A comparison of once-daily triple therapy with once-daily dual therapy in the treatment of symptomatic COPD

The IMPACT trial
Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol 92/55/22 mcg) is indicated as maintenance treatment in adult patients with moderate to severe chronic obstructive pulmonary disease (COPD) who are not adequately treated by a combination of an inhaled corticosteroid (ICS) and a long-acting $\beta_2$-agonist (LABA) or a combination of a long-acting $\beta_2$-agonist (LABA) and a long-acting muscarinic antagonist (LAMA).

Relvar Ellipta (fluticasone furoate/vilanterol 92/22 mcg) is indicated for the symptomatic treatment of adults with COPD with a forced expiratory volume in one second (FEV$_1$) <70% predicted normal (post-bronchodilator) with an exacerbation history despite regular bronchodilator therapy.

Anoro Ellipta (umeclidinium/vilanterol 55/22 mcg) is indicated as a maintenance bronchodilator treatment to relieve symptoms in adult patients with COPD.

“Inhaled pharmacotherapy for COPD has changed considerably since the last update of the NICE COPD guidelines (2010). As a result of this time lapse, most regional areas have developed their own local COPD guidelines and prescribing practices. During this time, we have seen an increasing trend to base these local guidelines on the international GOLD COPD treatment algorithms, which are updated annually. GOLD and NICE COPD guidelines have both recently been updated, with GOLD released early November and NICE due for release imminently (at the time of writing).

There has been a considerable change to the landscape of inhaled therapy over the past five years, with the advent of LABA/LAMA combination therapy, as well as increasing recognition of the risks of ICS—and potential biomarkers such as blood eosinophil count—that may help direct ICS treatment. This raises the question of who may benefit from triple inhaled therapy (ICS/LABA/LAMA) above dual combination therapy, and when. Decisions to alter treatment are now recommended to be based on symptoms (e.g. breathlessness) or exacerbation prevention, rather than severity of airflow obstruction.

Evidence from the IMPACT trial can be appreciated alongside the new NICE and GOLD algorithms and will help decision making. The primary outcome of IMPACT was exacerbation reduction, rather than changes in FEV$_1$, which helps direct application of its findings to real-world decision making. While NICE did not review the role of triple inhaled therapy, it is recommended as step-up therapy from combination therapy. The IMPACT trial will help inform which patients may, or may not, have increased benefit on triple inhaled therapy.

NICE supports the use of LABA/LAMA therapy in those with symptoms or exacerbations without features of asthma/steroid responsiveness (secure diagnosis of asthma, or atopy, high blood eosinophil count, or lung function variability) and suggests ICS/LABA therapy in those with features of asthma/steroid responsiveness. IMPACT included pre-defined analysis based on blood eosinophil and showed greater reduction in exacerbations in those with blood eosinophilia, supporting NICE recommendations. However, improvements were seen in the non-eosinophilic group, suggesting that triple inhaled therapy may still have a role in non-eosinophilic disease, although less pronounced.

Overall, the IMPACT trial will aid UK implementation of both national and international guidelines, particularly on for whom triple inhaled therapy may be best prescribed.”

Dr Neil Greening
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FEV$_1$=forced expiratory volume in 1 second; ICS=inhaled corticosteroid; LABA=long-acting $\beta_2$-agonist; LAMA=long-acting muscarinic antagonist
A comparison of once-daily triple therapy with once-daily dual therapy in the treatment of symptomatic COPD—the IMPACT trial

IMPACT provides clinically important outcomes to inform treatment decisions when a symptomatic, exacerbating population of COPD patients is managed with GOLD recommended treatment options

Approximately 3 million people in the UK have chronic obstructive pulmonary disease (COPD), with only one-third having a formal diagnosis. The mortality rate is high, with around 30,000 people dying each year in the UK as a result of COPD. One out of eight hospital admissions is due to an exacerbation of COPD, resulting in ill health and a poor quality of life for patients, as well as a large cost to the NHS. The economic burden associated with COPD rises as the frequency of exacerbations and the level of dyspnoea increases. The best predictor of future exacerbations, regardless of disease severity, is a history of exacerbations.

