Pt Tx Ctr - Hosp/Med Ctr)(Previous) 5F Admin BLDG, No.1 Zhongfu Road Nanjing, Jiangsu 210003 China</p>	6	5

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<b>Site No</b>	<b>Principal or Sub Investigator Name or Responsible Medical Personnel</b>	<b>Study Center and Address</b>	<b>Enrolled</b>	<b>Randomized</b>
AI447-114-0006*	<p><b>Huang, Yan, DR</b></p> <p>Hou, Zhouhua, DR</p> <p>(P) +8613874854142 (F) 8673189753766</p> <p>Email: drhyan@163.com</p>	<p>Xiangya Hospital Central-South University(Office) No.87 Xiang Ya Road Changsha, HUNAN 410008 China</p> <p>Xiangya Hospital Central-South University(Pt Tx Ctr - Hosp/Med Ctr) No.87 Xiang Ya Road Changsha, HUNAN 410008 China</p>	6	5
AI447-114-0007*	<p><b>Hou, Jinlin, MD</b></p> <p>Liang, Xieer, MD Sun, Jian, DR</p> <p>(P) +862061641941 (F) +862087719653</p> <p>Email: jlhoumu@163.com</p>	<p>Nanfang Medical College Nanfang Hospital(Office) No. 1838 Guangzhou da dao North Rd. Baiyun District Guangzhou, 510515 China</p> <p>Nanfang Medical College Nanfang Hospital(Pt Tx Ctr - Hosp/Med Ctr) No. 1838 Guangzhou da dao North Rd. Baiyun District Guangzhou, 510515 China</p>	6	6

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AI447-114-0009*	<p><b>Xu, Min, BSc</b></p> <p>Cao, Yang, BSc Liu, Huiyuan, BSc Luo, Chun, MD Xiao, Guangming, BSc Xie, Zhiwei, MD Yu, Weihua, BSc Zhuo, Li, MD</p> <p>(P) +8613710874513 (F) +862083710301</p> <p>Email: gz8hxm@126.com</p>	<p>Guangzhou No.8 People's Hospital(Office) 627 Dongfeng Road E. Guangzhou, GUANGDONG 510060 China</p> <p>Guangzhou No.8 People's Hospital(Pt Tx Ctr - Hosp/Med Ctr) 627 Dongfeng Road E. Guangzhou, GUANGDONG 510060 China</p>	8	7
AI447-114-0014*	<p><b>Niu, Junqi, MD</b></p> <p>Jin, Qinglong, MD Pan, Yu, MD</p> <p>(P) +8643185612468 (F) +8643185612468</p> <p>Email: jdyiniuqunqi@163.com</p>	<p>The 1st Hospital Of Jilin University(Office) No.71 Xinmin Street Changchun, JILIN 130021 China</p> <p>The 1st Hospital Of Jilin University(Pt Tx Ctr - Hosp/Med Ctr) No.71 Xinmin Street Changchun, JILIN 130021 China</p>	10	9

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AI447-114-0015*	<p><b>Chen, Xinyue, MD</b></p> <p>Jin, Yi, MD</p> <p>(P) +8613366209490 (F) +861063295285</p> <p>Email: chenxydoc@163.com</p>	<p>Beijing Youan Hospital, Capital Medical University(Office) No.8 You'anmen Outer West Toutiao Of Fengtai Beijing, BEIJING 100054 China</p> <p>Beijing Youan Hospital, Capital Medical University(Pt Tx Ctr - Hosp/Med Ctr) No.8 You'anmen Outer West Toutiao Of Fengtai Beijing, BEIJING 100054 China</p>	10	7
AI447-114-0016*	<p><b>Li, Jun, DR</b></p> <p>Chen, Nian, MD Dong, Li, MD Kong, Lianhua, MD Weng, Yali, MD</p> <p>(P) +862583711066 (F) +862583711066</p> <p>Email: prof.lijun@gmail.com</p>	<p>Jiangsu Province People's Hospital(Office) No.300 Guangzhou Road Nanjing, JIANGSU 210029 China</p> <p>Jiangsu Province People's Hospital(Pt Tx Ctr - Hosp/Med Ctr) No.300 Guangzhou Road Nanjing, JIANGSU 210029 China</p>	6	6

