



SAFETY & EFFICACY

Proven &
approved

Proven safe and effective



Safety

Efficacy (EU)

Studies with over

600

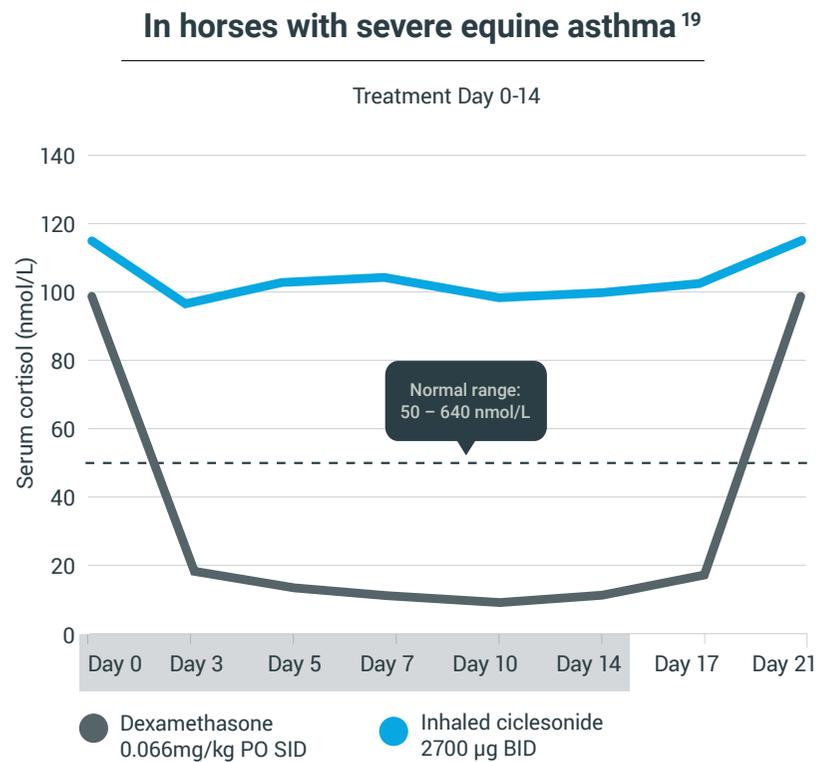
horses*

Proof of concept

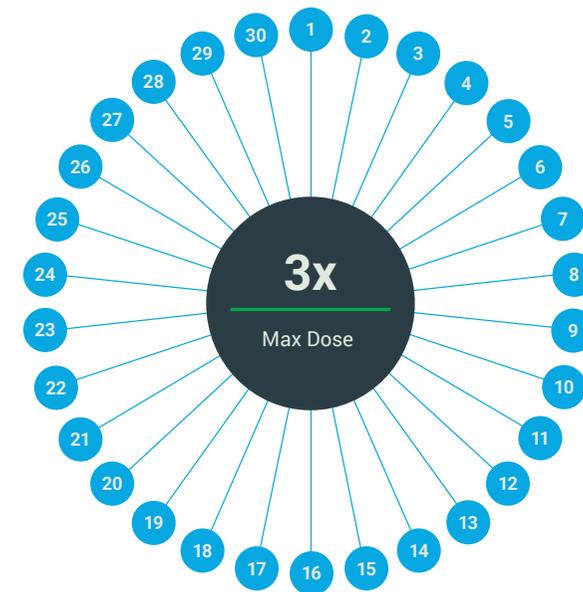
Efficacy (US)

*Treated with Aservo® EquiHaler® or placebo EquiHaler®

Inhaled ciclesonide was well tolerated with no statistically significant effect on **serum cortisol** levels ^{19, 23}