One of the management aims of COPD (as per GOLD 2019) is reducing the severity and frequency of exacerbations, which is key to improving patient quality of life and to reducing mortality, as well as minimising associated healthcare costs.

Classification of COPD

Chronic obstructive pulmonary disease is classified according to the severity of airway limitation, as measured using the forced expiratory volume in 1 second (FEV₁) after a bronchodilator is given:

- mild (stage 1): FEV₁ ≥80% of the predicted value
- moderate (stage 2): FEV₁ = 50–79% of the predicted value
- severe (stage 3): FEV₁ = 30–49% of the predicted value
- very severe (stage 4): FEV₁ < 30% of the predicted value.

Guidance from GOLD classifies COPD into four groups (A, B, C, and D) based on assessment of the patient’s symptoms or dyspnoea, and their history of moderate and severe exacerbations.

Treatment options

Pharmacological treatment can reduce symptoms and the risk of future exacerbations. The GOLD strategy recommends that treatment is individualised to the patient and guided by the severity of symptoms, risk of exacerbations, side-effects, co-morbidities, drug availability, and cost, while taking into account the patient’s response to treatment, preference, and ability to use different drug delivery systems.

Recently updated, GOLD 2019 suggests that highly symptomatic patients who are at risk of exacerbations (GOLD Group D) can start on a long-acting muscarinic antagonist (LAMA), a LAMA and long-acting beta₂-agonist (LABA), or an inhaled corticosteroid (ICS) and LABA, depending on their symptom burden or eosinophil score. Blood eosinophil levels are increasingly understood to be a biomarker for ICS sensitivity and effectiveness in reducing exacerbation rates. Treatment can then be escalated depending on whether the patient is predominantly dyspnoeic or exacerbating.

Both the exacerbating and dyspnoeic patient can be eligible for triple therapy (LAMA/LABA/ICS) if they continue to exacerbate despite dual therapy.

While GOLD gives suggestions for treatment strategies for patients in GOLD Groups C and D (see Figure 1, p.4), more evidence is needed to fully support these recommendations.

IMPACT trial

The InforMing the PAthway of COPD Treatment (IMPACT) trial published in April 2018 compared the use of a once-daily single-inhaler triple therapy with a once-daily single-inhaler dual therapy in patients with symptomatic COPD and a history of exacerbations in the previous year.

IMPACT was a randomised 52-week trial involving 10,355 patients across three treatment groups:

- a once-daily triple therapy containing an ICS (fluticasone furoate), a LAMA (umeclidinium) and a LABA (vilanterol) (F/U/V; n=4151) or
- a once-daily dual therapy containing an ICS and a LABA (FF/V; n=4134) or
- a once-daily dual therapy containing a LAMA and a LABA (U/V; n=2070).

The primary aim of the trial was to compare the rate of moderate/
Follow-up pharmacological treatment

1. IF RESPONSE TO INITIAL TREATMENT IS APPROPRIATE, MAINTAIN IT.
2. IF NOT:
   - Use exacerbation pathway if both exacerbations and dyspnoea need to be targeted
   - Place patient in box corresponding to current treatment and follow indications
   - Assess response, adjust and review
   - These recommendations do not depend on the ABCD assessment at diagnosis

* Consider if eos ≥300 or eos ≥100 AND ≥2 moderate exacerbations/1 hospitalisation
** Consider de-escalation of ICS or switch if pneumonia, inappropriate original indication or lack of response to ICS

eos=blood eosinophil count in cells per microliter; mMRC=modified Medical Research Council dyspnoea questionnaire; CAT=COPD Assessment Test™
severe exacerbations over the course of the trial in patients receiving triple therapy (FF/U/V) with those receiving FF/V and with those receiving U/V.\textsuperscript{11}

For consistency of administration, all therapies were given in the same type of inhaler, with each drug given in the same dose.\textsuperscript{11}

**Trial participants**

Participants were aged ≥40 years and had GOLD Group D COPD, with a COPD Assessment Test (CAT) score ≥10 and either an FeV\textsubscript{1} <50% predicted value and at least one moderate or severe exacerbation in the previous year or an FeV\textsubscript{1} of 50–80% of predicted value and at least two moderate exacerbations or one severe exacerbation in the previous year.\textsuperscript{11}

