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Diurnal Group plc

Global Leader in Endocrinology
Specialty Pharmaceuticals

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Investment Profile

	Global Markets	<ul style="list-style-type: none">• \$9.6bn market opportunity• Revenue-generating• Initial target: >\$3bn cortisol deficiency market
	Specialists in Rare Endocrine Disorders	<ul style="list-style-type: none">• Initial focus on unmet patient needs in adrenal insufficiency (AI), congenital adrenal hyperplasia (CAH) and hypogonadism
	In-Place Marketing Expertise	<ul style="list-style-type: none">• Established direct sales force in key territories in Europe• Forging commercial partnerships globally
	Pipeline Expansion	<ul style="list-style-type: none">• Line extension opportunities to related indications• Earlier pipeline product maturing• Potential to expand through in-licensing opportunities
	Strong Commercial Exclusivity	<ul style="list-style-type: none">• Robust protection in key markets• Granted patent exclusivity for lead products until 2034 + orphan drug designation¹ and regulatory exclusivity and patents
	Experienced Management	<ul style="list-style-type: none">• Established record in biotech, pharma, & financial sectors• World-recognized leader in endocrinology

1. Conditional and subject to grant of market authorization (and that Diurnal is the first sponsor to obtain market authorization for the relevant product and demonstrating significant clinical benefit).

Global Leader in Endocrinology Specialty Pharmaceuticals



Alkindi® & Alkindi Sprinkle®¹	1 st product designed specifically for children with AI & CAH	<ul style="list-style-type: none"> Launched: Europe and UK Launched: US Approved: Israel & Australia
Efmody®²	1 st hydrocortisone product closely mimicking cortisol circadian rhythm in adults & adolescents	<ul style="list-style-type: none"> Launched: Europe and UK



Name	Indication	Pre-clinical	Phase I	Phase II	Phase III	MAA/NDA	Est. regulatory opinion	Annual Addressable Market
Chronocort®	Congenital adrenal hyperplasia	US					2025	\$106m
	Adrenal insufficiency	EU US					2023 TBC	\$2,932m
DITEST™	Classical hypogonadism	US					2026 TBC	\$5,069m
		EU						
T3 modified-release	Hypothyroidism (T4 non-responders)	EU US					TBC TBC	\$656m
Oligonucleotide (siRNA)	Cushing's disease	EU US					TBC TBC	\$491m

Source: Company estimates based on Datamonitor Report (2015), pricing from British National Formulary (No. 80) and GBP:1.38 USD exchange rate.

1. Alkindi® is marketed under the brand name Alkindi Sprinkle® in the US. 2. Development name: Chronocort®.

Experienced Leadership: Bridging Discovery, Development, and Commercialization



Sam Williams

Interim Chairman

- 20+ years working in biotech
- Previous experience: top-ranked equity analyst and subsequently, as an entrepreneur and CEO
- Managing Partner of Life Sciences at IP Group plc and Non-Executive Chairman and/or Director for several portfolio companies



Martin Whitaker PhD

Chief Executive Officer

- 20+ years working in pharma and biotech
- Previous positions: Pfizer and Critical Pharmaceuticals
- Founder: D3 Pharma; successfully commercialized Plenachol®, a high-dose Vitamin D product



Richard Bungay

Chief Financial Officer

- 25+ years in senior financial positions
- Non-Executive Director at Cambridge Cognition
- Previous CFO positions: Mereo Biopharma, Glide Technologies, Verona Pharma, and Chroma Therapeutics
- Previous positions: Celltech and AstraZeneca



