## Appendix A. Key inclusion/exclusion criteria for the asthma and COPD studies.

| Key inclusion criteria | Asthma study | COPD study |
|------------------------|-------------|------------|
| Aged ≥18 y             |             |             |
| Established diagnosis of asthma (NIH 2007 criteria)\(^a\) |             | Established diagnosis of COPD (ATS/ERS 2004 guidelines)\(^b\) |
| Demonstrated historical reversibility of ≥12% and ≥200 mL reversibility of FEV\(_1\) within 10–40 min following 2–4 inhalations of salbutamol/albuterol inhalation aerosol (or equivalent nebulized treatment with salbutamol/albuterol solution) within 24 months of Visit 1 |             | Post-bronchodilator FEV\(_1\) of ≤70% of predicted and FEV\(_1\)/FVC ratio of <0.70 |
| Receiving maintenance inhaler therapy for asthma |             | Receiving maintenance therapy for COPD |
| No prior or ongoing use of the ELLIPTA dry powder inhaler |             | No use of the ELLIPTA dry powder inhaler within previous 6 months |
| Capable of continuing with current prescribed asthma maintenance inhaler therapy and SABA for rescue use as needed throughout the study |             | Capable of continuing with current prescribed COPD maintenance therapy and SABA for rescue use as needed throughout the study |

| Key exclusion criteria | Asthma study | COPD study |
|------------------------|-------------|------------|
| Current diagnosis of COPD |             |             |
| Current diagnosis of asthma |             |             |
Any change/planned change of asthma treatment within 4 weeks prior to screening/Visit 1
Any asthma exacerbation within 4 weeks, or any hospitalization or emergency department visit due to asthma within 3 months of screening/Visit 1

Other respiratory disorders

Use of an investigational drug and/or medical device/inhaler within 30 days of screening/Visit 1, or within five drug half-lives of the investigational drug, whichever was longer

History of life-threatening asthma, defined as an asthma episode that required intubation and/or was associated with hypercapnia, respiratory arrest, or hypoxic seizures
Daily asthma treatment with inhaled SABA only (as needed or regularly scheduled)
Poorly controlled or unstable asthma, which, in the investigator’s judgment, would affect the subject’s ability to

Any change of COPD treatment within 4 weeks of screening/Visit 1
Any COPD exacerbation requiring systemic corticosteroids and/or antibiotics within 4 weeks, or hospitalization for COPD within 3 months of screening/Visit 1

Other respiratory disorders or other clinically significant disease abnormalities
Lung volume reduction surgery within 12 months of screening/Visit 1

Long-term use of oxygen therapy
evaluate ease of use and correct use

ATS: American Thoracic Society; ERS: European Respiratory Society; NIH: National Institutes of Health; SABA: short-acting β2 agonist.

aAsthma diagnosed according to the 2007 guidelines of the NIH1; bCOPD diagnosed according to 2004 guidelines of ATS/ERS.2
Appendix B. Instructions for use.

| Step 1. Open the cover of the inhaler. See Figure A. |
|-----------------------------------------------------|
| • Slide the cover down to expose the mouthpiece. You should hear a “click.” The counter will count down by 1 number. You do not need to shake this kind of inhaler. **Your inhaler is now ready to use.** |
| • If the counter does not count down as you hear the click, the inhaler will not deliver the dose. Call your healthcare provider or pharmacist if this happens. |

| Figure A |
|----------|
| ![Figure A](image1.png) |

| Step 2. Breathe out. See Figure B. |
|-----------------------------------|
| • While holding the inhaler away from your mouth, breathe out (exhale) fully. Do not breathe out into the mouthpiece. |

| Figure B |
|----------|
| ![Figure B](image2.png) |
### Step 3. Inhale your medicine. See Figure C.

- Put the mouthpiece between your lips, and close your lips firmly around it. Your lips should fit over the curved shape of the mouthpiece.

- Take one long, steady, deep breath in through your mouth. **Do not** breathe in through your nose.

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**Figure C**

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**Do not block the air vent with your fingers.**

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### Figure D

- Do not block the air vent with your fingers. **See Figure D**

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**Figure E**

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### Figure E

- Remove the inhaler from your mouth and hold your breath for **about 3 to 4 seconds** (or as long as comfortable for you). **See Figure E.**
Step 4. Breathe out slowly and gently. See Figure F.

- You may not taste or feel the dose, even when you are using the inhaler correctly.
- **Do not** take another dose from the inhaler even if you do not feel or taste the dose.

Step 5. Close the inhaler. See Figure G.

