172P A multi-center, randomized, double-blind, parallel, two-group phase III clinical study on the efficacy and safety of QL1101 or bevacizumab in combination with paclitaxel and carboplatin in the first-line treatment of non-squamous non-small cell lung cancer

B. Han[1], K. Li[2], T. Chu[1], M. Bi[3], H. Zhang[4], Y. Yu[5], J. Shi[6], X. Zhang[7], Z. Chen[8], C. Han[9], T. Bai[9]

[1]Respiratory Medicine, Shanghai Chest Hospital, Shanghai, China, [2]Cancer Hospital, Tianjin, China, [3]Oncology, The First Affiliated Hospital of Bengbu Medical College, Bengbu, China, [4]4th Military Tangdu Hospital Medical University, Xi'an, China, [5]Oncology, Harbin Medical University Cancer Hospital, Harbin, China, [6]Oncology, Linyi Cancer Hospital, Linyi, China, [7]The Affiliated Hospital of Qingdao University, Qingdao, China, [8]Oncology, 2nd Hospital of Anhui Medical University, Hefei, China, [9]Qilu Pharmaceutical Co.,Ltd, Jinan, China

Background: QL1101 is a biosimilar molecule of bevacizumab (BEV,Avastin®) which is a monoclonal antibody (mAb) that binds and inhibits vascular endothelial growth factor (VEGF). The main purpose of the study is to evaluate whether the effectiveness of QL1101 is equivalent to that of Avastin®; the secondary purpose is to estimate the safety and immunogenicity.

Methods: The study planed the recruitment of 512 patients with locally metastatic or recurrent non-squamous cell non-small cell lung cancer (NCT03169335). into QL1101 (test group) or Avastin® (control group) in combination with paclitaxel/carboplatin (paclitaxel 175mg/m^2, carboplatin AUC=5) at a 1:1 ratio. QL1101 and Avastin (15mg/kg respectively) combined with chemotherapy, were given every 3 weeks as one treatment cycle for 6 cycles, then followed by QL1101 single-drug maintenance treatment. The primary endpoint was the best objective response rate (ORR) at week 18 evaluated by the blind independent imaging review committee.

Results: A total of 675 subjects were screened and 532 were eventually treated, including 266 in the trial group and 266 in the control group. At week 18, the ORR of the QL1101 group and Avastin group, evaluated by the blind independent imaging review committee, were 52.26% (CR:0, PR:139) .and 56.02% (1 cases CR, 148 PR), respectively. Risk ratio (RR) value and 90%CI was 0.933(0.818-1.064), which met the prespecified equivalence margins (0.75-1.33).The median progression-free survival in the two groups was 7.72 and 8.25 months, respectively (HR: 1.111 (0.919—1.342)). The adverse reverse incidence of CTCAE $\geq$ 3 in the two groups were: 31.20 % in the experimental group and 24.06 % in the control group, respectively ($P = 0.0808$). The immunogenicity of the two groups was similar, and no neutralizing antibodies were detected.

Conclusions: QL1101 and Avastin are equivalent in clinical efficacy in non-squamous cell non-small cell lung cancer patients, and the safety profile (including immunogenicity) is similar. There are no unexpected serious adverse reactions found.

Clinical trial identification: NCT03169335; May 30, 2017.

Legal entity responsible for the study: Qilu Pharmaceutical Co., Ltd, Shandong, People's Republic of China.

Funding: Qilu Pharmaceutical Co., Ltd, Shandong, People's Republic of China.

Disclosure: All authors have declared no conflicts of interest.