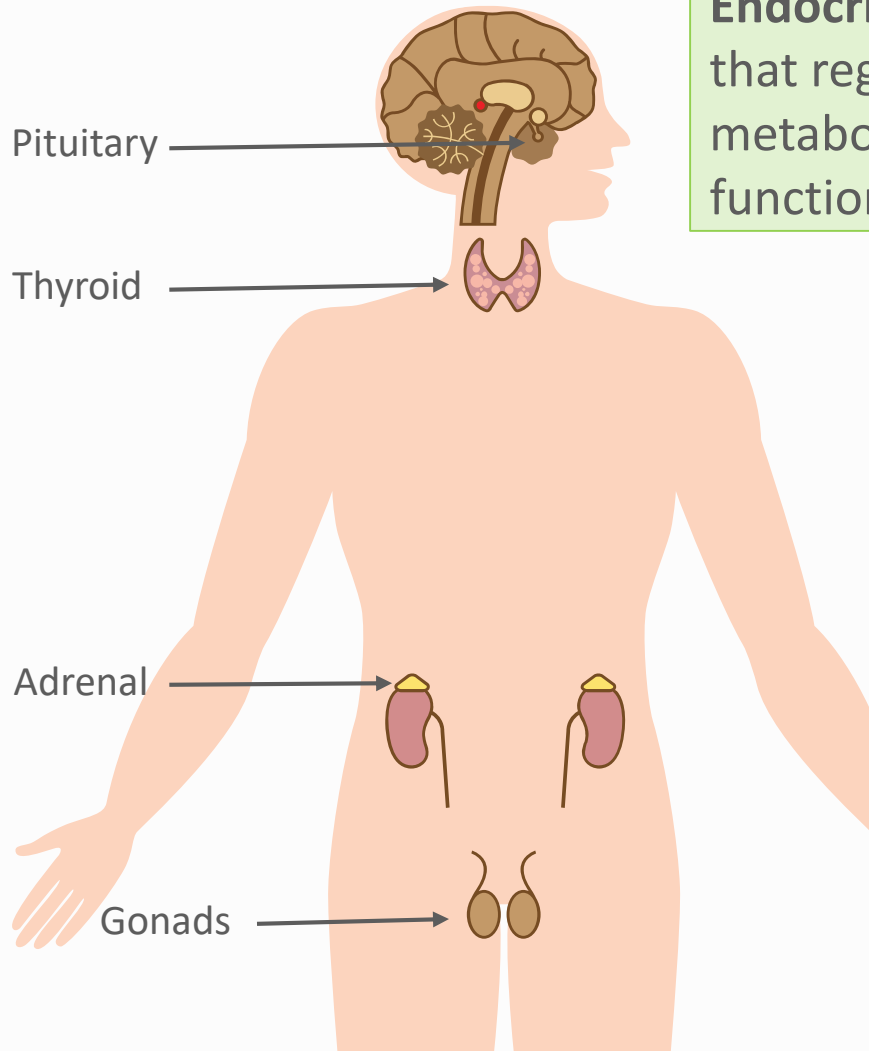
Richard Ross MD

Chief Scientific Officer

- 30+ years in senior medical positions
- Diurnal founder, world-leading endocrinologist & industry key opinion leader
- Professor of Endocrinology, University of Sheffield
- Recognized by the Endocrine Society's 2021 Laureate Awards for Outstanding Innovation


The Endocrine System Is Critical To Life

Endocrine system: hormone-producing glands that regulate vital body functions – including metabolism, growth and development, sexual function, reproduction, sleep, and behavior



Endocrine disorders can cause:

- **Chronic diseases** – including adrenal insufficiency, diabetes, hypogonadism, hypo- and hyperthyroidism
- **Life-long treatments** – often starting in infancy; dose adjustments often required
- **Serious health impact** – often associated with high morbidity and higher mortality




Building a “Life-Long” Adrenal Franchise

Alkindi®¹ & Alkindi Sprinkle®²

1st hydrocortisone product specifically designed for children (from birth to adolescence) suffering from AI and CAH

Efmody®

1st modified-release hydrocortisone product that mimics the physiological circadian rhythm of cortisol for the treatment of CAH in adolescents (>12 years) & adults in Europe