Patients in the three treatment groups had similar demographic characteristics, lung function, numbers of COPD exacerbations, and CAT scores at baseline. The mean age of participants was 65.3 years and two-thirds were men. Baseline blood eosinophil level was recorded and 43% of patients had a level <150 cells/microlitre.\textsuperscript{11}

Before the trial began, 38% of patients were taking ICS/LABA/LAMA, 29% were using an ICS and a LABA, and 8% were using a LAMA and a LABA. Patients continued on their own therapy for 2 weeks before being randomised to one of the three treatment groups.\textsuperscript{11}

A total of 9087 patients completed the trial (88%) and 77% of patients (n=7991) completed the trial taking the therapy assigned to them. A smaller percentage of patients in the FF/U/V group (18%, n=1040) discontinued treatment prematurely compared with patients in either the FF/V group (25%, n=1040) or in the U/V group (27%, n=566).\textsuperscript{11}

**Primary endpoint: moderate/severe exacerbations**

The primary outcome measure of moderate/severe exacerbation rate was found to be significantly lower among patients who were receiving FF/U/V at 0.91 per year, compared with 1.07 per year among those in the FF/V group (rate ratio with FF/U/V, 0.85; 95% confidence interval [CI], 0.80 to 0.90; 15% difference; p<0.001), and 1.21 per year among those in the U/V group (rate ratio with triple therapy, 0.75; 95% CI, 0.70 to 0.81; 25% difference; p<0.001) (see Figure 2, above).\textsuperscript{11}

**Secondary endpoints**

**Exacerbations resulting in hospitalisation**

The annual rate of severe exacerbations that resulted in hospitalisation was found to be significantly lower among patients in the FF/U/V group at 0.13 per year, compared with those in the U/V group at a rate of 0.19 per year (rate ratio with FF/U/V, 0.66; 95% CI, 0.56 to 0.78; 34% difference; p<0.001).

However, the rate was not significantly lower with FF/U/V compared with FF/V, which showed a rate of 0.15 per year (rate ratio with FF/U/V, 0.87; 95% CI, 0.76 to 1.01; 13% difference; p=0.06).\textsuperscript{11}

**Time to exacerbation**

Time-to-first-event analysis showed a lower risk of having moderate/severe exacerbations for people taking FF/U/V compared with those on FF/V (hazard ratio, 0.85; 95% CI, 0.80 to 0.91; 15% difference; p<0.001), and with those on U/V (hazard ratio, 0.84; 95% CI, 0.78 to 0.91; 16% difference; p<0.001).\textsuperscript{11}

**Blood eosinophil level**

Patients in the triple therapy group had a lower annual rate of moderate/severe exacerbations than those in either dual therapy group, regardless of their blood eosinophil level. However, a greater
reduction was observed in the annual rate of moderate/severe exacerbations in patients with a blood eosinophil level ≥150 cells/ microlitre.11

**Lung function**
A significant improvement was found in the difference in mean change from baseline in trough FEV1 between FF/U/V and FF/V at 97 ml (95% CI, 85 to 109; p<0.001) and between FF/U/V and U/V at 54 ml (95% CI, 39 to 69; p<0.001).11

**Health-related quality of life (HRQoL)**
HRQoL was measured using a COPD-specific version of the St George’s Respiratory Questionnaire (SGRQ). Significant differences were found between those in the FF/U/V group and those in the FF/V and U/V groups in both the mean change from baseline in the SGRQ total score and in the percentage of patients with ≥4 point decrease in SGRQ total score (p<0.001).11

**Pneumonia**
As might be expected, patients in the U/V group had a lower incidence of pneumonia than patients in both the FF/U/V group and the FF/V group11 because ICS use has been shown to increase the risk of pneumonia in patients with COPD.9

The risk of pneumonia in the FF/U/V group was significantly higher than in the U/V group (hazard ratio, 1.53; 95% CI, 1.22 to 1.92; p<0.001).11

**Conclusion**
The results of the IMPACT trial show that a once-daily combination of fluticasone furoate, umeclidinium, and vilanterol resulted in a lower rate of;11

› moderate or severe COPD exacerbations and better lung function and health-related quality of life than dual therapy with fluticasone furoate/vilanterol or umeclidinium/vilanterol
› hospitalisation due to COPD than umeclidinium/vilanterol.

