Exacerbation Reduction and Improved Quality of Life in Asthma with Extrafine Formulation Single-Inhaler Triple Therapy (efSITT): Six-Month Results of the TriMaximize Study

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TRIMAXIMIZE

BACKGROUND:

- The TriMaximize study was designed to observe patients who have switched to extrafine formulation single-inhaler triple therapy consisting of **beclomethasone dipropionate/formoterol fumarate/glycopyrronium (BDP/FF/G)** in a real-world setting over a period of one to three years.

METHODS:

- This is a multinational, observational study that follows patients with asthma being prescribed efSITT. Patients were recruited at 125 sites across six countries (DE, UK, AT, DK, FR and ES). Here we present the data from the interim analysis after 6 months of observation.
- Descriptive analyses of Health-Related Quality of Life (HRQoL) evaluated by Mini Asthma Quality of Life Questionnaire (Mini AQLQ)[1] and exacerbation rates were performed.

Table 1. Baseline characteristics of patients (n=1090).

Age, mean years (±SD)		58 (15)
Sex, n (%)	Female	690 (63.3)
	Male	400 (36.7)
BMI (kg/m^2), mean (±SD)		29.3 (7.8)
Smoking status, n (%)	Former smoker	340 (31.2)
	Current smoker	202 (18.5)
Pack years, mean (±SD)	Former smoker	19.1 (15.5)
	Current smoker	24.9 (15.5)
Time since stopped smoking, years (±SD)		14.8 (12.5)
Time since diagnosis at baseline visit, years (±SD)		14.4 (14.1)
FEV_1 % predicted at baseline visit, mean (±SD)		67.08 (16.96)
Exacerbation rate in the past year, mean (±SD)		1.8 (1.7)
Asthma maintenance treatment before switch to efSITT, n (%)	ICS/LABA (fixed)	787 (72.2)
	ICS/LABA (open)	34 (3.1)
	ICS/LABA/LAMA (fixed)	17 (1.6)
	ICS/LABA/LAMA (open)	252 (23.1)
Classification according to GINA criteria, n (%)	GINA Step 4	878 (82.6)
	GINA Step 5	185 (17.4)

Reference:

[1]Development and validation of the Mini Asthma Quality of Life Questionnaire, EF Juniper,GH Guyatt, FM Cox, PJ Ferrie, DR King European Respiratory Journal 1999 14: 32-38; DOI: 10.1034/j.1399-3003.1999.14a08.x

The TriMaximize study was funded by Chiesi. FT, RR, CSU, WP, VP, AB and CG have received fees for conducting the study. VB, DN and CF are employees of Chiesi GmbH.

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RESULTS:

Figure 1. Proportion of patients at baseline with one and two or more exacerbations (±SD) in the last 12 months under previous treatment, n=1090.

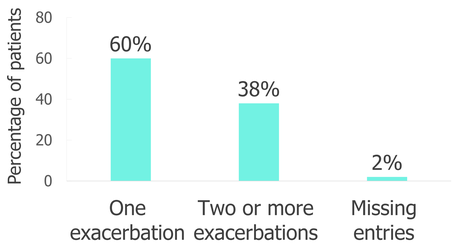


Figure 2. Severity of exacerbations at baseline in the last 12 months under previous treatment, n=1090.

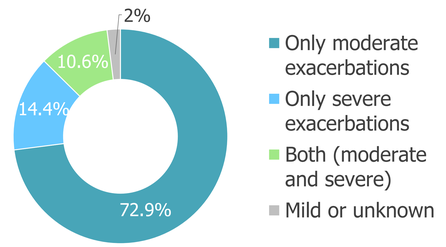


Figure 3. Mean exacerbation rate at baseline and after six months, stratified by prior asthma maintenance treatment.

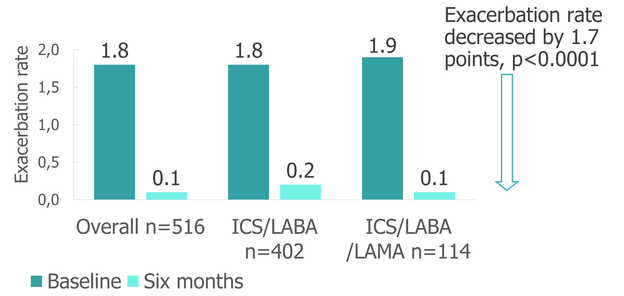


Figure 4. Asthma-related impairment of Health-Related Quality of Life (HRQoL) according to Mini AQLQ score at baseline and after six months (n=385).