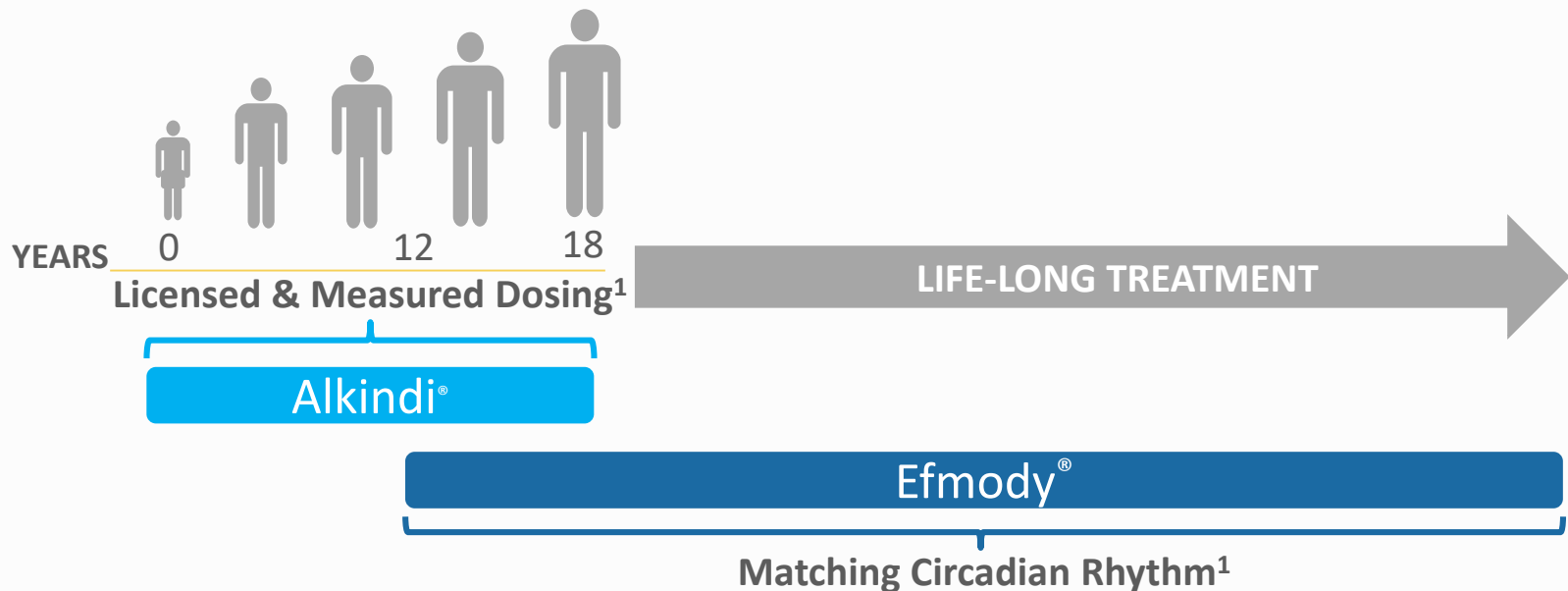


1. Alkindi® (hydrocortisone granules in capsules for opening); for children <18 years in Europe.

2. Alkindi Sprinkle® is the brand name sold in the US; for children <17 years in US.

Building a “Life-Long” Adrenal Franchise



Approx. 350,000+ children and adults in the EU and UK are estimated to have AI and/or CAH



Adrenal Insufficiency (AI) – A condition in which the adrenal glands lose their ability to produce hormones, including cortisol

Congenital Adrenal Hyperplasia (CAH) – Patients are born without an enzyme that stimulates the adrenal glands to release the hormone cortisol

Cortisol Deficiency Market Opportunity

	Prevalence (Estimated no. of patients)		
			Total
Pediatric AI (including CAH)	10,045	4,158	14,203
CAH adults	41,389	16,357	57,746
AI adults	298,299	154,793	453,093
Total	349,734	175,308	525,042



Alkindi®¹ & Alkindi Sprinkle®²

1st hydrocortisone product specifically designed for children
(from birth to adolescence) suffering from AI and CAH



1. Alkindi® (hydrocortisone granules in capsules for opening); for children <18 years in Europe.
2. Alkindi Sprinkle® is the brand name sold in the US; for children <17 years in US.