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**References**


Relvar Ellipta Prescribing information

Please consult the full Summary of Product Characteristics (SmPC) before prescribing. Relvar Ellipta (fluticasone furoate/vilanterol [as trifenate]) inhalation powder. Each single inhalation of fluticasone furoate (FF) 100 micrograms (mcg) and vilanterol (VI) 25 mcg provides a delivered dose of 92 mcg FF and 22 mcg VI. Each single inhalation of FF 200 mcg and VI 25 mcg provides a delivered dose of 184 mcg of FF and 22 mcg of VI. Indications: Asthma: Regular treatment of asthma in patients ≥12 years where a long-acting β₂-agonist (LABA) and inhaled corticosteroid (ICS) combination is appropriate; i.e. patients not adequately controlled on ICS and “as needed” short-acting inhaled β₂-agonists or patients already adequately controlled on both ICS and LABA. COPD: Symptomatic treatment of adults with COPD with a FEV₁<70% predicted normal (post-bronchodilator) and an exacerbation history despite regular bronchodilator therapy.

Dosage and administration: Inhalation only. Asthma: Adults and adolescents ≥12 years: one inhalation once daily of Relvar 92/22 mcg for patients who require a low to mid dose of ICS in combination with a LABA. If patients are inadequately controlled then the dose can be increased to one inhalation once daily Relvar 184/22 mcg. Relvar 184/22 mcg can also be considered for patients who require a higher dose of ICS in combination with a LABA. Regularly review patients and reduce dose to lowest that maintains effective symptom control. COPD: one inhalation once daily of Relvar 92/22 mcg. Relvar 184/22 mcg is not indicated for patients with COPD. Contraindications: Hypersensitivity to the active substances or to any of the excipients (lactose monohydrate & magnesium stearate). Precautions: Pulmonary tuberculosis, severe cardiovascular disorders or heart rhythm abnormalities, thyrotoxicosis, uncorrected hypokalaemia, patients predisposed to low levels of serum potassium, chronic or untreated infections, diabetes mellitus, paradoxical bronchospasm. In patients with moderate to severe hepatic impairment 92/22 mcg dose should be used. Acute symptoms: Not for acute symptoms, use short-acting inhaled bronchodilator. Warn patients to seek medical advice if short-acting inhaled bronchodilator use increases. Therapy should not be abruptly stopped without physician supervision due to risk of symptom recurrence. Asthma-related adverse events and exacerbations may occur during treatment. Patients should continue treatment but seek medical advice if asthma symptoms remain uncontrolled or worsen after initiation of Relvar. Systemic effects: Systemic effects of ICSs may occur, particularly at high doses for long periods, but much less likely than with oral corticosteroids. Possible Systemic effects include: Cushing’s syndrome, Cushingoid features, adrenal suppression, decrease in bone mineral density, growth retardation in children and adolescents. Eye symptoms such as blurred vision may be due to underlying serious conditions such as cataract, glaucoma or central serous chorioretinopathy (CSCR); consider referral to ophthalmologist. More rarely, a range of psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children). Increased incidence of pneumonia has been observed in patients with COPD receiving inhaled corticosteroids. Risk factors for pneumonia include: current smokers, old age, patients with a history of prior pneumonia, patients with a body mass index <25 kg/m² and patients with a FEV₁<50% predicted. If pneumonia occurs with Relvar treatment should be re-evaluated. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take Relvar. Interactions with other medicinal products: Interaction studies have only been performed in adults. Avoid β-blockers. Caution is advised when co-administering with strong CYP3A4 inhibitors (e.g. ketoconazole, ritonavir, cobicistat-containing products). Concomitant administration of other sympathomimetic medicinal products may potentiate the adverse reactions of FF/VI. Relvar should not be used in conjunction with other long-acting β₂-adrenergic agonists or medicinal products containing long-acting β₂-adrenergic agonists. Pregnancy and breast-feeding: Experience limited. Balance risks against benefits. Side effects: Very Common (≥1/10): headache, nasopharyngitis. Common (≥1/100 to <1/10): candidiasis of the mouth and throat, dysphonia, pneumonia, bronchitis, upper respiratory tract infection, influenza, oropharyngeal pain, sinusitis, pharyngitis, rhinitis, cough, abdominal pain, arthralgia, back pain, fractures, pyrexia, muscle spasms. Other important side effects include: Uncommon (≥1/1,000 to <1/100): blurred vision, hyperglycaemia. Rare (<1/10,000 to <1/1,000) paradoxical bronchospasm and hypersensitivity reactions including anaphylaxis, angioedema, rash, urticaria. See SmPC for other adverse reactions. Legal category: POM. Presentation and Basic NHS cost: Relvar Ellipta. 1 inhaler x 30 doses. Relvar Ellipta 92/22 - £22.00. Relvar Ellipta 184/22 - £29.50. Marketing authorisation (MA) nos. 92/22 mcg 1x30 doses [EU/1/13/886/002]; 184/22 mcg 1x30 doses [EU/1/13/886/005]. MA holder: Glaxo Group Ltd, 980 Great West Road, Brentford, Middlesex TW8 9GS, UK. Last date of revision: September 2018. UK/FFT/0227/15(6). Trademarks are owned by or licensed to the GSK group of companies. © 2018 GSK group of companies or its licensor. Relvar Ellipta was developed in collaboration with Innoviva Inc.
Dosage and administration:

