


Novartis: First QAB149 phase III data release and respiratory portfolio update

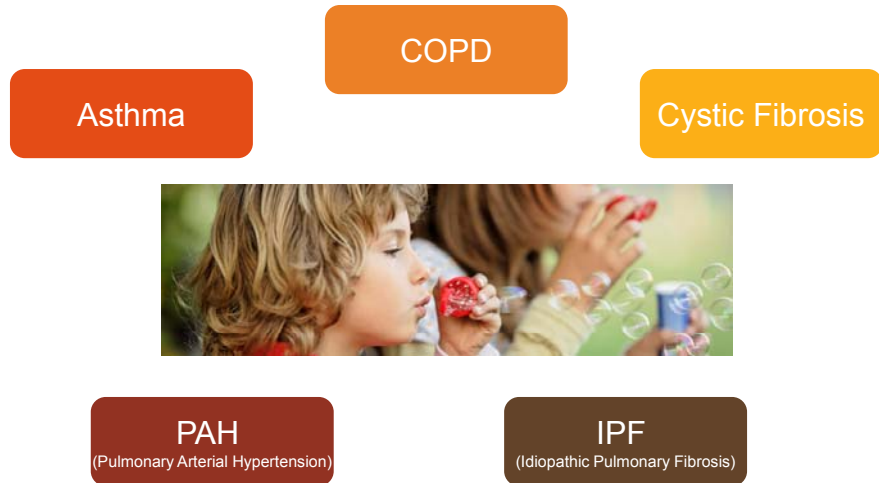
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Novartis respiratory portfolio strategy places the unmet needs of patients at the center of product development



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Novartis has the experience, capabilities and resources to develop a comprehensive respiratory portfolio

World-class global marketing & sales organization	Innovative, leading research & development	Global Alliances & Acquisitions
<ul style="list-style-type: none"> Successfully marketed respiratory products <ul style="list-style-type: none"> Xolair® - Asthma TOBI® - Cystic fibrosis Foradil® (ex-US) – COPD Proven ability at commercializing new chemical entities (NCEs) 	<ul style="list-style-type: none"> 3800 scientists working globally within Novartis Institutes for BioMedical Research (NIBR) 85M USD invested into a world-leading Respiratory Research and Development Center including a formulation and device development unit (Horsham, UK) 200 preclinical scientists dedicated to in-depth analysis of airway disease 	<ul style="list-style-type: none"> Alliances <ul style="list-style-type: none"> Schering-Plough (MFF258¹, QMF149¹) Genentech (Xolair²) Tanox (QGE031³) Sosei/Vectura (NVA237⁴) Cytos Biotechnology (NIC002A⁵) MicroDose Therapeutics (Piezo Electric Inhaler⁶) Acquisitions <ul style="list-style-type: none"> Nektar Therapeutics pulmonary business unit (new and complementary formulation and device technology capabilities⁷)

¹ MFF258; QMF149: Collaboration with Schering-Plough
² Xolair: Collaboration with Genentech
³ QGE031: Licensed from Tanox (a wholly owned subsidiary of Genentech)
⁴ NVA237: Licensed from Sosei R&D & Vectura Group plc
⁵ NIC002A: Licensed from Cytos Biotechnology
⁶ Piezo Electric Inhaler: Licensed from MicroDose Therapeutics
⁷ Nektar Therapeutics pulmonary business unit acquired in October 2008

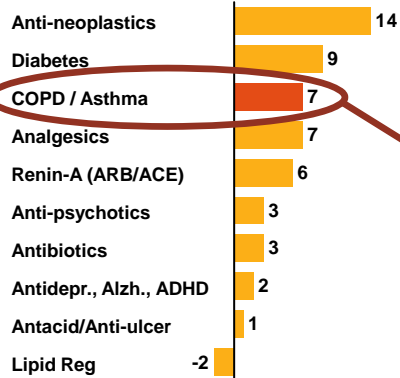
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The market segment is attractive and growing, with COPD alone worth \$9 Billion