Alkindi® and Alkindi Sprinkle®:¹ 1st Product Specifically Designed for Newborns and Children With AI and CAH



Patient Need

- Despite hydrocortisone being available for over 60 years, in the majority of territories there are **no licensed pediatric formulations** available to effectively treat AI and CAH²



Market Size

- Launched and revenue-generating
- Targeting the niche **\$0.2bn** pediatric cortisol deficiency market



Product/Innovation

- **No compounding** / parents crushing tablets for their children
- **Accurate, flexible and easy dosing**
- **Taste masked** to aid-compliance



Patent

- **Granted patents** until 2034 – orphan drug designation in US and regulatory exclusivity in Europe



In-Place Marketing Expertise

- Established **direct sales force** in key European territories

1. Available in the US under the brand name Alkindi® Sprinkle. 2 Living with CAH. <https://www.livingwithcah.com> . NIH. <https://www.niddk.nih.gov/health-information/endocrine-diseases/adrenal-insufficiency-addisons-disease/definition-facts>.

Establishing a Global Presence Through Expanded Partnerships

Alkindi® & Alkindi Sprinkle®¹

United States



- **License Agreement** with Eton Pharmaceuticals executed H1 2020
- **NDA Approved** September 2020
- **Launched & Available** November 2020 thru licensing partner Eton Pharmaceuticals

Rest of the World

Canada



Agreement extended with Eton Pharmaceuticals

China



Licensed; agreement with Citrine (inc. Taiwan, Macau and HK)

Australia



Approved (all ages); marketing & distribution agreement with Chiesi²

Turkey



Named patient; Distribution agreement with Er-Kim

Israel



Approved; marketing & distribution agreement with Medison

Japan



Seeking regulatory pathway confirmation

1. Available in the US under the brand name Alkindi® Sprinkle. 2. Marketing and distribution agreement with Emerge Health Pty (now Chiesi Australia Pty Ltd part of Chiesi Farmaceutici S.p.A.).
NDA = New Drug Application (FDA).

Generating Revenues with Significant Exclusivities

Alkindi®

European Medicine Agency Authorizations

- Launched 2018 with data and market exclusivity for 10 years (PUMA¹)
- 2 granted European patents; protection until 2034



Launched

UK, Germany,
Austria, Sweden,
Denmark, Norway,
Iceland & Italy



Distribution Agreements*

Frost Pharma –
Nordic Countries
Consilient/Goodlife –
Benelux Countries
EffRx –Switzerland



Pricing Agreement

The Netherlands

*Outside core territories

Nordic Countries = **Finland, Denmark, Norway, Sweden & Iceland**

Benelux Countries = **Belgium, the Netherlands & Luxembourg**

1. Pediatric Use Market Authorization.

Alkindi® and Alkindi Sprinkle®¹: Approval Supported By Clinical Study Results

Alkindi® & Alkindi Sprinkle®



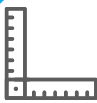
- Only precise, low-dose hydrocortisone granules available in 4 low-strengths for accurate dosing
- No need for compounding pharmacies



Median peak **cortisol levels** were **comparable to** normal ranges in **healthy children**



Well tolerated; no episodes of adrenal crisis or serious adverse reactions during clinical trials



No large declines or increases in growth during ~2.5-year follow-up study

Source: Neumann et al. Clinical Endocrinology (2017) and Neumann et al. JCEM (2021).

1. Available in the US under the brand name Alkindi Sprinkle® subject to an enhanced FDA pharmacovigilance programme

Efmody[®]

1st modified-release hydrocortisone product that mimics the physiological circadian rhythm of cortisol for the treatment of CAH in adolescents (>12 years) & adults in Europe



