PATIENT COPY

INCLUSION CRITERIA

Yes	No	*In order to participate in this study all participants must:*
☐	☐	1. Be able to read, understand, sign, and date the ICF.
☐	☐	2. Be between 18 to 75 years of age, inclusive, with moderate-to-severe asthma, treated with daily controller therapy therapy.
☐	☐	3. Have a body weight and BMI that would not prevent safety and efficacy evaluation.
☐	☐	5. Have a physician diagnosis of moderate-to-severe asthma for at least 12 months prior to Screening.
☐	☐	6. Have a stable regimen of medium-to-high dose Inhaled Corticosteroids in combination with Long Acting Bronchodilators at least 2 months prior to Baseline per the Investigator's discretion, which includes the following: a) any medium or high dose Inhaled Corticoseroid therapy (≥250 µg of fluticasone propionate twice a day or to a maximum of 1000 µg/day of fluticasone propionate or clinically comparable dose) in combination with a Long Acting Bronchodilator as second controller fixed dose combination.
☐	☐	7. Short acting bronchodilators such as Albuterol, should not be used within 4 to 6 hours, and Long Acting Bronchodilators should not be used for 24 hours prior to the test
☐	☐	8. Have experienced, within 1 year prior to Screening, any of the following asthma exacerbation events at least once: treatment with a systemic steroid, such as Prednisone or SoluMedrol (oral or parenteral) for worsening asthma OR hospitalization or emergency medical care visit for worsening asthma.
☐	☐	9. Agree to use acceptable, effective barrier contraception from Screening until 90 days after the last dose of study drug
☐	☐	10. Participants not of childbearing potential due to surgical sterilization (hysterectomy, bilateral oophorectomy or tubal ligation), congenital anomaly such as Mullerian agenesis, or postmenopausal defined as: a) At least 50 years of age with an intact uterus, not on hormone therapy, who has had no period for at least 1 year b) Aged 55 years or older not on hormone therapy, who has had at least 6 months of without a period c) At least 55 years of age with a diagnosis of menopause prior to starting hormone replacement therapy Note: Same sex couples not at risk for pregnancy are not required to use contraception.

EXCLUSION CRITERIA

Yes	No	*Participants are excluded if they:*
☐	☐	1. Have any uncontrolled current or recurrent concomitant illness, such as uncontrolled cardiovascular, neurological, renal, liver, gastrointestinal (gastrointestinal reflux disease), malignancy, autoimmune disease, human immunodeficiency virus [HIV], or other condition such as, obstructive sleep apnea, including psychiatric illnesses, such as, uncontrolled anxiety or depression that could affect the action, absorption, or disposition of the study drug, or could affect clinical or laboratory assessments, including any significant concomitant disorder, active bacterial, fungal, or viral infection, incompatible with participation in the study.
☐	☐	2. Are unable to swallow oral medication or more than 1 oral tablet at 1 dosing administration.
☐	☐	3. Had a malignancy within the last 5 years, with the exception of successfully treated basal cell carcinoma. (skin cancer)
☐	☐	4. Had major surgery or planned inpatient surgery within 8 weeks prior to Screening, or a planned major dental procedure or hospitalization during the Screening, Treatment, or Safety Follow-up Periods.
☐	☐	5. Had a moderate or severe asthma exacerbation at any time within 4 weeks prior to Screening or a severe asthma exacerbation within 8 weeks prior to Screening. exacerbations and usually does not require hospitalization (Section 8.6.14.6).
☐	☐	6. Have a history of life-threatening asthma defined as: significant asthma episode(s) involving intubation (tube down you throat), respiratory arrest, hypoxic seizures, or asthma-related syncopal episode(s)
☐	☐	7. Have pulmonary disease other than asthma including active lung infection, chronic obstructive pulmonary disease, bronchiectasis, pulmonary fibrosis, cystic fibrosis, hypoventilation syndrome associated with obesity, lung cancer, history of or planned lung lobectomy, alpha-1 anti-trypsin deficiency, primary ciliary dyskinesia, Churg-Strauss syndrome, allergic bronchopulmonary aspergillosis, or hyper-eosinophilic syndrome or other eosinophilic conditions, (eg, eosinophilic granulomatosis with polyangiitis)
☐	☐	8. Had bronchial thermoplasty within 2 years prior to Screening.
☐	☐	9. Are unable to use long acting bronchodilators and/or inhaled corticosteroids during the study as indicated in the protocol.
☐	☐	10. Are expected to require use of inhalers other than Inhaled CorticoSteroids, Long Acting Bronchodilators, and Short acting bronchodilators during the study period
☐	☐	11. Have a positive urine drug screen for drugs of abuse at Screening. Note: participant's use of cannabis (weed and gummies) products and alcohol will be assessed and eligibility determined by the Investigator
☐	☐	12. Have a positive screen for hepatitis B surface antigen (HBsAg), anti-hepatitis C virus (HCV) antibodies, or anti- HIV-1 and HIV-2 antibodies.

