Application form for ethic approval

Approval No. 20180948-2

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Research project &	Combined use of apatinib mesylate and vinorelbine versus single use of					
protocol version	vinorelbine in recurrer	nt or metasta	tic triple-negative breast cancer: study			
			,			
	protocol for a randomized controlled clinical trial					
	(Deecember of the control of the control of					
	movision)	(NE:	search project with a retrial after			
_	revision)					
Sponsor	Liaoning Cancer	Setting	Liaoning Cancer Hospital &			
	Hospital & Institute		Institute			
Researcher(s)	Tao Sun	Division	Department of Medical Oncology			
Date of censors	2018.10.16	Setting	The meeting room of the Ethics			
			Committee of Liaoning Cancer			
			Hospital & Institute			
Ethical review	☐ Meeting review ✓					
manner	☐ Fast review					
Documentation	See attachment					
Voting	Anticipated: 15 Actually voted: 14					
	Abstained: 0 Avoided: 0					
Review comments	On October 16, 2018, the Ethics Committee conducted a serious					
	discussion on the above-mentioned protocol and voted on it. There were					
	14 voters: 14 voting for the protocol, 0 agreeing on the protocol after					
	necessary amendments, 0 agreeing on re-check after necessary					
	amendments, and 0 voting against the protocol. The Ethics Committee					
	believes that the protocol is basically in line with ethical requirements					
	and can be conducted as a clinical trial.					
Other suggestions	Nil.		<u></u>			
Period of validity	2018.10.17 -	Periodic	☐ 3 months			
	2019.10.16	review	☐ 6 months			
			☐ 12 months ✓			
Decision	Agreement					
			Signature:			
			October 17, 2018			
Note: The responsibi	lities, personnel compos	sition, function	ons, operating procedures and records			
of the Ethics Committee follow ICH-GCP and relevant laws and regulations in China.						
Researcher: Date:						
Sponsor:			Date:			

辽宁省肿瘤医院医学伦理委员会审查批件

伦理批件编号: 20180948-2

项目名称及 版本号	甲磺酸阿帕替尼联合长春 性乳腺癌的多中心、随机;			用于一线及以上三阴 肝项目,修正后重审)	
申办/参研单 位名称	辽宁省肿瘤医	院	临床试验机构	辽宁省肿瘤医院	
研究者	孙 涛		研究所在科室	乳腺内科病区	
审查日期	2018. 10. 16		审查地点	辽宁省肿瘤医院 伦理委员会会议室	
伦理审查方式	√□会议审查 □快速审查				
审查文件	详见附件				
投票情况	应到人数: 15 人 实到人数: 14 人 弃权人数: 0 人 回避委员: 0 人				
审查意见	伦理委员会于2018年 进行了投票表决。投票人 必要的修正后重审0票,2 要求,可以开展临床研究。	数: 14人,同意 下同意 0 票。伦理	14票,作必要的	修正后同意 0 票,作	
其他意见或建 议	无				
批件有效期	2018. 10. 17-2019. 10. 16	跟踪审查频率	口3 个月	6个月 12个月	
决 议	同意		会主任/授权者3 年(0月 V 元	1+0	

注:本伦理委员会的职责、人员组成、作用、操作程序及记录遵循 ICH-GCP 和中国 的相关法律法规。

1.临床研究人员签收: 34 34 日期:	218.10.30
2.申办单位人员签收: 日期:	

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