COPD / Asthma rank third in sales growth rates for top 10 therapy areas

in %



Only 38% of COPD patients are diagnosed with only 50% controlled

COPD: 2008 \$9B USD total market segment with + 4.7% vs PY (CAGR 03-08 +13.7%)

Average treated COPD patient will receive 2X 'maintenance' therapies

Source: IMS Health MIDAS MAT September 2008 (top 10 ATC-2 classes)

Sources: Decision Resources – COPD, June 2008 (prevalence, diagnosis rate, smoking rates), DSP VI (patient share, compliance and level of control), CHS (treatment rate), GOLD guidelines; Growth rates as per unified forecast model; WHO estimates 2007

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COPD disease dynamics support the rationale for building a strong presence in this area

COPD



2007: 210 million people, 3 million deaths annually, 5th leading cause of death

2025: 4th leading cause of death globally

- Increased diagnosis rates
- Globally aging population
- Lack of treatments that reverse the inflammatory disease progression
- Continuing tobacco use, especially in Emerging Growth Markets (EGMs)
- Increasing pollution in EGMs

Source: WHO estimates 2007; numbers used are worldwide numbers

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QAB149 phase III ATS COPD abstracts show sustained efficacy, symptom relief, good safety & tolerability

Study Abstract, Author	Main abstract focus	Dose(s) Evaluated (placebo controlled)	Dur.	Patients	Key Conclusions
INVOLVE (B2334), Dahl	52 week FEV1 efficacy vs placebo	QAB149 300µg/600µg qd	1 year	1732	• Effective and sustained 24-hour bronchodilator
INHANCE (B2335S Stage 2), Fogarty	26 week FEV1 efficacy vs placebo	QAB149 150µg/300µg qd tiotropium 18µg qd [ol]	6 mo	1683 (433 tiotropium)	• Effective and sustained 24-hour bronchodilator • Safe and well-tolerated
INLIGHT (B2346), Siler	12 week FEV1 efficacy	QAB149 150µg	3 mo	416	• Effective and sustained 24-hour bronchodilator • Safe and well-tolerated
INVOLVE (B2334), Magnussen	12, 26 & 52 week FEV1 efficacy vs formoterol	QAB149 300µg/600µg qd formoterol 12µg bid	1 year	1732	• Superior bronchodilator efficacy vs formoterol
INVOLVE (B2334), Buhl	52 week exacerbations and breathlessness	QAB149 300µg/600µg qd formoterol 12µg bid	1 year	1732	• Superior reduction in breathlessness vs formoterol • Significant delay to first exacerbation vs placebo • Superior symptom control vs formoterol
INVOLVE (B2334), Nonikov	52 week days of poor control	QAB149 300µg/600µg qd formoterol 12µg bid	1 year	1732	• Superior symptom control vs formoterol • Significant reduction in rescue medication use vs. formoterol
INVOLVE (B2334), Chung	52 week safety & tolerability	QAB149 300µg/600µg qd formoterol 12µg bid	1 year	1732	• Safety and tolerability similar to formoterol and placebo
INHANCE (B2335 Stage 1), Barnes	Dose-ranging adaptive/seamless design	QAB149 150µg/300µg qd tiotropium 18µg qd [ol]	6 mo	805 (433 tiotropium)	• 150µg/300µg qd doses met predefined selection criteria
B1202, Kato	Japan FEV1 efficacy	QAB149 150µg qd	TBD	50	• Effective and sustained 24-hour bronchodilation • Safe and well-tolerated
B2318, Khindri	Isotime and exercise capacity	QAB149 300µg qd	14 days	27	• Increased peak and isotime inspiratory capacity
B2339, Khindri	Definitive QT in healthy subjects	QAB149 150µg/300µg/600µg qd	14 days	404	• Shows a very small and not clinically relevant effect on QT-interval

ATS also features 3 oral QAB149 presentations

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QAB149 combines fast onset with true 24-hour bronchodilation in a convenient once-daily dose

Data overview

Fast onset (within five minutes)