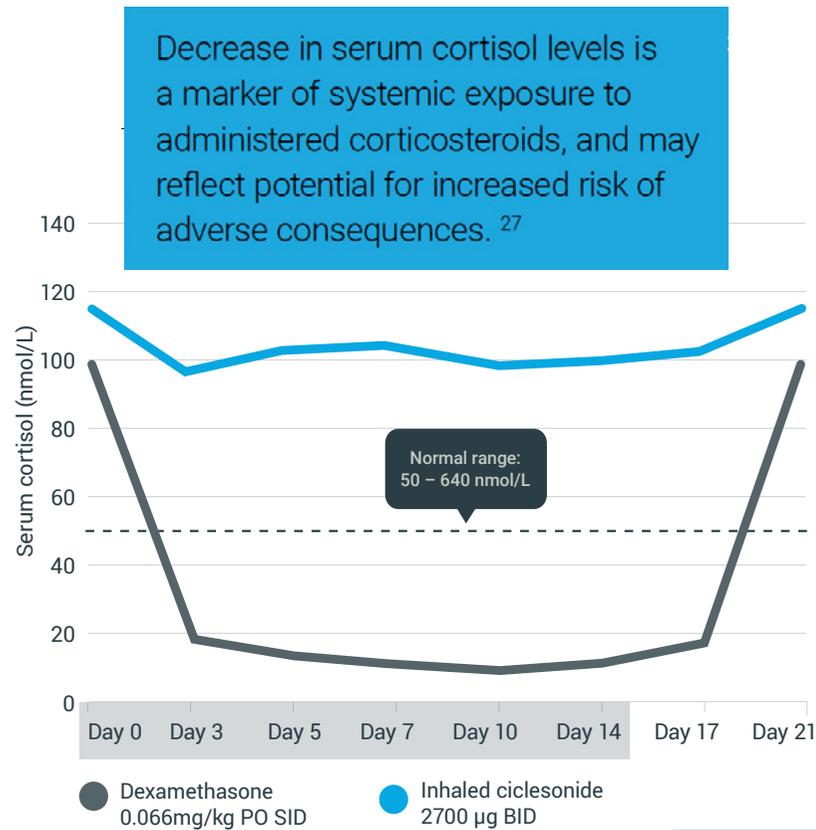


In healthy horses at 3x the dose and 3x the duration ²³

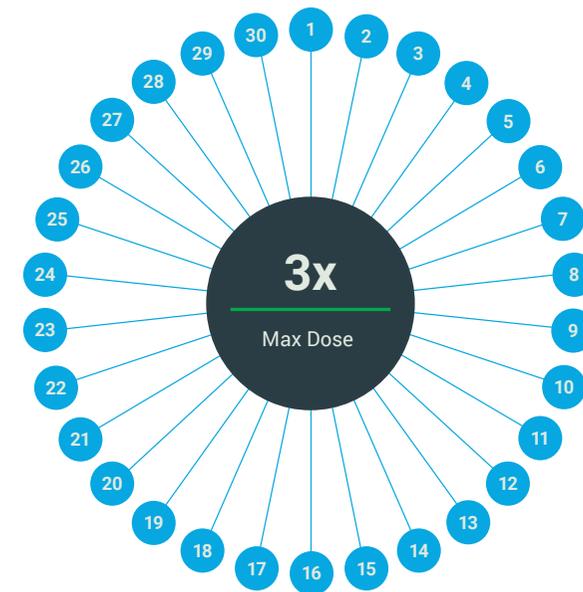


Favorable SAFETY profile

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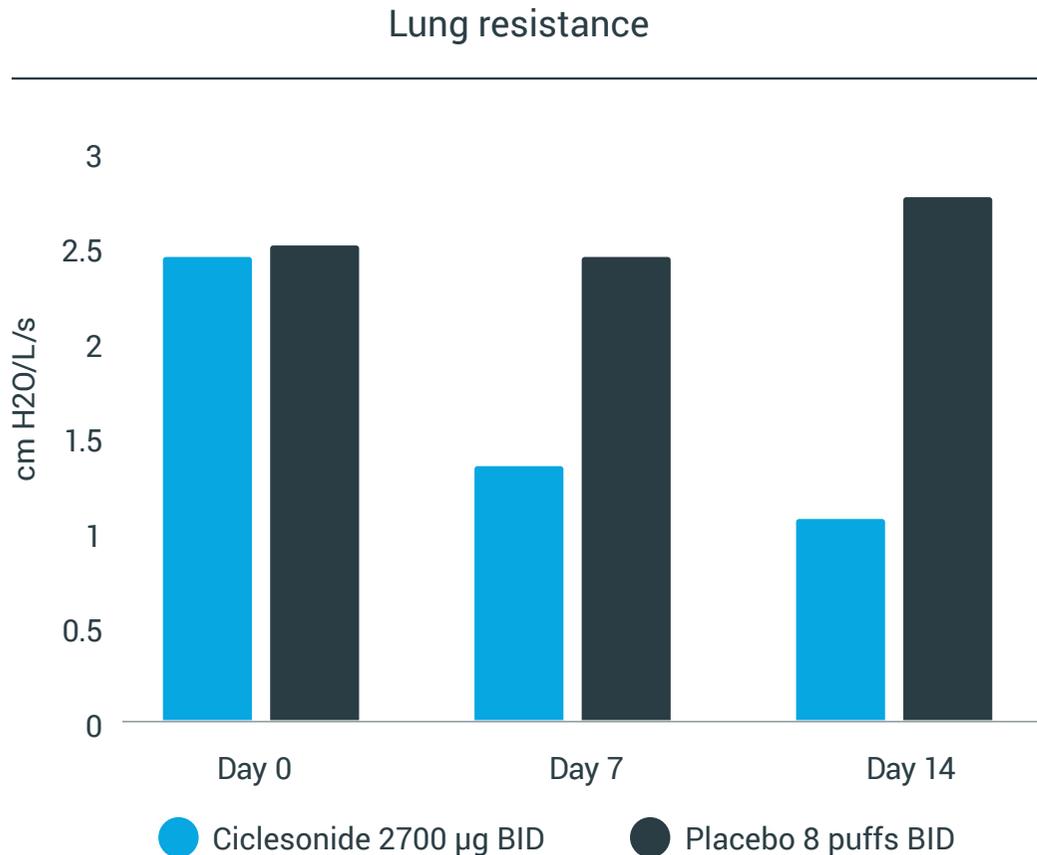