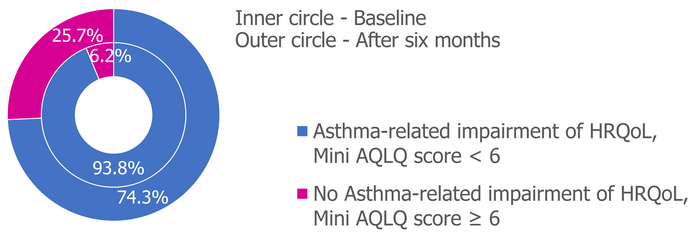


Figure 5. Mean Mini AQLQ score including the sub-domains at baseline and after six months (n=385).

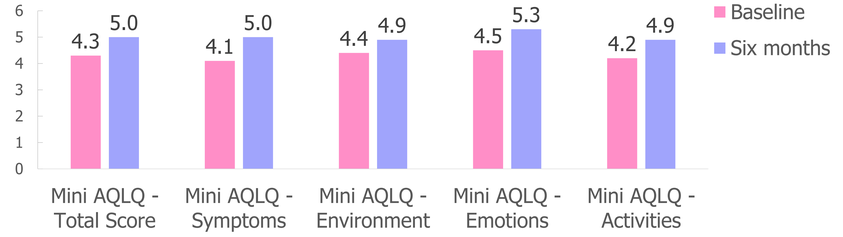
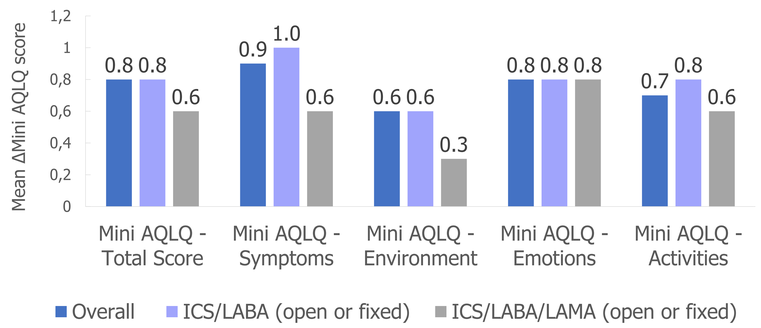


Figure 6. Change in mean Mini AQLQ domains scores after six months, stratified by prior asthma maintenance treatment (overall n=385, ICS/LABA n=318, ICS/LABA/LAMA n=67, all p<0.0001, except ICS/LABA/LAMA environment p <0.0293).



Minimal clinically important difference (MCID) for Mini AQLQ score of 0.5 points was met or exceeded in the overall population an in the patients on prior ICS/LABA and ICS/LABA/LAMA.

Table 2. Responders for Mini AQLQ score at six months of treatment according to MCID ≥ 0.5 points, stratified by prior asthma maintenance treatment.

Prior asthma maintenance treatment	Patients with mean ΔMini AQLQ score ≥ 0.5, n (%)
ICS/LABA (open or fixed) n=318	182 (57.2)
ICS/LABA/LAMA (open or fixed) n=67	34 (50.7)
Overall n=385	**216 (56.1)**

Overall, 56.1% of patients met or exceeded the MCID of 0.5 points for the Mini AQLQ and were classified as responders.

CONCLUSIONS:

Exacerbation reduction and improvement in HRQoL were observed six months after switching to efSITT from dual as well as free triple combinations.

Impact of Extrafine Formulation Single-Inhaler Triple Therapy on Asthma Control and Treatment Adherence after Six Months of Treatment in Patients with Asthma - TriMaximize Study

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TRIMAXIMIZE

BACKGROUND:

- The TriMaximize study observes patients who have switched to extrafine formulation single-inhaler triple therapy (efSITT) consisting of **beclomethasone dipropionate/formoterol fumarate/glycopyrronium (BDP/FF/G)** in a real-world setting over a period of one to three years.

METHODS:

- This is a multinational, observational study that follows patients with asthma being prescribed efSITT. Patients were recruited at 125 sites across six countries (DE, UK, AT, DK, FR and ES). Here we present the data from the interim analysis after six months of observation.

- Asthma control was assessed by the Asthma Control Test (ACT)[1] and treatment adherence was evaluated using the Test of Adherence to Inhalers (TAI)[2].

Table 1. Baseline characteristics of patients (n=1090).

