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

T. Greulich[1], V. Bogoevska[2], D. Nachtigall[2], R. Russell[3], C. Suppli Ulrik[4], W. Pohl[5], V. Plaza[6], A. Bourdin[7], S. Baumeister[2], C. Gessner[8]*.

[1]PneumoPraxis Marburg, Marburg, [2]Chiesi GmbH, Hamburg, [3]King's College London, London, [4]Department of Respiratory Medicine, Copenhagen University Hospital Hvidovre, Hvidovre, [5]Karl Landsteiner Institute for Clinical and Experimental Pneumology, Clinic Hietzing, Vienna, [6]Hospital de la Santa Creu i Sant Pau, Barcelona, [7]Hôpital Arnaud de Villeneuve, University of Montpellier, Montpellier, [8]Specialized Practice for Pulmonary Medicine, Leipzig. *Corresponding author: ch.gessner@pneumologe-leipzig.de

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/m²), 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

RESULTS:

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

Baseline — Month 6
- ACT ≤ 15 (uncontrolled)
- ACT 16-19 (partly controlled)
- ACT 20-25 (controlled)

Baseline: 61.3%, 20.6%, 18.1%
Month 6: 27.0%, 24.5%, 48.5%

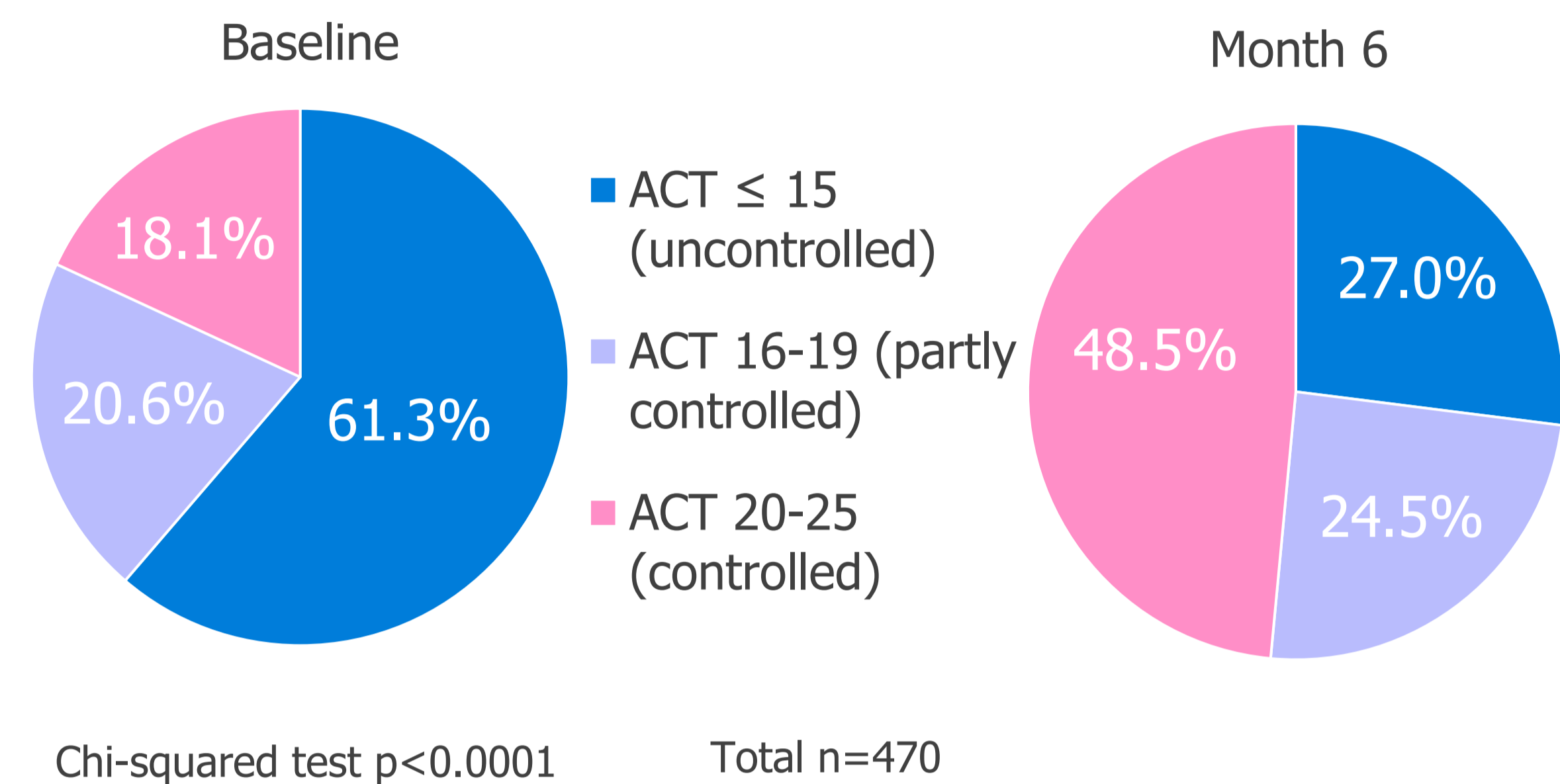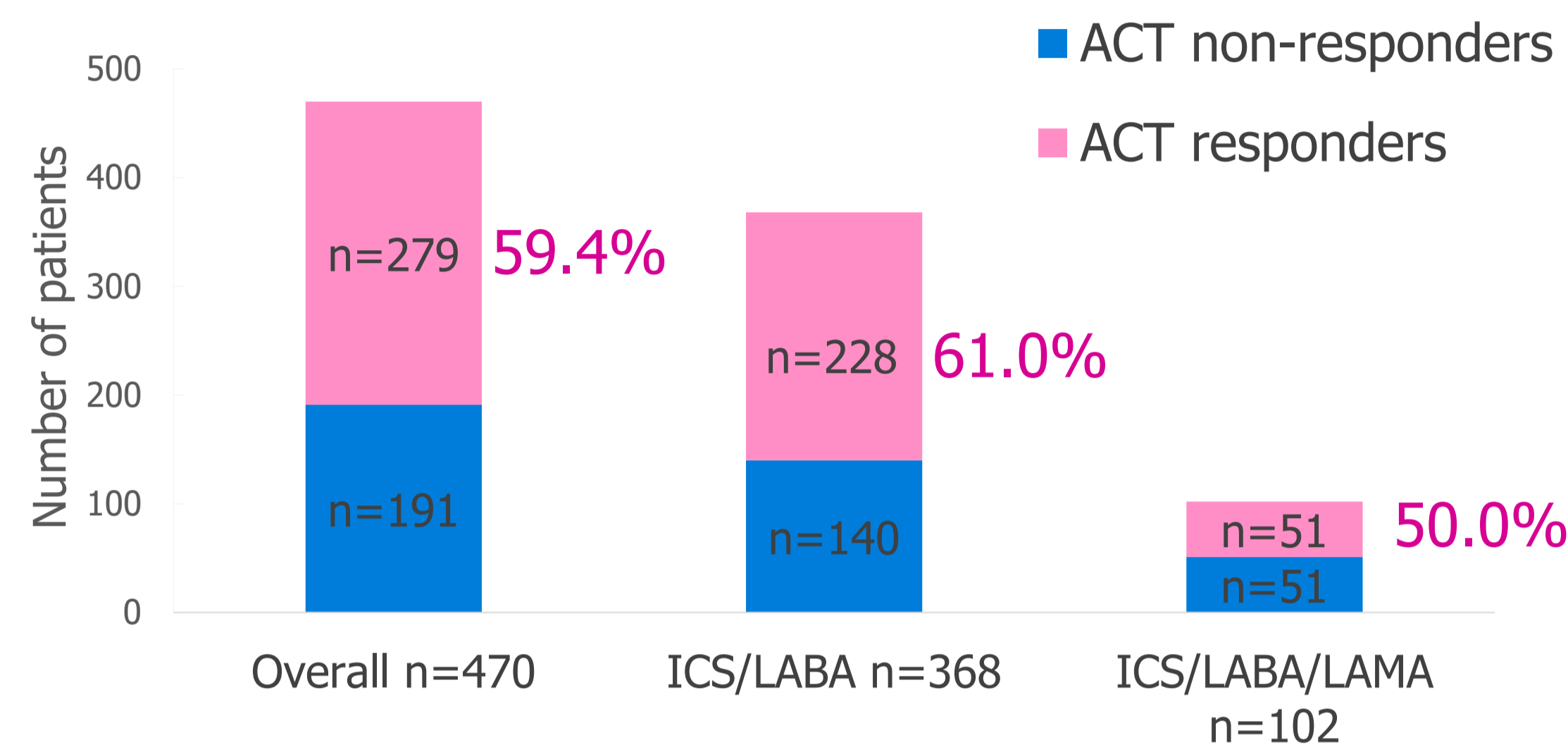Chi-squared test p<0.0001   Total n=470

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.