In healthy horses at 3x the dose and 3x the duration ²³



Aservo[®] EquiHaler[®] has been used in horses diagnosed with PPID with no relevant adverse events. ^{21, 22}

PROOF OF CONCEPT: Pulmonary function is the gold standard of evidence



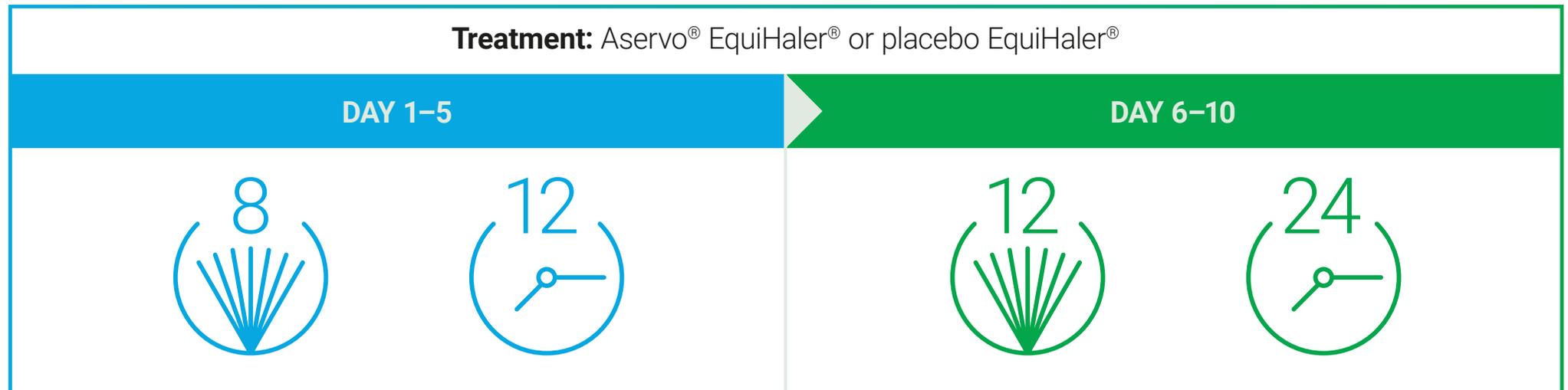
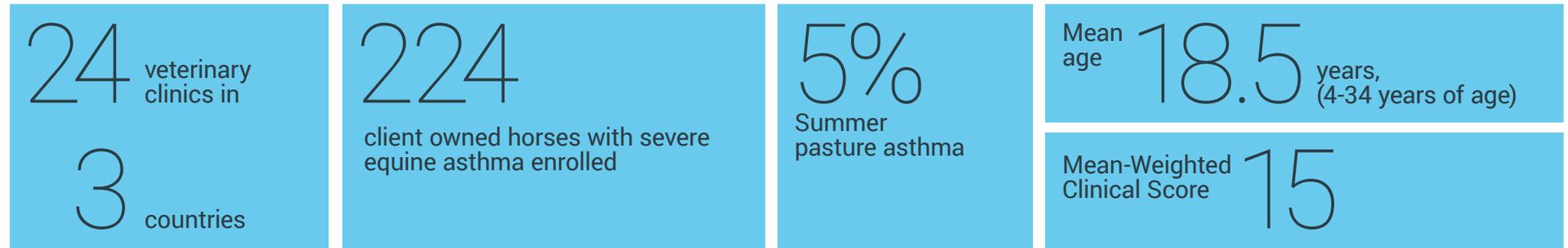
Inhaled ciclesonide significantly improved lung function in horses with severe equine asthma in a moldy hay challenge.¹⁹

Moldy Hay Challenge Model: Horses were fed moldy hay throughout the study. Exposure to moldy hay is an experimental model to induce airway obstruction and exacerbations in asthmatic horses.

