LUNG CANCER—NON-SMALL CELL METASTATIC

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Bevacizumab biosimilar and reference bevacizumab in subjects with stage IIIB/IV non-squamous non-small cell lung cancer (STELLA): Design of a confirmatory, double-blind, randomized, controlled study.

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Background: MB02 is a bevacizumab biosimilar developed to stringent guidelines, including non-clinical and preclinical investigations and a clinical trial as first-line treatment in metastatic colorectal cancer (Romera A et al. Lancet Gastroenterol Hepatol 2018;3 (12): 845-855). A clinical trial (STELLA) has been initiated to confirm there are no clinically meaningful differences between MB02 and reference bevacizumab (Avastin) in terms of efficacy, safety, and immunogenicity (NCT03296163). **Methods:** STELLA study is a multinational, double-blind, randomized, parallel-group, equivalence study comparing the efficacy and safety of MB02 vs reference bevacizumab plus chemotherapy in subjects with stage IIIB/IV non-squamous non-small cell lung cancer (NSCLC). Subjects aged 18-80 years, with ECOG status ≤1 and histologically

confirmed NSCLC not receiving curative intent surgery or systemic therapy for advanced disease are randomized (1:1) to receive: chemotherapy (paclitaxel 200 mg/m^2 and carboplatin AUC6) and either MB02 or reference bevacizumab 15 mg/kg every 3 weeks for up to 6 cycles (unless disease progression or treatment intolerance). Randomization is stratified by sex, smoking status, disease diagnosis (newly/recurrent), and stage. After 6 cycles, subjects can continue to receive MB02/reference bevacizumab in monotherapy every 3 weeks (until disease progression, treatment intolerance, death, withdrawal or end of study). The primary objective is to compare the objective response rate (ORR) between arms by week 18 (independently assessed) measured by RECIST v1.1. Progression free survival and overall survival (at 18 and 52 weeks), safety and immunogenicity will be assessed as secondary objectives. A sample size of 600 subjects was assumed providing about 89% power to show equivalence of MB02 plus chemotherapy with reference bevacizumab plus chemotherapy on a primary endpoint of risk ratio based on ORR. To date, 596 subjects have been recruited from more than 15 countries worldwide (Europe, Asia, Latin-America, Africa and Middle-East). At their last meeting in September, 2018 the independent data safety monitoring board (DSMB) recommended that the study continue without change. Clinical trial information: NCT03296163.