

**ELIGIBILITY CHECKLIST 4**

**E4**

Patient ID:   1    
 Patient Initials:         
 Visit Number:   0     4    
 Visit Date:     /     /      
                   month      day      year  
 Interviewer ID:       

*(Clinic Coordinator completed)*

- |            |                                                                                                                                                                                                                                           |                                                      |                                                     |
|------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------|-----------------------------------------------------|
| <b>01</b>  | 1. Since the first study visit, has the patient experienced a significant asthma exacerbation as defined in the Manual of Operations?                                                                                                     | <input checked="" type="checkbox"/> <sub>1</sub> Yes | <input type="checkbox"/> <sub>0</sub> No            |
| <b>02</b>  | 2. Has the patient taken any non-study anti-asthma medications since the first study visit?                                                                                                                                               | <input checked="" type="checkbox"/> <sub>1</sub> Yes | <input type="checkbox"/> <sub>0</sub> No            |
| <b>03</b>  | 3. On average in the last 4 weeks of the run-in period, did the patient use the rescue inhaler less than 6 puffs per week?                                                                                                                | <input type="checkbox"/> <sub>1</sub> Yes            | <input type="checkbox"/> <sub>0</sub> No            |
| <b>03A</b> | If <b>Yes</b> , was the PC <sub>20</sub> for methacholine more than 8 mg/ml at Visit 1?                                                                                                                                                   | <input checked="" type="checkbox"/> <sub>1</sub> Yes | <input type="checkbox"/> <sub>0</sub> No            |
| <b>04</b>  | 4. On average in the last 4 weeks of the run-in period, did the patient use the rescue inhaler more than 56 puffs per week?                                                                                                               | <input checked="" type="checkbox"/> <sub>1</sub> Yes | <input type="checkbox"/> <sub>0</sub> No            |
| <b>05</b>  | 5. On average in the last 4 weeks of the run-in period, did the patient demonstrate the ability to adhere to the scheduled use of the metered dose inhaler at least 75% of the time ( <i>at least 42 puffs each week since visit 2</i> )? | <input type="checkbox"/> <sub>1</sub> Yes            | <input checked="" type="checkbox"/> <sub>0</sub> No |
| <b>06</b>  | 6. On average during the run-in period, has the patient recorded symptoms in the symptom diary at least 5 days per week?                                                                                                                  | <input type="checkbox"/> <sub>1</sub> Yes            | <input checked="" type="checkbox"/> <sub>0</sub> No |
| <b>07</b>  | 7. Is there any new information that makes the patient ineligible according to the eligibility criteria?<br>If <b>Yes</b> , describe _____                                                                                                | <input checked="" type="checkbox"/> <sub>1</sub> Yes | <input type="checkbox"/> <sub>0</sub> No            |

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Visit Number: 0 4

08 8. Does the patient wish to withdraw consent from the study?  1 Yes  0 No

09 9. Is there any other reason for which this patient should not be included in the study?  1 Yes  0 No

10 10. Is the patient eligible? *If any of the shaded boxes are filled in, the patient is NOT eligible.*  1 Yes  0 No  
☞ If **No**, please complete the Termination of Study Participation form (TERM).

***If the patient is eligible and will participate in the study, run the randomization program. If an electronic connection is impossible, call the DCC at (717) 531 - 4262.***

11 11. Study drug packet number. \_\_\_\_\_