Age, mean years (±SD)		58 (15)
Sex, n (%)	Female	690 (63.3)
	Male	400 (36.7)
BMI (kg/m^2), mean (±SD)		29.3 (7.8)
Smoking status, n (%)	Former smoker	340 (31.2)
	Current smoker	202 (18.5)
Pack years, mean (±SD)	Former smoker	19.1 (15.5)
	Current smoker	24.9 (15.5)
Time since stopped smoking, years (±SD)		14.8 (12.5)
Time since diagnosis at baseline visit, years (±SD)		14.4 (14.1)
FEV_1 % predicted at baseline visit, mean (±SD)		67.08 (16.96)
Exacerbation rate in the past year, mean (±SD)		1.8 (1.7)
Asthma maintenance treatment before switch to efSITT, n (%)	ICS/LABA (fixed)	787 (72.2)
	ICS/LABA (open)	34 (3.1)
	ICS/LABA/LAMA (fixed)	17 (1.6)
	ICS/LABA/LAMA (open)	252 (23.1)
Classification according to GINA criteria, n (%)	GINA Step 4	878 (82.6)
	GINA Step 5	185 (17.4)

References:

[1] Schatz M. et al., Asthma Control Test: reliability, validity, and responsiveness in patients not previously followed by asthma specialists. J Allergy Clin Immunol, 2006. 117: p. 549-556.

[2] Plaza V, Fernández-Rodríguez C, Melero C, et al. Validation of the 'Test of the Adherence to Inhalers' (TAI) for Asthma and COPD Patients. J Aerosol Med Pulm Drug Deliv. 2016;29(2):142–152. doi: 10.1089/jamp.2015.1212

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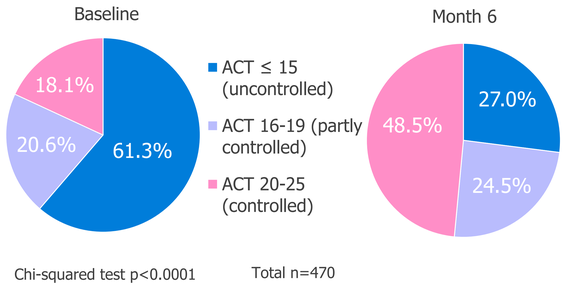
RESULTS:

Figure 1. Total mean ACT score at baseline and month six, n=470.



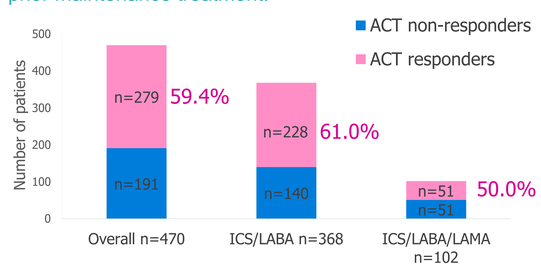
Chi-squared test p<0.0001 Total n=470

Table 2. Mean ACT score (±SD) and the change from baseline at month six, stratified by prior maintenance treatment.

Prior asthma maintenance treatment	ACT score at baseline	ACT score month 6	ΔACT score	Paired t-test
Overall population	14.7 (4.8) n=989	18.2 (4.6) n=513	**3.8** (4.7) n=470	p<0.0001
ICS/LABA (open or fixed)	14.6 (4.7) n=749	18.3 (4.5) n=400	**4.1** (4.7) n=368	p<0.0001
ICS/LABA/LAMA (open or fixed)	15.0 (5.0) n=240	17.9 (5.0) n=113	**2.7** (4.4) n=102	p<0.0001

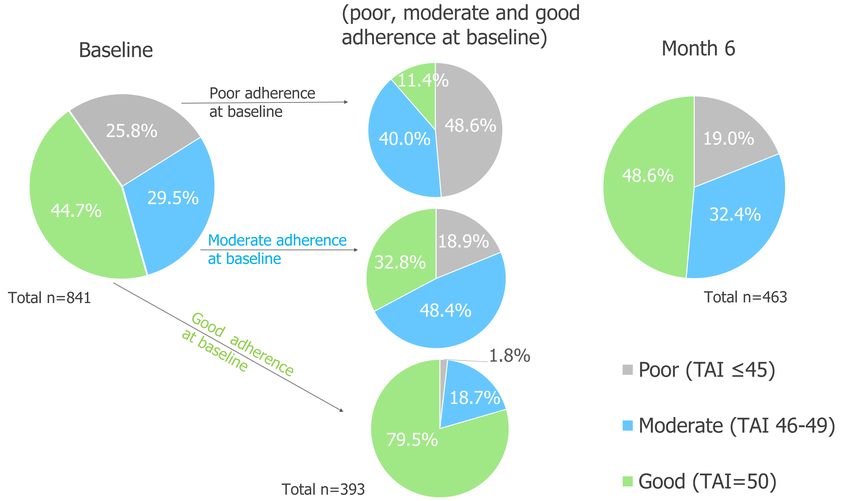
MCID for ACT score of 3 points was met or exceeded in the overall population and in the patients on prior ICS/LABA.