☐	☐	13. Have any clinically significant ECG abnormality at Screening, as determined by the Investigator.
☐	☐	14. Have a history of uncontrolled hypertension as deemed by the Investigator, a systolic blood pressure ≥160 mmHg, or diastolic blood pressure >95 mmHg during the Screening Period, measured in the reclining position after at least 5 minutes of rest
☐	☐	15. Had treatment with marketed or experimental biologics including Fasenra, mepolizumab, Cinqair, Xolair, Dupixent, and Tezspire within 6 months or 5 half-lives of Baseline.
☐	☐	16. Have received an investigational agent within the last 28 days or 5 half-lives, whichever is longer, prior to Baseline.
☐	☐	17. Have received a live or live-attenuated vaccine within 28 days prior to Baseline or plans to receive a live or live-attenuated vaccine during the study and up to 28 days after the last study drug administration.
☐	☐	18. Use immunosuppressive medication (eg, methotrexate, troleandomycin, oral gold, cyclosporine, azathioprine, intra-articular corticosteroids, intramuscular long-acting depot corticosteroid, systemic [oral] corticosteroids) within 3 months prior to Baseline or more than 3 courses of systemics corticosteroids within the 6 months prior to Baseline
☐	☐	19. Are using any medication (prescription or over-the-counter) that may interfere with study drug safety evaluations, per the Investigators discretion, within 14 days prior to Baseline.
☐	☐	20. More than 3 courses of systemic corticosteroids within the 6 months prior to Baseline
☐	☐	21. Methylxanthines (theophylline, aminophyllines) chromalyn, nedocramil, ipratropium bromide or other inhaled anti-cholinergic agents (tiotropium), inhaled antibiotics (eg, aztreonam lysine, tobramycin, azithromycin), cromones, mucolytics (acetylcysteine, bromhexin, guaifensin) within 14 days prior to Baseline
☐	☐	22. Long-acting muscarinic antagonists, leukotriene receptor antagonists (montelukast, zafirlukast), leukotriene synthesis inhibitors (zileuton) within 28 days prior to Baseline
☐	☐	23. Have sleep-wake inversion, like, night shift workers that interferes with timing of study procedures
☐	☐	24. Are a current smoker, including the use of tobacco or nicotine products and e-cigarettes,active vaping of any products containing nicotine, or former smoker with cessation within 6 months of Screening, or history of >10 pack-years. Smoking is prohibited from the time of Screening until the last Follow-up Visit.
☐	☐	25. Are unwilling to refrain from or limit alcohol use during any part of the study at the discretion of the Investigator.
☐	☐	26. Are pregnant or breast-feeding or are planning to become pregnant during the duration of the study and for 90 days after the last dose of study drug.
☐	☐	27. Plan to donate sperm within 90 days (male participants) or donate or preserve ova within 120 days after the last dose of study drug (female participants)
☐	☐	28. Have a history of, or is currently suffering from, severe allergic or anaphylactic reactions or sensitivity or allergy to any components in the investigational product.

☐	☐	29. Have donated plasma within 7 days of Screening or >499 mL of blood within 56 days of Screening.