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AI447-114-0017*	<p><b>Wang, Maorong, DR</b></p> <p>Geng, Jiabao, MD Hao, Kunyan, MD Wang, Shouming, BSc Yang, Zhiguo, MD</p> <p>(P) +862580864029 (F) +862580864029</p> <p>Email: maorongwang@126.com</p>	<p>Nanjing Bayi Hospital(Office) No.34 34 Biao,yang Gongjing Nanjing, JIANGSU 210002 China</p> <p>China PLA 81 Hospital(Pt Tx Ctr - Hosp/Med Ctr) 305 Zhongshan East Road Nanjing, JIANGSU 210002 China</p>	6	3
AI447-114-0018*	<p><b>Xie, Qing, DR</b></p> <p>Cai, Wei, DR Wang, Hui, MD</p> <p>(P) +862164370045 (F) +8665295080</p> <p>Email: xieqingrjh@163.com</p>	<p>Shanghai Ruijin Hospital Sh Jiaotong Uni Of Med Science(Office) No.197,ruijin Er Road Shanghai, SHANGHAI 200025 China</p> <p>Shanghai Ruijin Hospital Sh Jiaotong Uni Of Med Science(Pt Tx Ctr - Hosp/Med Ctr) 1F No.36 BLDG No. 197 Ruijin Er Road Shanghai, Shanghai 200025 China</p>	7	6

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<b>Site No</b>	<b>Principal or Sub Investigator Name or Responsible Medical Personnel</b>	<b>Study Center and Address</b>	<b>Enrolled</b>	<b>Randomized</b>
AI447-114-0019*	<p><b>Wei, Lai, DR</b></p> <p>Huang, Rui, DR Rao, Huiying, DR Yang, Ming, MD</p> <p>(P) +8613910901926 (F) +861088325534</p> <p>Email: weilai@pkuph.edu.cn</p>	<p>Peking University People'S Hospital(Office) No.133 Fu Nei Da Jie Western City District Beijing, BEIJING 100034 China</p> <p>Peking University People'S Hospital(Pt Tx Ctr - Hosp/Med Ctr) No.133 Fu Nei Da Jie Western City District Beijing, BEIJING 100034 China</p>	15	14
AI447-114-0020*	<p><b>Jia, Ji-Dong, DR</b></p> <p>Cui, Yan, DR Ma, Hong, DR Ou, Xiaojuan, BSc Wang, Qianyi, MD Wang, Xiaoming, DR Wu, Xiaoning, DR You, Hong, DR</p> <p>(P) +861063139708 (F) +861063138019 Email: jiamd@263.net</p>	<p>Beijing Friendship Hospital, Affiliated Of C.U.M.S(Office) No. 95, Yongan Rd Xicheng District Beijing, Beijing 100050 China</p> <p>Beijing Friendship Hospital, Affiliated Of C.U.M.S(Pt Tx Ctr - Hosp/Med Ctr) No. 95, Yongan Rd Xicheng District Beijing, Beijing 100050 China</p>	12	12

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AI447-114-0021*	<p><b>Wang, Guiqiang, MD</b></p> <p>Huo, Na, MD Li, Jun, DR Wang, Yan, DR Zhao, Hong, DR</p> <p>(P) +861066551383 (F) +861066551383</p> <p>Email: john131212@hotmail.com</p>	<p>Peking University First Hospital(Office) No. 8 Xishiku Dajie Beijing, BEIJING 100034 China</p> <p>Peking University First Hospital(Pt Tx Ctr - Hosp/Med Ctr) No. 8 Xishiku Dajie Beijing, BEIJING 100034 China</p>	5	4
AI447-114-0022*	<p><b>Zhang, Mingxiang, MD</b></p> <p>Song, Wei, MD Sun, Xingan, MD Wu, Xiaofeng, MD Yang, Zhiyong, MD Zhu, Hongxin, MD</p> <p>(P) +8618640208855 (F) +862423385232</p> <p>Email: zmxsheny@163.com</p>	<p>The Sixth People's Hospital of Shenyang(Office) No 85 Heping south street Heping District shenyang, liaoning 110006 China</p> <p>The Sixth People's Hospital of Shenyang(Pt Tx Ctr - Hosp/Med Ctr) No 85 Heping south street Heping District shenyang, liaoning 110006 China</p>	14	13
AI447-114-	<b>Dou, Xiaoguang, MD</b>	Shengjing Hospital Of China Medical	5	5