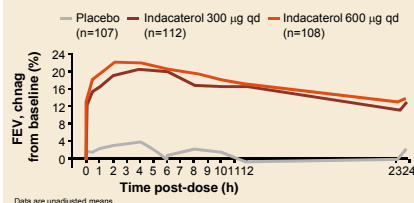
- Both QAB149 doses had a rapid onset of action, with FEV₁ differences versus placebo at 5 minutes post-dose on day 1 of 130mL for QAB149 300µg and 150mL for QAB149 600µg (p<0.001)¹

24-hour profile

- Both QAB149 doses had significantly higher values of FEV₁ which exceeded the 120mL threshold for clinical relevance compared with placebo, throughout the 24-hour period²

INVOLVE Study B2334¹

Change from baseline in FEV₁ from 5 min to 24 h post-dose measured on Day 1 in subset with serial spirometry measurements



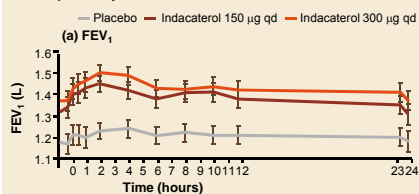
Data are unadjusted means

1. Dahl, et al. ATS 2009

2. Fogarty, et al. ATS 2009

INHANCE Study B2335S²

Serial measurements of (a) FEV₁ and (b) FVC from -50 min to 24 h post-dose measured at week 26 in the subset of patients with serial spirometry measurements



Data are least means ± SE. Treatment differences: p<0.001 for indacaterol (both doses) vs placebo at all time points

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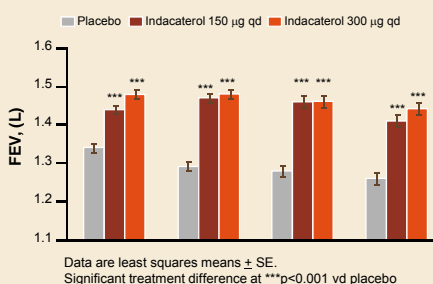
QAB149 provides significant and sustained improvements in trough FEV₁ through 26 weeks of therapy

Data overview

- 24-h post-dose FEV₁ at 12 weeks (the primary efficacy variable) significantly higher in patients receiving either QAB149 dose than with placebo¹
 - Both QAB149 doses exceeded the 120mL threshold for clinical relevance^{2,3} (180mL vs. placebo)¹
- Bronchodilator effect of both doses of QAB149 was sustained over the course of the 6-month study¹
 - Week 26: QAB149 150 and 300µg vs. placebo – 160 and 180mL, respectively)¹

INHANCE Study B2335S¹

24-h post-dose FEV₁, after 1 day, 2 weeks, 12 weeks and 26 weeks of treatment



- Fogarty, et al. ATS 2009
- Donohue JF. COPD 2005;2:111–24.
- Pellegrino R, et al. Eur Respir J 2005;26:948–68.

N.B. doses submitted for registration of QAB149 are 150 and 300µg via single-dose dry powder inhaler (SDDPI)
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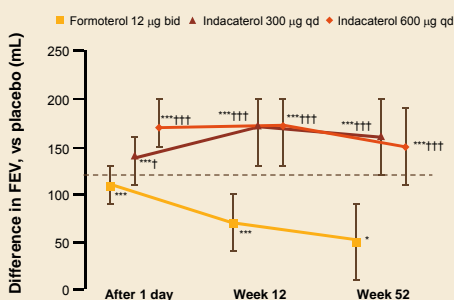
QAB149 delivers superior improvements in lung function when directly compared with formoterol

Data overview

- 24-h post-dose FEV₁ after 12 weeks significantly higher in patients receiving either QAB149 dose than with formoterol¹
 - Both QAB149 doses exceeded the 120mL threshold for clinical relevance^{2,3} (170mL vs. placebo), unlike formoterol (70mL vs. placebo)¹
- Bronchodilator effect of both doses of QAB149 was sustained over the course of the 1-year study, while the formoterol–placebo difference declined¹
 - Week 52: QAB149 300 and 600µg vs. placebo – 160 and 150mL, respectively; formoterol vs. placebo – 50mL)¹

