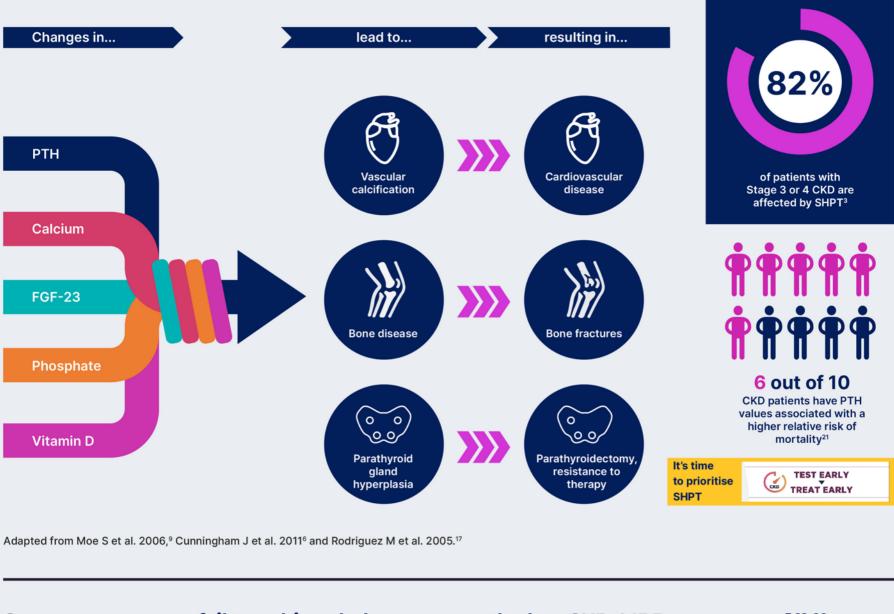


Up to

SHPT is part of the broader systemic syndrome CKD-MBD.9 Characterised by excessive PTH secretion and hyperplasia of the parathyroid glands, 6 SHPT is associated with negative consequences if left unmanaged 5-20



Current treatments fail to achieve balance across the key CKD-MBD parameters<sup>3,22-26</sup>

NVD IR calcifediol

The optimal treatment for SHPT in patients with Stage 3 or 4 CKD would:3

Ca

Rayaldee® is an oral,

429 adult patients

PTH responder rates increased with duration of

therapy throughout the 52 weeks<sup>2,3</sup>

(>30% PTH reduction)

40%\*\*\*

22%\*

110

100

90 -

110 •

100

90

80

70

60

4.5

4.0

3.5

10.5

10.0

0

4

8

12

Serum 25D<sup>2</sup>

0

8

12

16

50%\*\*\*

prolonged-release

formulation of 25D

Reduce PTH by increasing serum 25D to the sufficient level

## 25D PTH

25D

address this:3,22-28

Optimal treatment<sup>3</sup>

ergocalciferol)3,22-25

(e.g. paricalcitol)3,2

NVD (cholecalciferol and

AVD and AVD analogues

Nutritional vitamin D, active vitamin D and active vitamin D analogues fail to

++

+

-0

Effects on key CKD-MBD parameters

0

0

0

0

Which is required for

sustained PTH

open-label

(n=298)

PTH responder rates were reliably maintained across

advancing stage3t

(>30% PTH reduction at Weeks 20-26)