EFFICACY European Pivotal Study²¹



Prospective, multicenter, double blind, randomized, placebo-controlled clinical trial



How severe is severe Equine Asthma?

Variable	Descriptor	Score
Respiratory rate (breaths/min)	<16	0
	16-20	1
	21-25	2
	26-30	3
	>30	4
Nasal discharge	None	0
	Serous	1
	Mucopurulent	3
Abdominal lift	None	0
	Mild (perceptible heave line)	1
	Pronounced (abdomen, thorax, and anal movement)	3
Nasal flaring	None	0
	Present	1
Tracheal sounds	Normal (tubular sound)	0
	Increase in intensity	1
	Mucus movement	3
Bronchial tones	Normal	0
	Audible ventral and dorsal sounds	2
Crackles	None	0
	Present	2
Wheezes	None	0
	Present	2
Cough	None	0
	Inducible by tracheal massage	1
	Intermittent	2
	Paroxysmal	3
Total (maximum)		23

Weighted Clinical Score is a 23- point scoring system that provides a systematic way of performing a detailed clinical examination to evaluate the equine respiratory system.

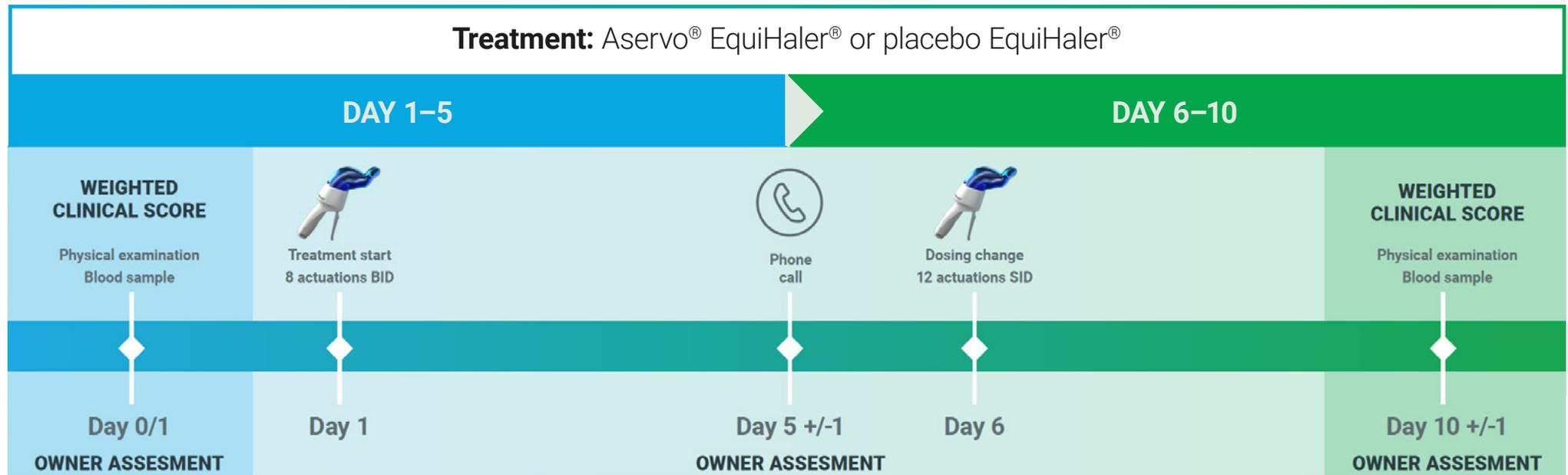
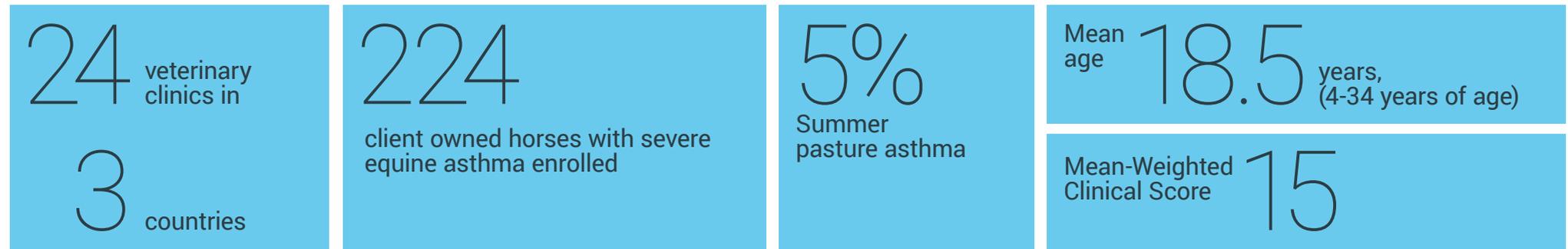
Clinical scores are helpful in both **diagnosis** of equine asthma and assessment of **treatment response**.²⁸