One inhalation once daily.

Contraindications:

Hypersensitivity to the active substances or to any of the excipients (lactose monohydrate & magnesium stearate).

Precautions:

Paradoxical bronchospasm, unstable or life-threatening cardiovascular disease or heart rhythm abnormalities, convulsive disorders or thyrotoxicosis, pulmonary tuberculosis or patients with chronic or untreated infections, narrow-angle glaucoma, urinary retention, hypokalaemia, patients predisposed to low levels of serum potassium, diabetes mellitus. In patients with moderate to severe hepatic impairment patients should be monitored for systemic corticosteroid-related adverse reactions. Eye symptoms such as blurred vision may be due to underlying serious conditions such as cataract, glaucoma or central serous chorioretinopathy (CSCR); consider referral to an ophthalmologist. Increased incidence of pneumonia has been observed in patients with COPD receiving inhaled corticosteroids.

Risk factors for pneumonia include: current smokers, older age, patients with a low body mass index and severe COPD. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take Anoro.

Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol [as trifenatate]) Prescribing information

Please consult the full Summary of Product Characteristics (SmPC) before prescribing. Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol [as trifenatate]) inhalation powder. Each single inhalation provides a delivered dose (the dose leaving the mouthpiece) of 55 micrograms of fluticasone furoate (FF), 62.5 micrograms of umeclidinium (UMEC) and 22 micrograms of vilanterol (as trifenatate). Indications: Treatment of chronic obstructive pulmonary disease (COPD). Dosage and administration: Inhalation only. One inhalation once daily.

Anoro Ellipta (umeclidinium bromide/vilanterol [as trifenatate]) Prescribing information

(Please consult the full Summary of Product Characteristics (SmPC) before prescribing) Anoro Ellipta 55/22mcg (umeclidinium bromide/vilanterol [as trifenatate]) inhalation powder. Each single inhalation provides a delivered dose (the dose leaving the mouthpiece) of 55 micrograms umeclidinium (equivalent to 65 micrograms of umeclidinium bromide) and 22 micrograms of vilanterol (as trifenatate). Indications: Anoro is indicated as a maintenance bronchodilator treatment to relieve symptoms in adults with COPD who are not adequately treated by a combination of an inhaled corticosteroid (ICS) and a long-acting β2-agonist (LABA) or a combination of a long-acting β2-agonist and a long-acting muscarinic antagonist.

Anoro is indicated as a maintenance bronchodilator treatment to relieve symptoms in adults with moderate to severe COPD who are not adequately treated by an ICS/LABA combination.