38%\*\*

3%

CKD stage 4

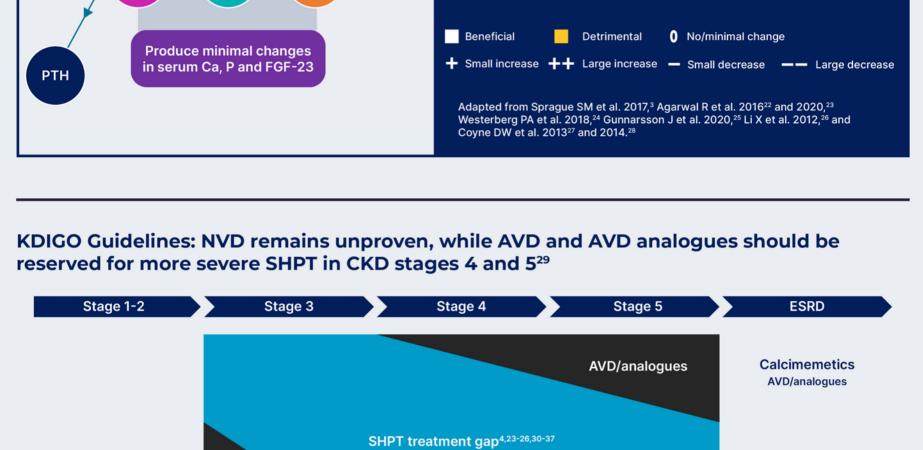
41% \*\*

suppression4,38-40

FGF-23

0

0



with CKD Stage 3 or 4 and vitamin D insufficiency or deficiency<sup>1</sup>

It gradually raises and

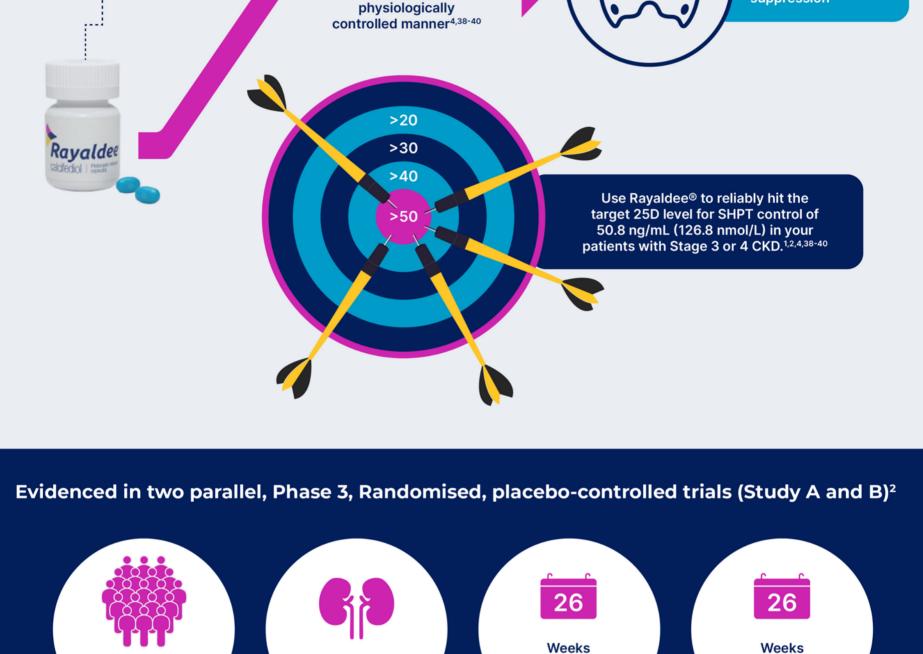
maintains 25D above

50.8 ng/mL

(126.8 nmol/L) in a

Rayaldee® is now approved for the treatment of SHPT in adults

Rayaldee® gradually increases 25D to the level required for sustained PTH suppression<sup>4,38-40</sup>



placebo-controlled

Primary endpoint: number (n, %) of patients in the ITT population who attained a mean decrease of

≥30% in PTH after 26 weeks2

Placebo (per protocol population)

\*p<0.05

\*\*p<0.01

\*\*\*p<0.0001

†Figures estimated from Kaplan-Meier<sup>3</sup>

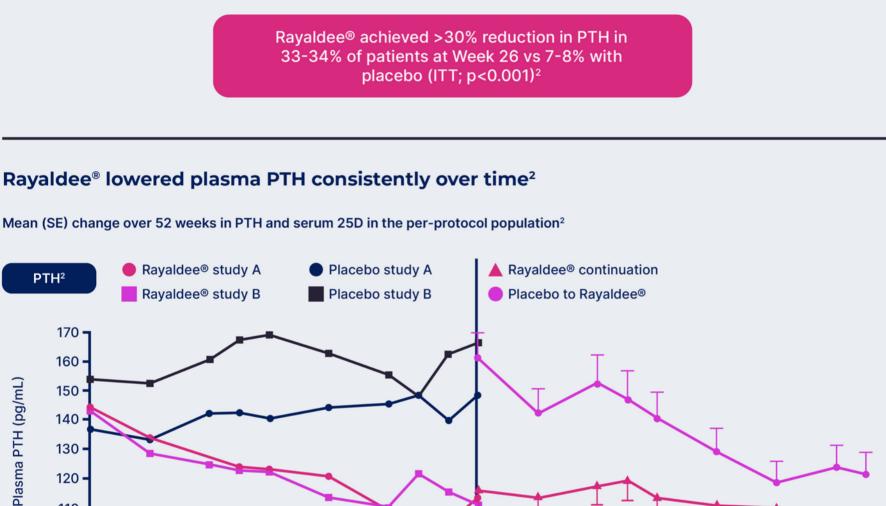
## 12% <8%

Rayaldee® significantly, reliably and sustainably reduces PTH vs placebo<sup>2</sup>

Primary endpoint: 1/3 patients achieved ≥30% PTH reduction with Rayaldee® at Week 26 (ITT population)<sup>2</sup>

with Stage 3 or 4 CKD

## Week 12 Week 26 Week 52 Week 12-26 CKD stage 3



24

Time (weeks)