Weighted Clinical Score (WCS) **positively correlated** with severity of pulmonary obstruction in severely asthmatic horses.¹⁹

EFFICACY European Pivotal Study²¹



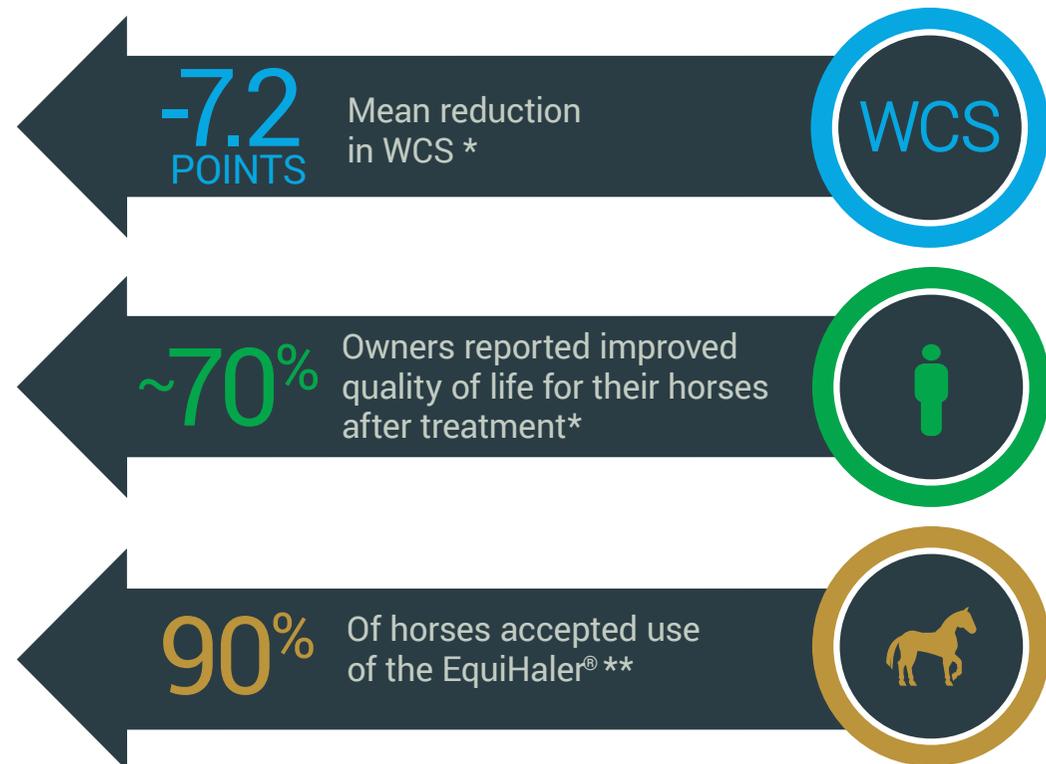
Prospective, multicenter, double blind, randomized, placebo-controlled clinical trial



EFFICACY of ciclesonide for horses with severe equine asthma²¹

Efficacy - EU study results:

Ciclesonide treatment was significantly **better** at improving **clinical signs** of severe equine asthma as compared to placebo (P<0.0001) after **10 days** of administration.