Figure 2. Proportion of patients with mean ΔACT score ≥ 3 points (ACT responder) at month six, stratified by prior maintenance treatment.



Overall, 59.4% of patients exceeded the MCID of 3 points for ACT and were classified as responders.

Figure 3. Change of adherence according to TAI-patient domain score from baseline to six months.

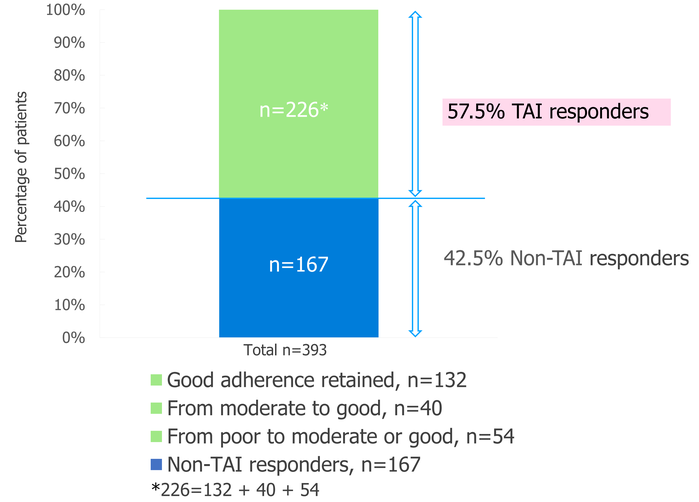


Adherence 6 months after switch to efSITT	Adherence at baseline, n (%) Poor	Moderate	Good
Poor (TAI ≤45)	51 (48.6)	23 (18.9)	3 (1.8)
Moderate (TAI 46-49)	42 (40.0)	59 (48.4)	31 (18.7)
Good (TAI=50)	12 (11.4)	40 (32.8)	132 (79.5)

Coloured in yellow: The patients who achieved the higher adherence category or maintained the good adherence at month six (TAI responders).

No change in TAI-health care professional domain was observed (the score at the baseline and after six months was 3.0, SD ±0.3).

Figure 4. TAI responders according to change to a higher adherence category at month six.



CONCLUSION:

Switching from dual as well as triple combinations significantly improves asthma control and adherence after six months of efSITT.

Improvement in Lung Function after Six Months of Treatment with Extrafine Formulation Single-Inhaler Triple Therapy (efSITT) in Patients with Asthma - TriMaximize Study

C. Gessner[1]*, V. Bogoevska[2], D. Nachtigall[2], R. Russell[3], C. Suppli Ulrik[4], W. Pohl[5], V. Plaza[6], A. Bourdin[7], C.P. Criée [8], F. Trinkmann[9]*

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TRIMAXIMIZE

BACKGROUND:

- The TriMaximize study observes patients who have switched to extrafine formulation single-inhaler triple therapy (efSITT) consisting of **beclomethasone dipropionate/formoterol fumarate/glycopyrronium (BDP/FF/G)** in a real-world setting. The clinical efficacy and safety of efSITT has already been shown in clinical trials[1].

METHODS:

- This is a multinational, observational study that follows patients with asthma being prescribed efSITT over a period of one to three years. Patients were recruited at 125 sites across six countries (DE, UK, AT, DK, FR and ES). Here we present the data from the interim analysis after 6 months of observation.
- Pre-bronchodilator lung function was measured by spirometry and body plethysmography at baseline and after six months of treatment with efSITT along with additional descriptive analyses.

Table 1. Baseline characteristics of patients (n=1090).

Age, mean years (±SD)		58 (15)
Sex, n (%)	Female	690 (63.3)
	Male	400 (36.7)
BMI (kg/m^2), mean (±SD)		29.3 (7.8)
Smoking status, n (%)	Former smoker	340 (31.2)
	Current smoker	202 (18.5)
Pack years, mean (±SD)	Former smoker	19.1 (15.5)
	Current smoker	24.9 (15.5)
Time since stopped smoking, years (±SD)		14.8 (12.5)
Time since diagnosis at baseline visit, years (±SD)		14.4 (14.1)
FEV_1 % predicted at baseline visit, mean (±SD)		67.08 (16.96)
	ICS/LABA*	67.73 (16.56)
	ICS/LABA/LAMA*	64.97 (18.10)
Exacerbation rate in the past year, mean (±SD)		1.8 (1.7)
Asthma maintenance treatment before switch to efSITT, n (%)	ICS/LABA*	821 (75.3)
	ICS/LABA/LAMA*	269 (24.7)
Classification according to GINA criteria, n (%)	GINA Step 4	878 (82.6)
	GINA Step 5	185 (17.4)