28

32

36

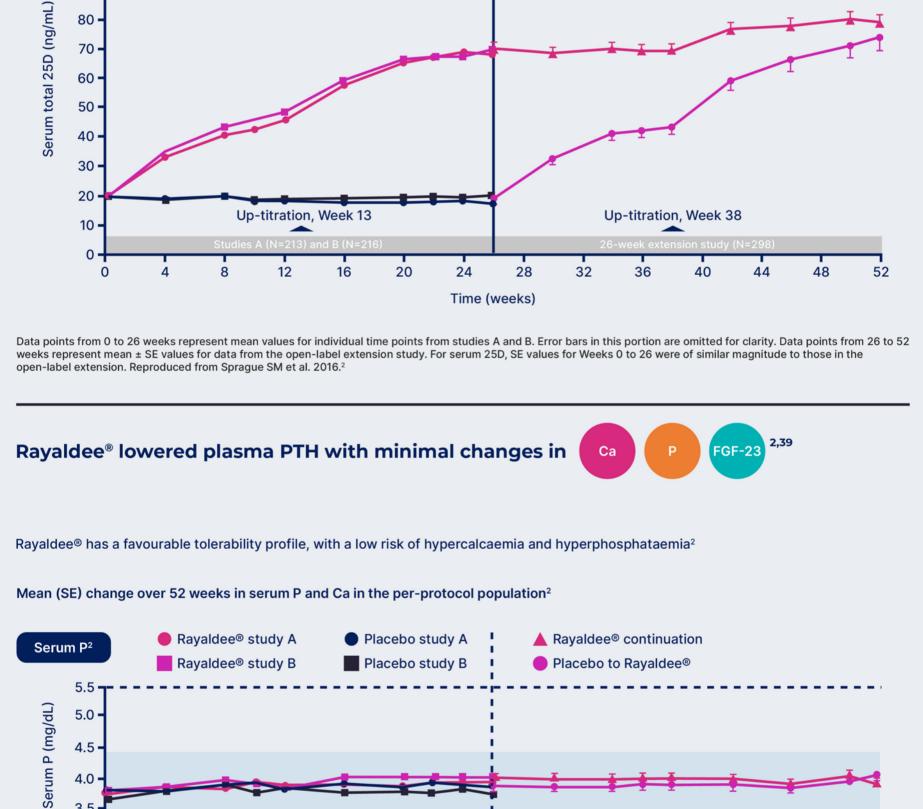
40

44

48

52

20



Physiological range: 2.5-4.5 mg/dL (0.8-1.5 mmol/L) Serum Ca<sup>2</sup>

20

Hyperphosphataemia: two consecutive serum p values >5.5 mg/dL (>1.78 mmol/L)

24

Time (weeks)

28

32

36

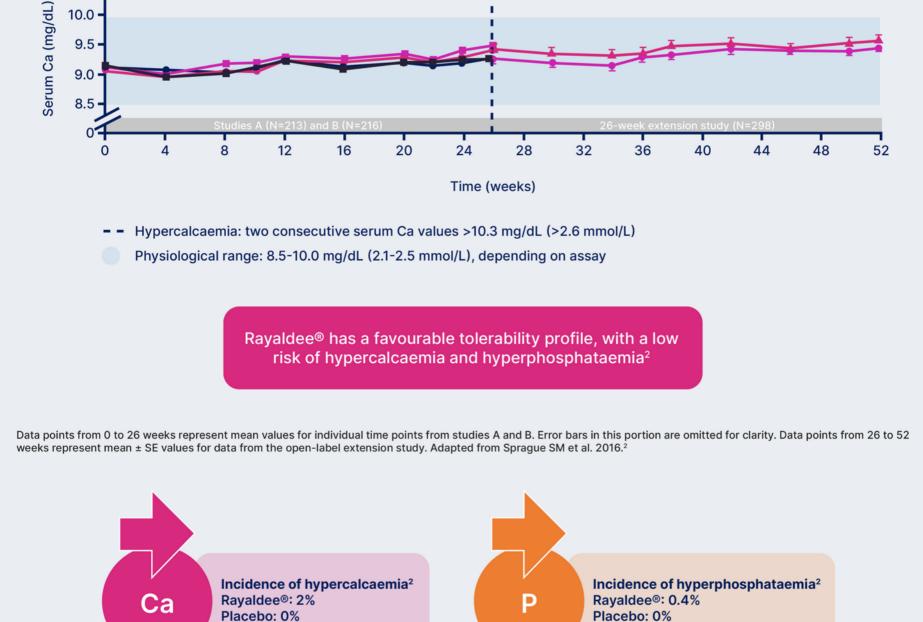
40

44

48

52

16



**Treatment with Rayaldee® achieves balance across** the key CKD-MBD parameters1-4

25D = 25-hydroxyvitamin D; AVD = active vitamin D; Ca = calcium; CKD = chronic kidney disease; CKD-MBD = chronic kidney disease—mineral and bone disorder; ESRD = end stage renal disease; FGF-23 = fibroblast growth factor-23; IR = immediate release; ITT = intention-to-treat; KDIGO = Kidney Disease: Improving Global

Outcomes; NVD = nutritional vitamin D; P = phosphate; PTH = parathyroid hormone; SE = standard error; SHPT = secondary hyperparathyroidism.

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