INVOLVE Study B2334¹

Differences versus placebo in 24-h post-dose FEV₁, after 1 day, at Week 12 and Week 52 of treatment

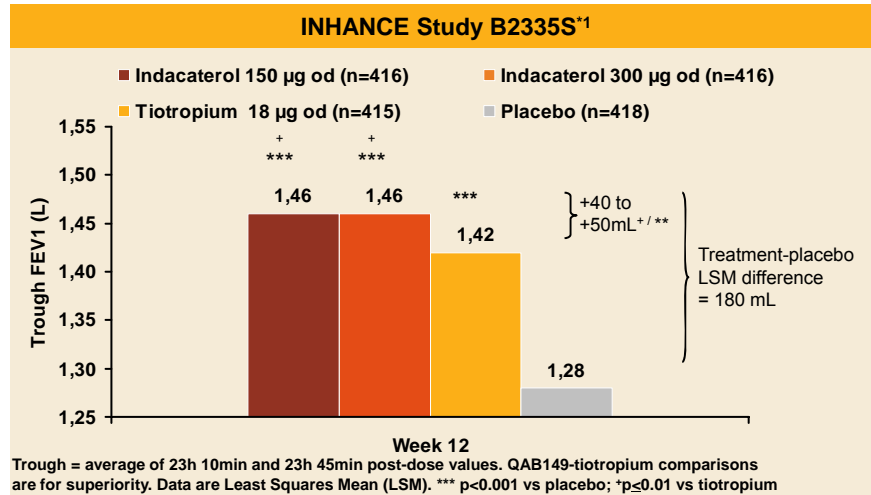


- Magnussen, et al. ATS 2009
- Donohue JF. COPD 2005;2:111–24.
- Pellegrino R, et al. Eur Respir J 2005;26:948–68.

N.B. doses submitted for registration of QAB149 are 150 and 300µg via single-dose dry powder inhaler (SDDPI)
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A head-to-head comparison vs tiotropium* has demonstrated QAB149 superiority in lung function improvement



* Data from open-label tiotropium arm of INHANCE 26-week study was not presented at ATS and will be presented later this year
 1. Novartis data on file. ** Represents FEV₁ mL superiority range vs tiotropium for 150 and 300 µg head-to-head comparisons.

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QAB149 effect on symptoms, including breathlessness, is encouraging as indicated by reduced rescue medication use

Data overview

- Both QAB149 doses showed a beneficial effect on reduction of cough, wheeze, and in particular breathlessness¹
- Breathlessness (or dyspnoea) is one of the key characteristic symptoms of COPD, and often leads to activity limitation, eventually confining patients to their home
- These symptomatic improvements were achieved with a significantly lower use of rescue medication compared with formoterol²

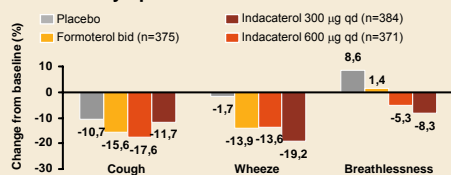
1. Buhl, et al. ATS 2009

2. Nonikov, et al. ATS 2009

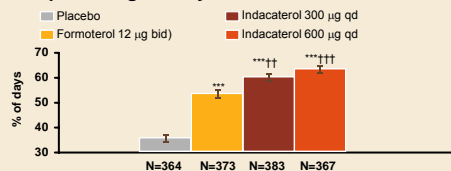
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INVOLVE Study B2334^{1,2}

Change from baseline in mean scores for individual symptoms over 52 weeks



The percentage of days with no rescue use



Data are least squares means ± SE. ***p<0.001 vs placebo; †††p<0.01; ††††p<0.001 vs formoterol



