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(71) Applicant: **ASTRAZENECA AB** [SE/SE]; SE-151 85, Södertälje (SE).

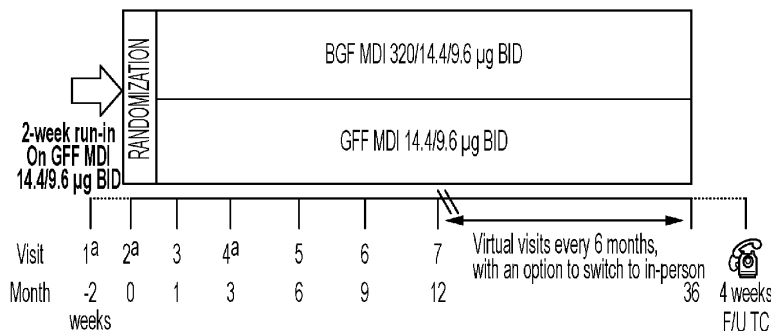
(71) Applicant (for EG only): **ASTRAZENECA PHARMACEUTICALS LP** [US/US]; 1800 Concord Pike, P.O. Box 15437, Wilmington, DE 19850-5437 (US).

(72) Inventors: **MUSHUNJE, Alec**; 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge CB2 0AA (GB). **PATEL, Mehul**; 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge CB2 0AA (GB). **BOWEN, Karin**; 1800 Concord Pike, P.O. Box 15437, Wilmington, DE 19803 (US).

(74) Agent: **WOODHOUSE, Scott, M.**; Medler Ferro Woodhouse & Mills, 8201 Greensboro Drive, Suite 1060, McLean, VA 22102 (US).

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(54) Title: TRIPLE COMBINATION THERAPY FOR COPD



a. Visit conducted in-person; all other visits may be conducted virtually or in-person.

NOTE: Each participant is expected to be followed for up to 3 years (with a minimum of 3 months) or until 632 participants have at least one primary severe cardiopulmonary event adjudicated by the CEC (see Section 4.1 for more details).

BGF = budesonide, glycopyrronium, and formoterol fumarate; BID = twice daily; F/U = follow-up

GFF = glycopyrronium and formoterol fumarate; MDI = metered dose inhaler; TC = telephone contact

FIG. 1

(57) Abstract: The present disclosure provides a method of treating chronic obstructive pulmonary disease (COPD) in a subject with a triple combination therapy. The method comprises administering to the subject twice daily a therapeutically effective dose of a composition comprising budesonide, glycopyrronium and formoterol fumarate, wherein the dose is administered to the subject via a metered dose inhaler, and the subject is at an elevated risk of a COPD exacerbation event and cardiovascular disease.

[Continued on next page]

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