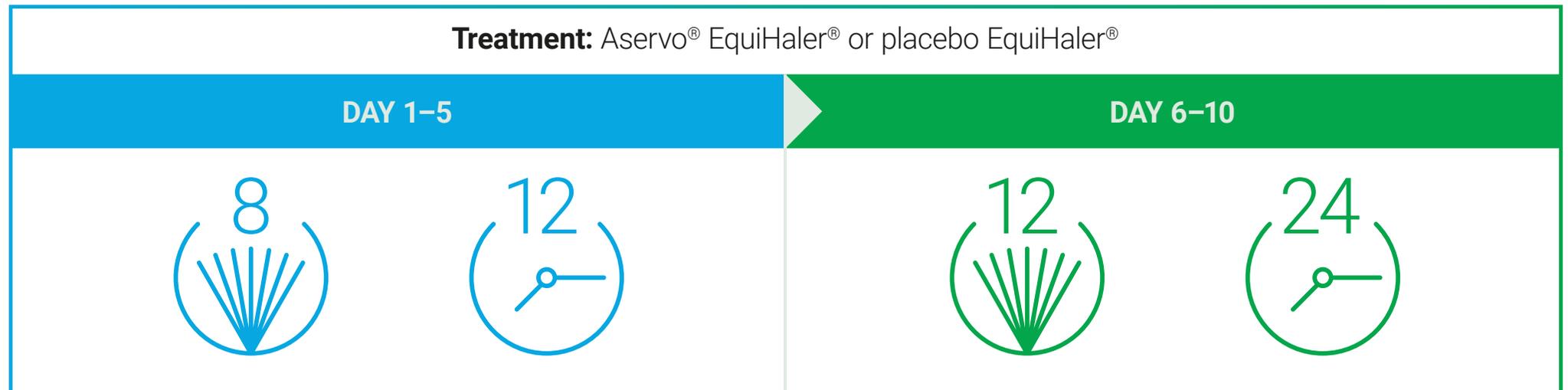
* For ciclesonide group

** For both groups (out of screened horses)

EFFICACY US Pivotal Study²²



Prospective, multicenter, double blind, randomized, placebo-controlled clinical trial



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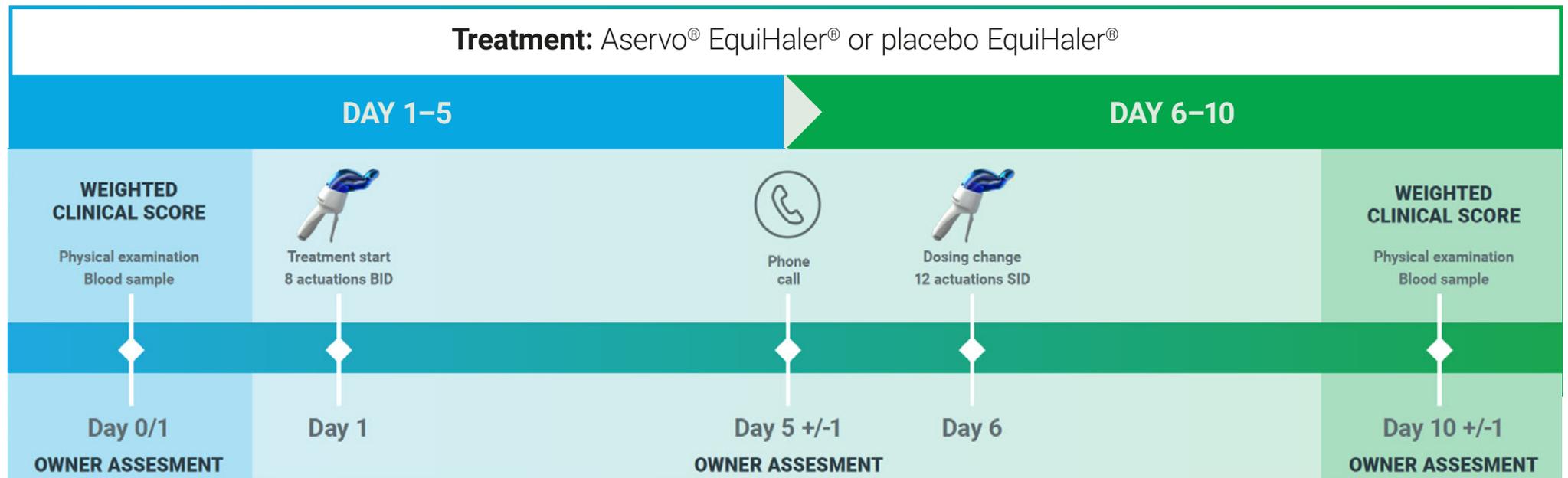
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EFFICACY US Pivotal Study²²



Prospective, multicenter, double blind, randomized, placebo-controlled clinical trial



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