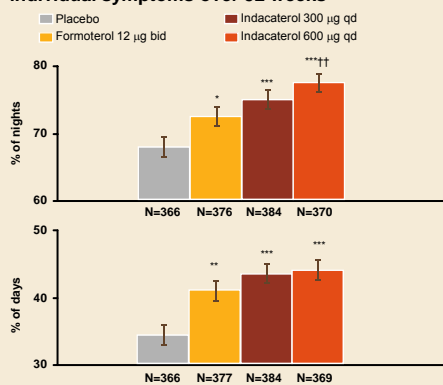
This improvement also increased nights free of awakenings and days when patients were able to perform usual activities

Data overview

- The percentages of nights free of awakenings and days when patients were able to perform their usual activities were increased with both QAB149 and formoterol versus placebo, with QAB149 having the greater effect

INVOLVE Study B2334¹

Change from baseline in mean scores for individual symptoms over 52 weeks



1. Nonikov, et al. ATS 2009

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QAB149 significantly delays time to first exacerbation in COPD patients compared to placebo

Data overview

- Hazard ratios for time to first exacerbation were significantly lower than placebo for QAB149 300µg (p=0.030), QAB149 600µg (p=0.003) and formoterol (p=0.034)¹
- Exacerbations have serious negative impacts on patients' lung function, quality of life and socioeconomic costs²
- Thus, reducing exacerbations is a major component of effective COPD management²

INVOLVE Study B2334^{1,2}

Summary statistics and analysis of time to first exacerbation

	Indacaterol		Formoterol
	300 µg (n=437)	600 µg (n=425)	(n=434)
Hazard ratio compared with placebo (95% CI)	0.77 (0.606, 0.975)	0.69 (0.538, 0.882)	0.77 (0.605, 0.981)
p-value vs placebo	0.030	0.003	0.034

1. Buhl, et al. ATS 2009

2. GOLD Guidelines 2007

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...and long-term safety and tolerability in COPD also appear to be comparable to formoterol and placebo

Data overview

- Overall incidence of adverse events was similar across the treatment groups¹
- Discontinuations due to adverse events occurred at a lower frequency with QAB149 than with formoterol or placebo¹
- No safety concerns associated with QAB149 600µg – a dose 2–4 times the therapeutic dose (150–300 µg)² – given for 1 year¹

INVOLVE Study B2334¹

Adverse events, n (%)

	Indacaterol		Formoterol	Placebo
	300 µg (n=437)	600 µg (n=425)	(n=434)	(n=432)
Any adverse events	310 (70.9)	276 (64.9)	283 (65.2)	267 (61.8)
▪ COPD worsening	140 (32.0)	117 (27.5)	134 (30.9)	150 (34.7)
▪ Naso-pharyngitis	73 (16.7)	80 (18.8)	64 (14.3)	56 (13.0)
Adverse events leading to discontinuation	36 (8.2)	24 (5.6)	42 (9.7)	40 (9.3)
▪ COPD worsening	5 (1.1)	4 (0.9)	17 (3.9)	17 (3.9)
▪ Dyspnea	4 (0.9)	2 (0.5)	1 (0.2)	3 (0.7)

1.Chung, et al. ATS 2009
2.Barnes, et al. ATS 2009

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QAB149: compelling profile is emerging anchored by significant lung function improvements vs comparators

QAB149 overview

- Sustained 24-hr bronchodilation (FEV₁)¹
 - Up to 180mL trough FEV₁ versus placebo
- Statistically superior FEV₁ vs.
 - formoterol² – +100mL (p<0.01)
 - tiotropium³ – +40-50mL (p<0.01)
- Symptoms and events vs.
 - Placebo⁴ – Reduced symptoms including breathlessness; exacerbations
 - Formoterol⁴ – Reduced breathlessness
- Once daily⁵
- Fast onset⁶: 1st 5 minutes post-dose
- Tolerability & safety comparable to placebo⁷

- FEV₁**
 - Superior efficacy benefit
- Symptoms**
 - Reduced breathlessness; vs placebo; vs formoterol
 - Reduced exacerbations vs placebo
- Once daily**
- Fast onset**
- Good tolerability and safety**