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0023*	<p>Bai, Han, PhD Wang, Jingyan, MD Zhao, Lianrong, DR</p> <p>(P) +8613334234847 (F) +862496615162221</p> <p>Email: guang40@163.com</p>	<p>University(Office) No. 39 Huaxiang Street Tiexi District Shenyang, Liaoning 110002 China</p> <p>Shengjing Hospital Of China Medical University(Pt Tx Ctr - Hosp/Med Ctr) No. 39 Huaxiang Street Tiexi District Shenyang, Liaoning 110002 China</p>		
AI447-114-0024*	<p><b>Xie, Wen, MD</b></p> <p>Wang, Yanbin, MD Yan, Jie, MD</p> <p>(P) +861084322816 (F) +861084322446</p> <p>Email: xiewen6218@163.com</p>	<p>Beijing Ditan Hospital Capital Medical University(Office) #8 Jingshun Eastern St. Chaoyang District Beijing, BEIJING 100015 China</p> <p>Beijing Ditan Hospital Capital Medical University(Pt Tx Ctr - Hosp/Med Ctr) #8 Jingshun Eastern St. Chaoyang District Beijing, BEIJING 100015 China</p>	10	10
AI447-114-0025*	<p><b>Lin, Shumei, DR</b></p>	<p>The 1st Affiliated Hospital Of M.C Of Xian Jiaotong Uni(Office)</p>	5	5

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<b>Site No</b>	<b>Principal or Sub Investigator Name or Responsible Medical Personnel</b>	<b>Study Center and Address</b>	<b>Enrolled</b>	<b>Randomized</b>
	<p>Ye, Feng, DR</p> <p>(P) +862985324086 (F) +862989362862</p> <p>Email: linshumei123@126.com</p>	<p>No.277, Yanta West Road Yanta District Xi'an, SHAN3XI 710061 China</p> <p>The 1st Affiliated Hospital Of M.C Of Xian Jiaotong Uni(Pt Tx Ctr - Hosp/Med Ctr) No.277, Yanta West Road Yanta District Xi'an, SHAN3XI 710061 China</p>		
AI447-114-0027*	<p><b>Jia, Zhansheng, PhD</b></p> <p>Hao, Chunqiu, DR Kang, Wen, DR Wang, Wei, MD</p> <p>(P) +862984777455 (F) +862984717528</p> <p>Email: jiazsh@fmmu.edu.cn</p>	<p>Tangdu Hospital(Office) No.1 Xinsi Road Of Baqiao Xi'an, SHAN3XI 710038 China</p> <p>Tangdu Hospital(Pt Tx Ctr - Hosp/Med Ctr) No.1 Xinsi Road Of Baqiao Xi'an, SHAN3XI 710038 China</p>	6	4
AI447-114-0029*	<p><b>Lee, Youn-Jae, MD, PhD</b></p>	<p>Inje University Busan Paik Hospital(Office) 75, Bokji-ro, Busanjin-gu, Busan, 47392</p>	7	5

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Site No	Principal or Sub Investigator Name or Responsible Medical Personnel	Study Center and Address	Enrolled	Randomized
	<p>Jung, Eun Uk, MD, PhD Park, Sung Jae, MD, PhD</p> <p>(P) +82528908974 (F) +82518956438</p> <p>Email: yjyh0105@inje.ac.kr</p>	<p>Korea, Republic of</p> <p>Inje University Busan Paik Hospital(Pt Tx Ctr - Hosp/Med Ctr) 75, Bokji-ro, Busanjin-gu, Busan, 47392 Korea, Republic of</p> <p>Inje University Busan Paik Hospital(Office)(Previous) #75, Bokji-ro, Busanjin-gu Busan, 614-735 Korea, Republic of</p> <p>Inje University Busan Paik Hospital(Pt Tx Ctr - Hosp/Med Ctr)(Previous) #75, Bokji-ro, Busanjin-gu Busan, 614-735 Korea, Republic of</p>		