Indications:

- Maintenance treatment in adult patients with moderate to severe COPD who are not adequately treated by a combination of an inhaled corticosteroid (ICS) and a long-acting β2-agonist (LABA) or a combination of a long-acting β2-agonist and a long-acting muscarinic antagonist.
- A maintenance bronchodilator treatment to relieve symptoms in adults with COPD who are not adequately treated by a combination of an ICS/LABA combination.

Dosage and administration:

- One inhalation once daily.
- Contraindications: Hypersensitivity to the active substances or to any of the excipients (lactose monohydrate & magnesium stearate).
- Precautions: Paradoxical bronchospasm, unstable or life-threatening cardiovascular disease or heart rhythm abnormalities, convulsive disorders or thyrotoxicosis, pulmonary tuberculosis or patients with chronic or untreated infections, narrow-angle glaucoma, urinary retention, hypokalaemia, patients predisposed to low levels of serum potassium, diabetes mellitus. In patients with moderate to severe hepatic impairment patients should be monitored for systemic corticosteroid-related adverse reactions. Eye symptoms such as blurred vision may be due to underlying serious conditions such as cataract, glaucoma or central serous chorioretinopathy (CSCR); consider referral to an ophthalmologist. Increased incidence of pneumonia has been observed in patients with COPD receiving inhaled corticosteroids.

Risk factors for pneumonia include: current smokers, older age, patients with a low body mass index and severe COPD. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take Anoro.

Trelegy Ellipta was developed in collaboration with Innoviva Inc.

Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol [as trifenatate]) Prescribing information

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Contraindications: Hypersensitivity to the active substances or to any of the excipients (lactose monohydrate and magnesium stearate).

Precautions: Anoro should not be used in patients with asthma. Treatment with Anoro should be discontinued in the event of paradoxical bronchospasm and alternative therapy initiated if necessary. Cardiovascular effects may be seen after the administration of muscarinic receptor antagonists and sympathomimetics therefore Anoro should be used with caution in patients with severe cardiovascular disease. Anoro should be used with caution in patients with urinary retention, narrow angle glaucoma, convulsive disorders, thyrotoxicosis, hypokalaemia, hyperglycaemia and severe hepatic impairment. No dosage adjustment is required in patients with renal or mild to moderate hepatic impairment.

Acute symptoms: Anoro is not indicated for acute episodes of bronchospasm.

Wear patients to seek medical advice if short-acting inhaled bronchodilator use increases, a re-evaluation of the patient and of the COPD treatment regimen should be undertaken. Interactions with other medicinal products: Avoid β-blockers. Caution is advised when co-administering with strong CYP3A4 inhibitors (e.g. ketoconazole, clarithromycin, itraconazole, ritonavir, telithromycin). Anoro should not be used in conjunction with other long-acting β2-adrenergic agonists or medicinal products containing long-acting muscarinic antagonists. Caution is advised with concomitant use with methylxanthine derivatives, steroids or non-potassium-sparing diuretics as it may potentiate possible hypokalaemic effect of β2-adrenergic agonists. Fertility, pregnancy, and breast-feeding: No available data. Balance risks against benefits. Side effects: Common (≥1/100 to <1/10): urinary tract infection, sinusitis, nasopharyngitis, pharyngitis, upper respiratory tract infection, headache, cough, oropharyngeal pain, constipation and dry mouth. Other important side effects include: Uncommon (≥1/1,000 to <1/100): supraventricular tachyarrhythmia, tachycardia, atrial fibrillation; Not known (cannot be estimated from the available data) vision blurred; See SmPC for other adverse reactions. Legal category: POM. Presentation and Basic NHS cost: Trelegy Ellipta 92/55/22 mcg - £44.50, 1 inhaler x 30 doses. Marketing authorisation (MA) no. 92/55/22 mcg 1x30 doses [EU/1/17/1236/02]; MA holder: GSK Trading Services Ltd., Currabinny, Co. Cork Ireland. Last date of revision: November 2018. UK/TLY/0031/17/1. Trademarks are owned by or licensed to the GSK group of companies. 2018 GSK group of companies or its licensor Trelegy Ellipta was developed in collaboration with Innoviva Inc.

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