US and EU files submitted in December 2008 for COPD

1. Fogarty, et al. ATS 2009; Dahl, et al. ATS 2009; 2. Magnussen, et al. ATS 2009; 3. Data on file; 4. Buhl, et al. ATS 2009; 5. Fogarty, et al. ATS 2009; Dahl, et al. ATS 2009; 6. Fogarty, et al. ATS 2009; Dahl, et al. ATS 2009; Feldman, et al. ATS 2009; 7. Fogarty, et al. ATS 2009; Chung, et al. ATS 2009

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Compelling QAB149 profile will be further enhanced by the INERGIZE COPD clinical study program

'INERGIZE' studies introduced to US investigators at ATS:

insist

- Head-to-head lung function improvement vs salmeterol

intensity

- Head-to-head lung function improvement vs tiotropium

invigorate

- Long-term head-to-head vs tiotropium assessing lung function and exacerbations

intrust 1

intrust 2

- Effectiveness of QAB149 in combination with tiotropium

Further phase III QAB149 phase III data will be presented at major medical congresses in 2009

nergize
COPD Clinical Trials

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QAB149 delivered to patients in the Concept1 device, which is doing well in the phase III program

Data overview

- Evolution of the Foradil® Aerolizer®, which is approved in more than 60 countries
- Simple and intuitive to use helps patients to use properly every time
- Little airflow resistance required² allows comfortable and easy inhalation for all patients, even those with severe obstruction
- Clear audio/taste/visual feedback provides patients confidence that the full dose has been taken every time³
 - Hear (spinning capsule)
 - Feel (lactose taste)
 - See (empty capsule)
- New small, compact and sleek device appeals to patients⁴

During QAB149 Phase III studies, more than **350,000 Concept1 devices** were used **successfully** with only 21 returned¹

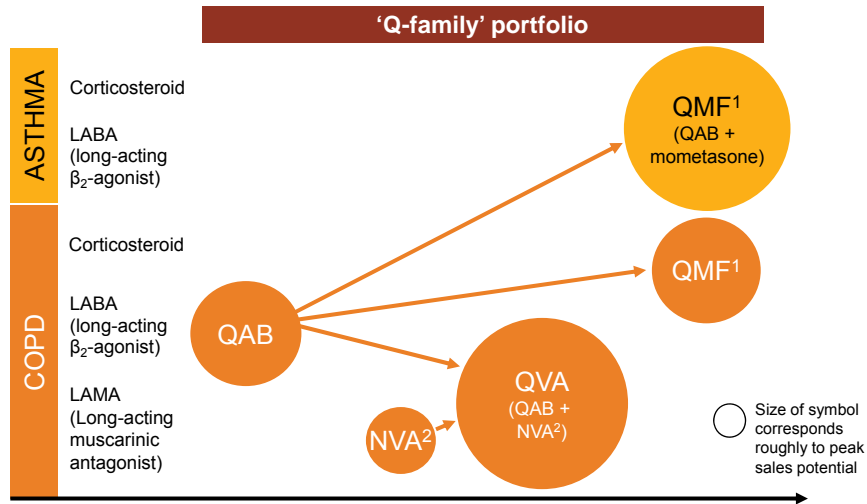


1. Inhalers, Concept1 and comparator devices, QAB149B_CD, Final report_01, Clinical complaint device evaluation report, Novartis data on file.
2. Concept1 (a New Single Dose Dry Powder Inhaler) Peak Inspiratory Flow Rate Study with COPD Patients R. Pavkov, D. Singh, I. Reiffeld, Poster abstract, Respiratory Drug Delivery 2008.
3. QAB149 300 microgram Inhalation powder hard capsule 6001037_P2_M_840_1 Drug product Pharmaceutical development, Novartis Data on file.
4. MR Dec 2007 Insights Research, Base: 41 patients (23 US, 18Ger), 28 HCP (14 US, 14 Ger)

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QAB149 is the foundation of a potential once-daily inhaled therapy portfolio with unique benefits



1. Alliance with Schering-Plough; 2. Licensed from Sosei R&D & Vectura Group plc
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