<b>Appendix 1.5 List and Description of Investigators for Study AI447114</b>				
<b>Site No</b>	<b>Principal or Sub Investigator Name or Responsible Medical Personnel</b>	<b>Study Center and Address</b>	<b>Enrolled</b>	<b>Randomized</b>
AI447-114-0032*	<p><b>Burnevich, Eduard Z., MD, PhD</b></p> <p>Yakusheva, Marina S., MD</p> <p>(P) +74957283226 (F) +74956854667</p> <p>Email: eduard.z.burnevich@mtu-net.ru</p>	<p>City Clinical Hospital #24(Office) Pistovaya str.,build10 Moscow, 127015 Russian Federation</p> <p>City Clinical Hospital #24(Pt Tx Ctr - Hosp/Med Ctr) Pistovaya str.,build10 Moscow, 127015 Russian Federation</p>	10	10
AI447-114-0033*	<p><b>Yakovlev, Alexey A, MD, PhD</b></p> <p>Komarova, Alexandra, MD, PhD Musatov, Vladimir, MD Sokolova, Olga</p> <p>(P) +78127178960 (F) +78127178960</p> <p>Email: infectrial@mail.ru</p>	<p>Clinical Infectious Hospital #30 Named After S.P. Botkin(Office) 3, Mirgorodskaya Street St. Petersburg, 191167 Russian Federation</p> <p>Clinical Infectious Hospital #30 Named After S.P. Botkin(Pt Tx Ctr - Hosp/Med Ctr) 3, Mirgorodskaya Street Department 21 St. Petersburg, 191167 Russian Federation</p>	10	10

<b>Appendix 1.5 List and Description of Investigators for Study AI447114</b>				
<b>Site No</b>	<b>Principal or Sub Investigator Name or Responsible Medical Personnel</b>	<b>Study Center and Address</b>	<b>Enrolled</b>	<b>Randomized</b>
AI447-114-0035*	<p><b>Zakharova, Natalia G, MD, PhD</b></p> <p>Fedorov, Pavel, DR Minin, Pavel, DR Romanova, Svetlana, MD</p> <p>(P) +78122514939 (F) +78122512760</p> <p>Email: aidscenterspb@mail.ru</p>	<p>St Petersburg AIDS Center(Office) SPT AIDS C 179A OBVODNIY CANAL Saint Petersburg, 190103 Russian Federation</p> <p>St Petersburg AIDS Center(Pt Tx Ctr - Hosp/Med Ctr) 179a, Obvodny Channel St.petersburg, 190103 Russian Federation</p>	10	10

Appendix 1.5 List and Description of Investigators for Study AI447114				
Site No	Principal or Sub Investigator Name or Responsible Medical Personnel	Study Center and Address	Enrolled	Randomized
AI447-114-0037*	<p><b>Jung, Yong Jin, MD, PhD</b></p> <p>Joo, Sae Kyung, MD, MS Kim, Hwi Young, MD, PhD</p> <p>(P) +8228701851 (F) +8228701859</p> <p>Email: jjj0601@snu.ac.kr</p>	<p>SMG-SNU Borame Medical Center(Office) 20, Boramae-ro 5-gil, Dongjak-gu, Seoul, 07061 Korea, Republic of</p> <p>SMG-SNU Borame Medical Center(Pt Tx Ctr - Hosp/Med Ctr) 20, Boramae-ro 5-gil, Dongjak-gu, Seoul, 07061 Korea, Republic of</p> <p>SMG-SNU Borame Medical Center(Office)(Previous) 20 Boramae-ro 5-gil, Dongjak-gu Seoul, 156-707 Korea, Republic of</p> <p>SMG-SNU Borame Medical Center(Pt Tx Ctr - Hosp/Med Ctr)(Previous) 20 Boramae-ro 5-gil, Dongjak-gu Seoul, 156-707 Korea, Republic of</p>	7	7