*(fixed or open)

RESULTS:

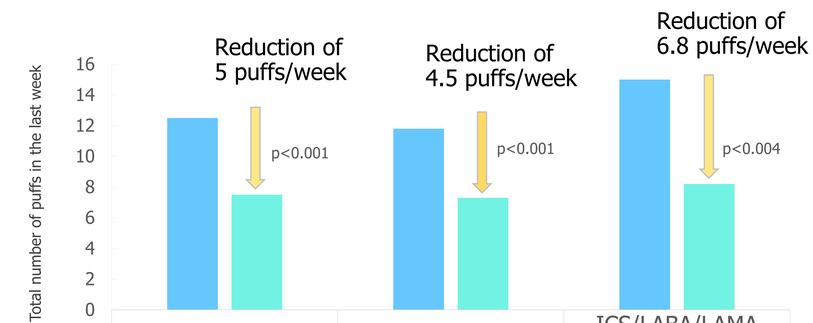
Table 2. Mean change from baseline in lung function parameters after six months of treatment with BDP/FF/G, stratified by prior asthma maintenance treatment.

Parameters	Overall population	Prior ICS/LABA*	Prior ICS/LABA/LAMA*
FEV_1 (mL) (±SD)	**130** (460) p<0.0001 n=389	**150** (440) p<0.0001 n=312	**70** (540) p<0.2797 n=77
FEV_1 (% of predicted) (±SD)	**3.95** (13.51) p<0.0001 n=338	**4.09** (13.18) p<0.0001 n=278	**3.43** (14.85) p<0.0575 n=70
RV/TLC (% of predicted) (±SD)	**-7.79** (39.33) p=0.0017 n=256	**-9.07** (37.52) p=0.0007 n=205	**-2.64** (45.95) p=0.6828 n=51
sRtot (% of predicted) (±SD)	**-19.31** (84.52) p<0.0163 n=114	**-28.08** (80.04) p<0.0011 n=92	**17.37** (94.49) p=0.3983 n=22
MEF 25-75 (L/s) (±SD)	**0.10** (0.98) p=0.2430 n=142	**0.12** (0.85) p=0.1387 n=112	**0.01** (1.38) p=0.9656 n=30

For the mean change only patients with spirometry and/or body plethysmography performed at baseline and month six were included (a total of 453 patients, 355 were previously treated with ICS/LABA and 98 patients with ICS/LABA/LAMA).

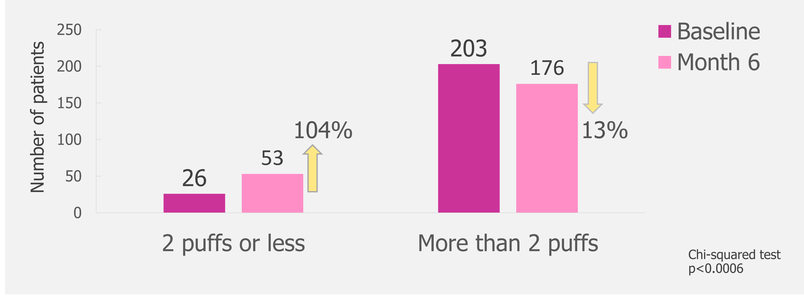
*(fixed or open); FEV_1 - forced expiratory volume in 1st second; RV/TLC - residual volume to total lung capacity ratio; sRtot - total specific resistance; MEF 25-75 - maximum expiratory flow at 25-75% of forced vital capacity (FVC); ICS - Inhaled corticosteroid; LABA - Long-acting beta2-agonist; LAMA - Long-acting muscarinic antagonist.

Figure 1. Mean change in total number of puffs of rescue medication in the week before baseline and at month six, stratified by prior asthma maintenance treatment (n=229).



	Overall n=229	ICS/LABA n=178	ICS/LABA/LAMA n=51
Baseline	12.5	11.8	15.0
Month 6	7.5	7.3	8.2

Figure 2. Number of patients taking a rescue medication in the previous week comparing baseline and month six for high and low users (n=229).



CONCLUSION:

Significant lung function improvement and reduction in rescue medication use were observed in asthma patients six months after switching to efSITT. This especially includes parameters of peripheral obstruction (sRtot) and hyperinflation (RV/TLC).

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References:

[1] Virchow J.C. et al., Single inhaler extrafine triple therapy in uncontrolled asthma (TRIMARAN and TRIGGER): two double-blind, parallel-group, randomised, controlled phase 3 trials. The Lancet, 2019. 394(10210): p. 1737-1749.

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