- ACT non-responders
- ACT responders

Overall n=470: n=279 59.4%, n=191
ICS/LABA n=368: n=228 61.0%, n=140
ICS/LABA/LAMA n=102: n=51 50.0%, n=51

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

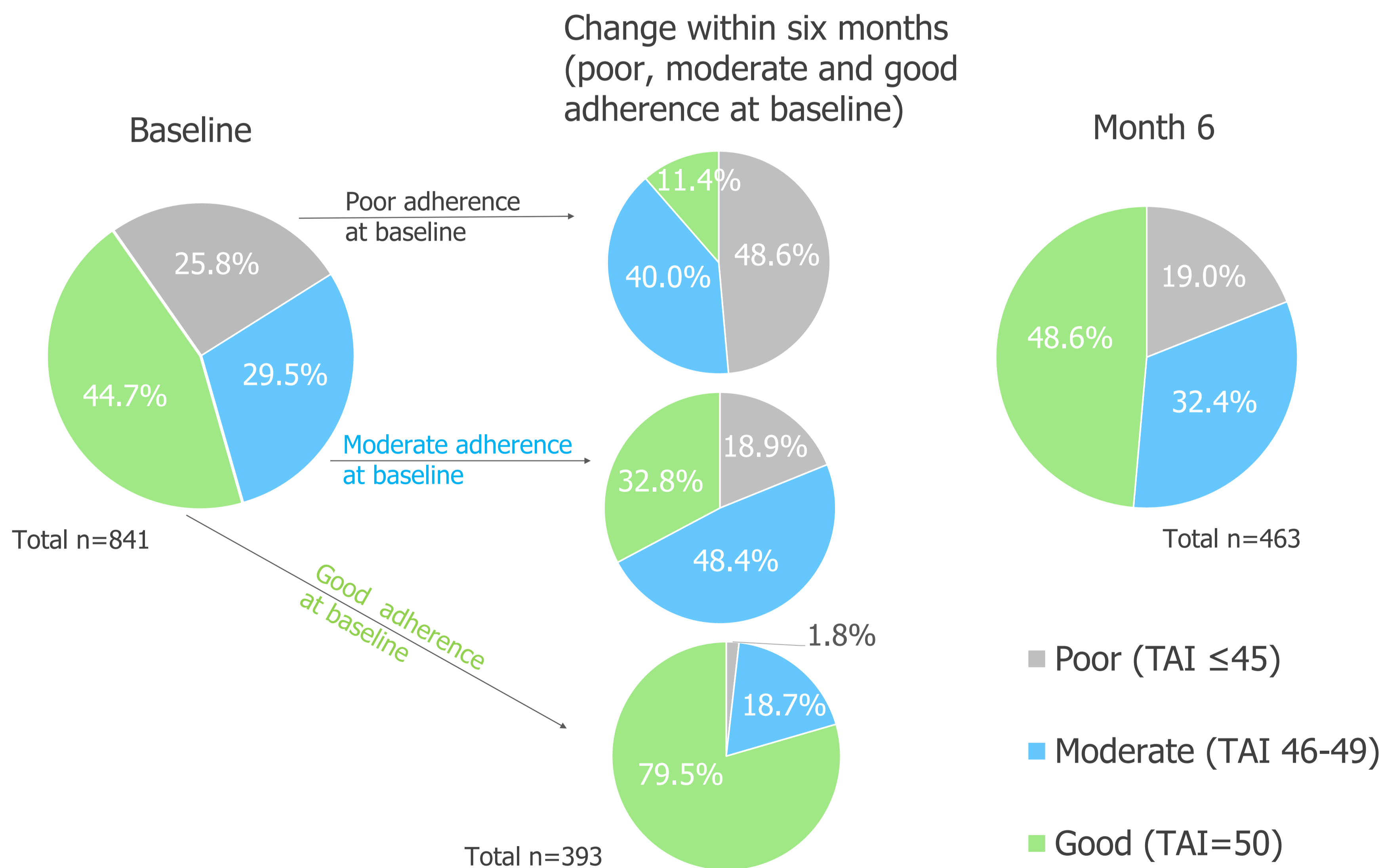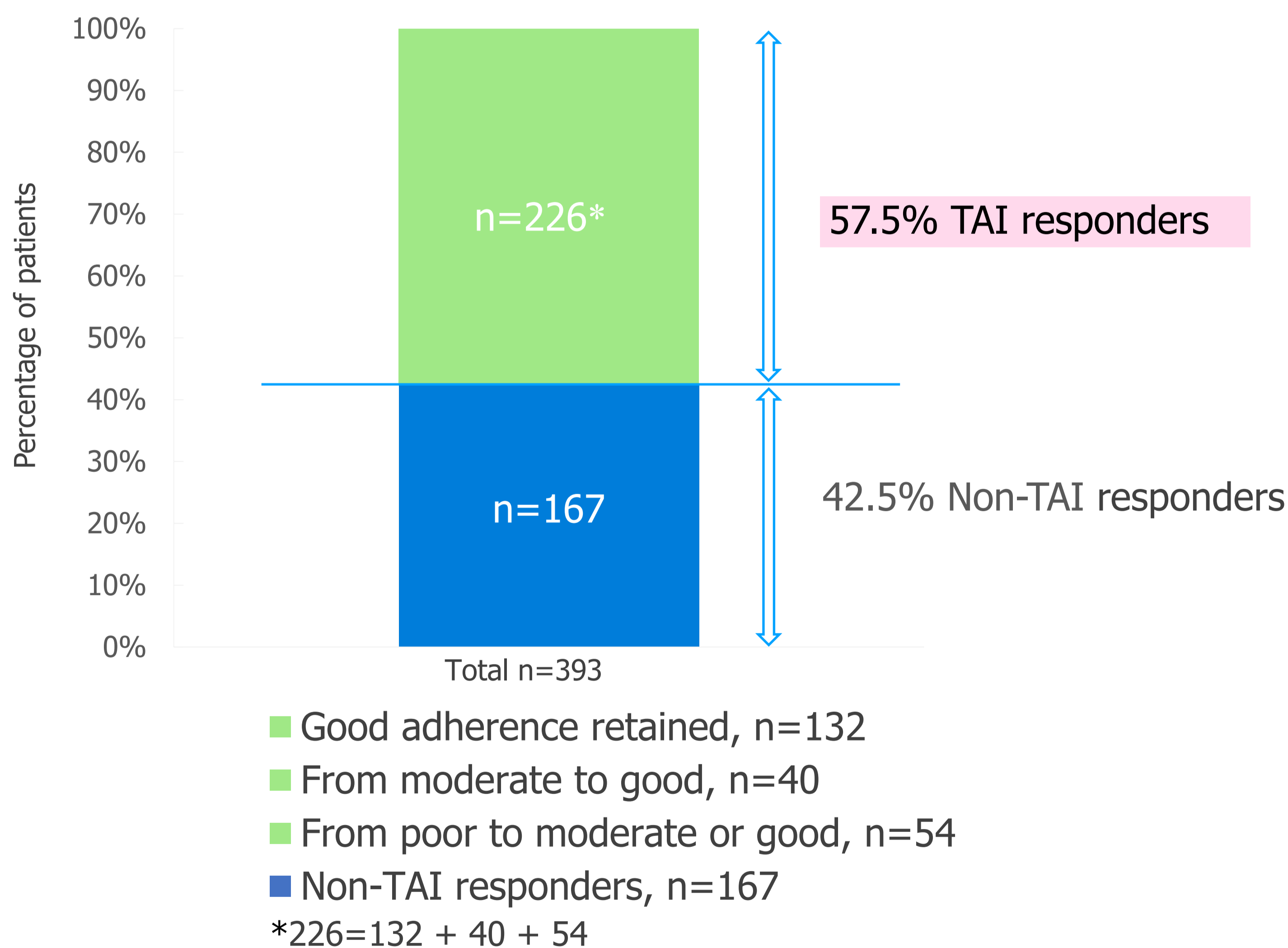Figure 3. Change of adherence according to TAI-patient domain score from baseline to six months.

Baseline — Change within six months (poor, moderate and good adherence at baseline) — Month 6

Baseline: 25.8%, 29.5%, 44.7% Total n=841

Poor adherence at baseline: 11.4%, 40.0%, 48.6%
Moderate adherence at baseline: 18.9%, 48.4%, 32.8%
Good adherence at baseline: 1.8%, 18.7%, 79.5% Total n=393

Month 6: 19.0%, 32.4%, 48.6% Total n=463

- Poor (TAI ≤45)
- Moderate (TAI 46-49)
- Good (TAI=50)

	Adherence at baseline, n (%)		
Adherence 6 months after switch to efSITT	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.

n=226* — 57.5% TAI responders
n=167 — 42.5% Non-TAI responders
Total n=393

- Good adherence retained, n=132
- From moderate to good, n=40
- From poor to moderate or good, n=54
- Non-TAI responders, n=167

*226=132 + 40 + 54

CONCLUSION:

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