<b>Appendix 1.5 List and Description of Investigators for Study AI447114</b>				
<b>Site No</b>	<b>Principal or Sub Investigator Name or Responsible Medical Personnel</b>	<b>Study Center and Address</b>	<b>Enrolled</b>	<b>Randomized</b>
AI447-114-0038*	<p><b>Ye, Jun, MD</b></p> <p>Li, Weizheng, BSc Xue, Dongying, MD Yan, Ping, BSc</p> <p>(P) +02162572723</p> <p>Email: pzxgrk@163.com</p>	<p>Shanghai Putuo District Center Hospital(Office) 164 Lanxi Road Building 1 Shanghai, China</p> <p>Shanghai Putuo District Center Hospital(Pt Tx Ctr - Hosp/Med Ctr) 164 Lanxi Road Building 1 Shanghai, China</p>	5	5
AI447-114-0039*	<p><b>Wang, Fusheng, DR</b></p> <p>Jiang, Tianjun, DR Li, Yuanyuan, DR</p> <p>(P) +861066833460 (F) +861063879892</p> <p>Email: fswang302@163.com</p>	<p>302 Military Hospital of China(Office) No. 100, West Fourth Ring Road Fengtai District Beijing, 100039 China</p> <p>302 Military Hospital of China(Pt Tx Ctr - Hosp/Med Ctr) No. 100, West Fourth Ring Road Fengtai District Beijing, 100039 China</p>	15	15

<b>Appendix 1.5 List and Description of Investigators for Study AI447114</b>				
<b>Site No</b>	<b>Principal or Sub Investigator Name or Responsible Medical Personnel</b>	<b>Study Center and Address</b>	<b>Enrolled</b>	<b>Randomized</b>
AI447-114-0040*	<p><b>Wu, Shanming, BSc</b></p> <p>Li, Tao, BSc Liu, Jinhua, MD</p> <p>(P) +8613671893128 (F) +862156974969</p> <p>Email: wusm96@163.com</p>	<p>Shanghai Public Health Clinical Center(Office) 3F outpatient No. 56 Shui Dian Road Shanghai, Shanghai 200083 China</p> <p>Shanghai Public Health Clinical Center(Pt Tx Ctr - Hosp/Med Ctr) 4F Medical BLDG No. 56 Shui Dian Road Shanghai, Shanghai 200083 China</p>	5	3

<b>Appendix 1.5 List and Description of Investigators for Study AI447114</b>				
<b>Site No</b>	<b>Principal or Sub Investigator Name or Responsible Medical Personnel</b>	<b>Study Center and Address</b>	<b>Enrolled</b>	<b>Randomized</b>
AI447-114-0041*	<p><b>Jiang, Xiangjun, MD</b></p> <p>Chu, Leilei, MD Cui, Yanxin, MD Jin, Wenwen, MD Li, Changyan, BSc Li, Weina, MD Lin, Zhonghua, MD Xin, Yongning, MD Zhang, Mei, BSc</p> <p>(P) +8653283926612 (F) +8653282818912</p> <p>Email: drxj@163.com</p>	<p>Qingdao Municipal Hospital(Office) 1 Jiaozhou Road Qingdao, SHANDONG 266011 China</p> <p>Qingdao Municipal Hospital(Pt Tx Ctr - Hosp/Med Ctr) 1 Jiaozhou Road Qingdao, SHANDONG 266011 China</p>	8	7
AI447-114-0045*	<p><b>Tan, Youwen, DR</b></p> <p>Chen, Li, BSc Ge, Guohong, DR Wang, Lina, BSc Wu, Di, BSc</p> <p>(P) +8651188970656 (F) +8651188970665</p>	<p>The Third People's hospital of Zhenjiang(Office) No.300 Daijiamen Runzhou district Zhengjiang, Jiangsu 212000 China</p> <p>The Third People's hospital of Zhenjiang(Pt Tx Ctr - Hosp/Med Ctr) No.300 Daijiamen Runzhou district Zhengjiang, Jiangsu 212000 China</p>	6	5
AI447-114-				

<b>Appendix 1.5 List and Description of Investigators for Study AI447114</b>				
<b>Site No</b>	<b>Principal or Sub Investigator Name or Responsible Medical Personnel</b>	<b>Study Center and Address</b>	<b>Enrolled</b>	<b>Randomized</b>
0045*DPS# Cont'd	Email: tyw915@sina.com			
AI447-114-0047*	<b>Tang, Hong, MD</b>  Du, Lingyao, MD Ma, Yuanji, MD  (P) +862881812226 (F) +862885422175  Email: htang6178@163.com	West China Hospital, Sichuan University(Office) No.37 Guoxue Xiang Chengdu, SICHUAN 610041 China  West China Hospital, Sichuan University(Pt Tx Ctr - Hosp/Med Ctr) No.37 Guoxue Xiang Chengdu, SICHUAN 610041 China	5	5

\* - Non IND Sites