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Authors: Jian-Hai Guo, Shao-Xing Liu, Song Gao, Fu-Xin Kou, Xin Zhang, Di Wu, Xiao-Ting Li, Hui Chen, Xiao-Dong Wang, Peng Liu, Peng-Jun Zhang, Hai-Feng Xu, Guang Cao, Lin-Zhong Zhu, Ren-Jie Yang, Xu Zhu

Correspondence to: Xu Zhu, MD, Chief Doctor, Doctor, Full Professor, Professor, Department of Interventional therapy, Key Laboratory of Carcinogenesis and Translational Research (Ministry of Education/Beijing), Peking University Cancer Hospital and Institute, Beijing 100142, China.
drzhuxu@163.com

This study was registered at ClinicalTrials.gov. The registration identification number is NCT01997957.

Xu Zhu