- You can clean the mouthpiece if needed, using a dry tissue, before you close the cover. Routine cleaning is not required.
- Slide the cover up and over the mouthpiece as far as it will go.
Supplementary Table 1. ELLIPTA correct use checklist.

| Steps identified in the ELLIPTA package insert.\(^3,4\) | Patient actions to be checked by the trained HCP at: Visit 1 (up to 3 attempts); Visit 2 (1 attempt). | Check YES OR NO to respond to each action/step. |
|---|---|---|
| **Step 1. Open the cover of the inhaler. See Figure A.\(^a\)** | Patient slides the cover completely down to expose the mouthpiece until a “click” is heard. | Yes \[\square\] No \[\square\] |
| Slide the cover down to expose the mouthpiece. You should hear a “click.” The counter will count down by 1 number. | Patient does not shake the inhaler. (Note: a “Yes” response indicates that the patient did not shake the inhaler after the click is heard) | Yes \[\square\] No \[\square\] |
| You do not need to shake this kind of inhaler. **Your inhaler is now ready to use.** | Patient breathes out (exhales) while holding the inhaler away from their mouth. | Yes \[\square\] No \[\square\] |
| If the counter does not count down as you hear the click, the inhaler will not deliver the dose. Call your healthcare provider or pharmacist if this happens. | Patient does not breathe into the mouthpiece. (Note: a “Yes” response indicates that the patient did not breathe into the mouthpiece) | Yes \[\square\] No \[\square\] |
| **Step 2. Breathe out. See Figure B.\(^a\)** | | |
| While holding the inhaler away from your mouth, breathe out (exhale) fully. | | |
| Do not breathe out into the mouthpiece. | | |
Steps identified in the ELLIPTA package insert.\textsuperscript{3,4}  

| Patient actions to be checked by the trained HCP at: Visit 1 (up to 3 attempts); Visit 2 (1 attempt). Check YES OR NO to respond to each action/step. |
|---|
| **Step 3. Inhale your medicine. See Figure C.\textsuperscript{a}**  
Put the mouthpiece between your lips, and close your lips firmly around it. Your lips should fit over the curved shape of the mouthpiece.  
Take one long, steady, deep breath in through your mouth. **Do not** breathe in through your nose.  
Do not block the air vent with your fingers. **See Figure D.\textsuperscript{a}**  
Remove the inhaler from your mouth and hold your breath for about 3 to 4 seconds (or as long as comfortable for you). **See Figure E.\textsuperscript{a}**  
| Patient places mouthpiece between lips, and closes lips firmly around it.  
Patient takes one long steady deep breath in through their mouth.  
Patient **does not** block air vent with fingers. (Note: a “Yes” response indicates that the patient **did not** block the air vent with their fingers)  
Patient removes inhaler from his/her mouth and holds his/her breath. |

| **Step 4. Breathe out slowly and gently. See Figure F.\textsuperscript{a}**  
You may not taste or feel the dose, even when you are using the inhaler correctly.  
**Do not** take another dose from the inhaler even if you do not feel or taste the dose.  
| Patient breathes out slowly and gently. |

| **Step 5. Close the inhaler. See Figure G.\textsuperscript{a}**  
You can clean the mouthpiece if needed, using a dry tissue, before you close the cover. Routine cleaning is not required.  
Slide the cover up and over the mouthpiece as far as it will go.  
| Patient closes the inhaler completely. |

\textsuperscript{a}For figures please refer to the Instructions for Use (Appendix B)
Appendix C. ELLIPTA inhaler ease-of-use questionnaire.

INSTRUCTIONS: The administrator (investigator or designee) will complete the following questions related to the ELLIPTA inhaler used during this study. Check only one response for the question asked.

ELLIPITA inhaler questionnaire (Version A)

Instructions: Please complete the following questions related to the ELLIPTA inhaler that you used during this study. Choose only one response for each question.

1. How easy or difficult is it to use the ELLIPTA inhaler?
   □ Very easy
   □ Easy
   □ Difficult
   □ Very difficult

2. How easy or difficult is it to tell how many doses are left in the ELLIPTA inhaler?
   □ Very easy
   □ Easy
   □ Difficult
   □ Very difficult

3. If your current daily inhaled asthma/COPD medication* was available in the ELLIPTA inhaler, how likely or unlikely would you be to request the medication in the ELLIPTA inhaler from your doctor?
   □ Very likely
   □ Likely
   □ Unlikely
   □ Very unlikely

*As relevant; asthma medication for subjects in the asthma study and COPD medication for subjects in the COPD study
ELLIPTA inhaler questionnaire (VERSION B)

Instructions: Please complete the following questions related to the ELLIPTA inhaler that you used during this study. Choose only one response for each question.

1. How easy or difficult is it to use the ELLIPTA inhaler?
   □ Very Difficult
   □ Difficult
   □ Easy
   □ Very Easy

2. How easy or difficult is it to tell how many doses are left in the ELLIPTA inhaler?
   □ Very Difficult
   □ Difficult
   □ Easy
   □ Very Easy

3. If your current daily inhaled asthma/COPD medication was available in the ELLIPTA inhaler, how likely or unlikely would you be to request the medication in the ELLIPTA inhaler from your doctor?
   □ Very Unlikely
   □ Unlikely
   □ Likely
   □ Very Likely

*aAs relevant; asthma medication for subjects in the asthma study and COPD medication for subjects in the COPD study*
Supplementary references

1. National Asthma Education and Prevention Program. Expert Panel Report 3 (EPR-3): Guidelines for the diagnosis and management of asthma – Summary Report 2007. *J Allergy Clin Immunol* 2007; 120(5 Suppl): S94–138.

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3. GlaxoSmithKline. ARNUITY ELLIPTA (fluticasone furoate inhalation powder), for oral inhalation use. Highlights of prescribing information. Revised May 2018. Available at:
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