

1 **Additional file 1: Trial committee organization and contributions and role.**

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3 **Principal investigator (PI) and research physicians at main study site**

4 **Organization: the Fourth Affiliated Hospital of China Medical University**

5 **Contributions and role:** Principal investigator, original study design: Hang-yu Li (Email:li_hangyu@126.c
6 om)

7 **Organization of Steering committee and member appointment:** Qing Fan, De-wei Zhang, Da-ye
8 Yang, Hong-wu Li, Shi-bo Wei, Liang Yang, Hang-yu Li, Fu-quan Yang, Shao-jun Zhang, Yao-qiang Wu,
9 Wei-de An, Zhong-shu Dai, Hui-yong Jiang, Fu-rong Wang, Shi-feng Qiao

10 Communication and exchange of opinion with PI at each site

11 Preparation of IRB documents and CRF

12 Trial management (randomized allocation management, AE data collection at each site, participant
13 enrollment supervision, study site inspection and visits, budget allocation and management)

14 Cooperation with CRO in data collection, quality control, monitoring, and analysis

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16 **Steering committee (SC)**

17 **Organization and role:** All authors of this manuscript

18 **Contributions:** Protocol revision and decision on final protocol

19 Organization of Trial Management Committee and member appointment

20 Designation of participant recruitment study sites

21 Inspection of study progress, and decision on protocol revision, if needed

22 Determination of study result publication timing and method

23 Decision on authorship in accordance with Authorship eligibility guidelines

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25 **Trial Management Committee**

26 **Organization:** PI and investigators at each clinical trial participant enrollment site

27 Fu-quan Yang, Shengjing Hospital of China Medical University

28 Shao-jun Zhang, Fengtian Hospital of Shenyang Medical College

29 Yao-qiang Wu, The First Hospital of Dandong City

30 Wei-de An, The First Affiliated Hospital of Dalian Medical University

31 Zhong-shu Dai, General Hospital of Benxi Steel and Iron (Group) Co., LTD, Fifth Clinical College of China
32 Medical University

33 Hui-yong Jiang, General Hospital of Shenyang Military Area

34 Fu-rong Wang, The 202nd Hospital of PLA

35 Shi-feng Qiao, The First Affiliated Hospital of Liaoning Medical University

36 Hang-yu Li*, The Fourth Affiliated Hospital of China Medical University

37 **Organization and role:** Submission and obtaining study protocol approval from relevant IRB of each
38 study site

39 Clinical trial execution following protocol (e.g. participant recruitment, enrollment, data collection, CRF

- 1 entry)
- 2 Collection and report of AEs