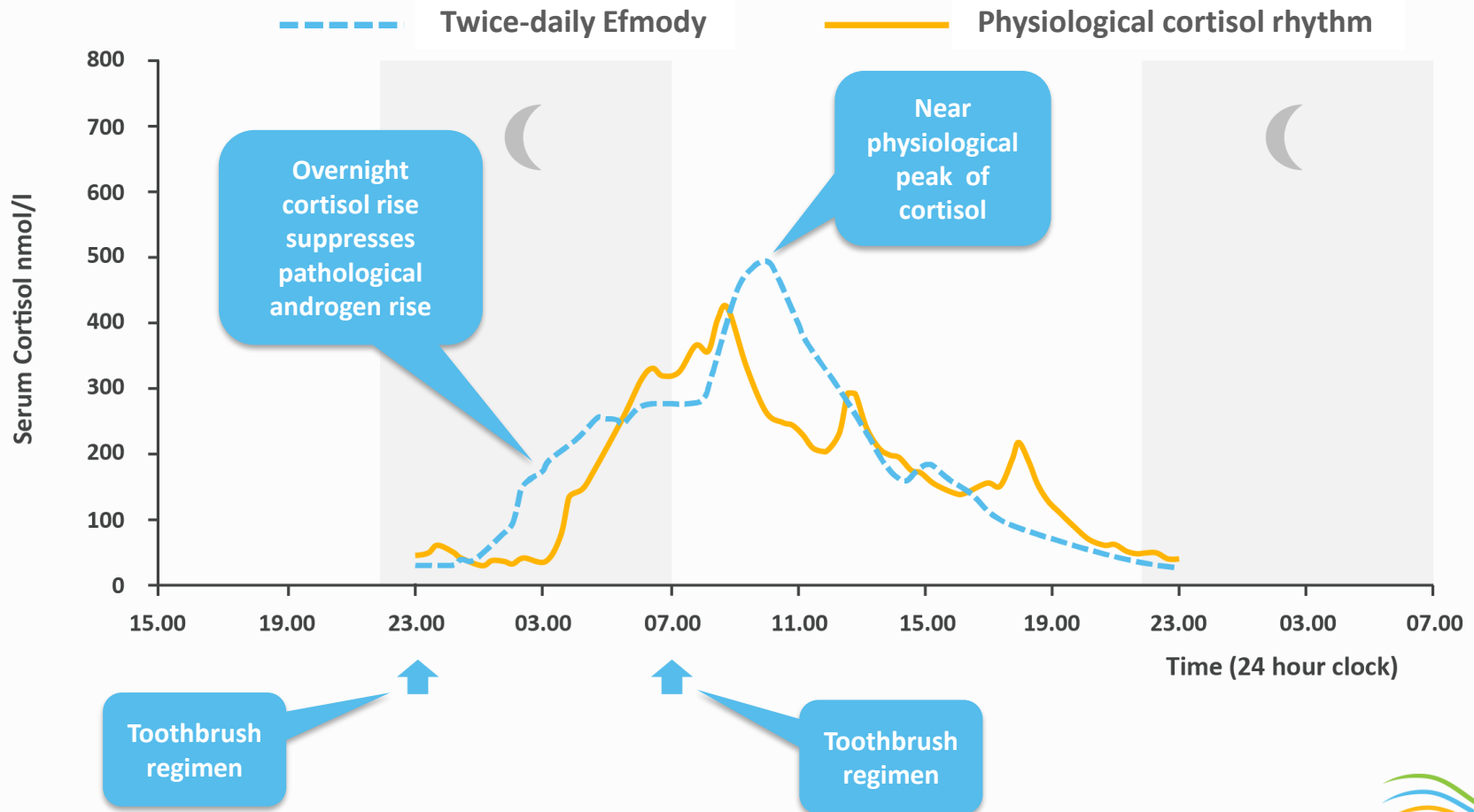
	Patient Needs	<ul style="list-style-type: none"> • No standard treatment regimen leading to high steroid doses used • Poor disease control leading to high morbidity and higher mortality
	Market Size	<ul style="list-style-type: none"> • \$0.3bn market opportunity (Europe & US) for CAH
	Product/ Innovation	<ul style="list-style-type: none"> • Modified-release drug delivery technology mimics physiological cortisol circadian secretion
	Patent	<ul style="list-style-type: none"> • Granted patents until 2034 – orphan drug designation in the US
	In-place Marketing Experience	<ul style="list-style-type: none"> • Existing direct sales force in key territories in Europe
	Pipeline/ Expansion Opportunities	<ul style="list-style-type: none"> • \$2.8bn market opportunity (Europe & US) for AI

Mimics the Physiological Rhythm of Cortisol during the Day and Overnight



Efmody®

First physiological treatment of adults and adolescent patients with congenital adrenal hyperplasia (CAH) in Europe¹

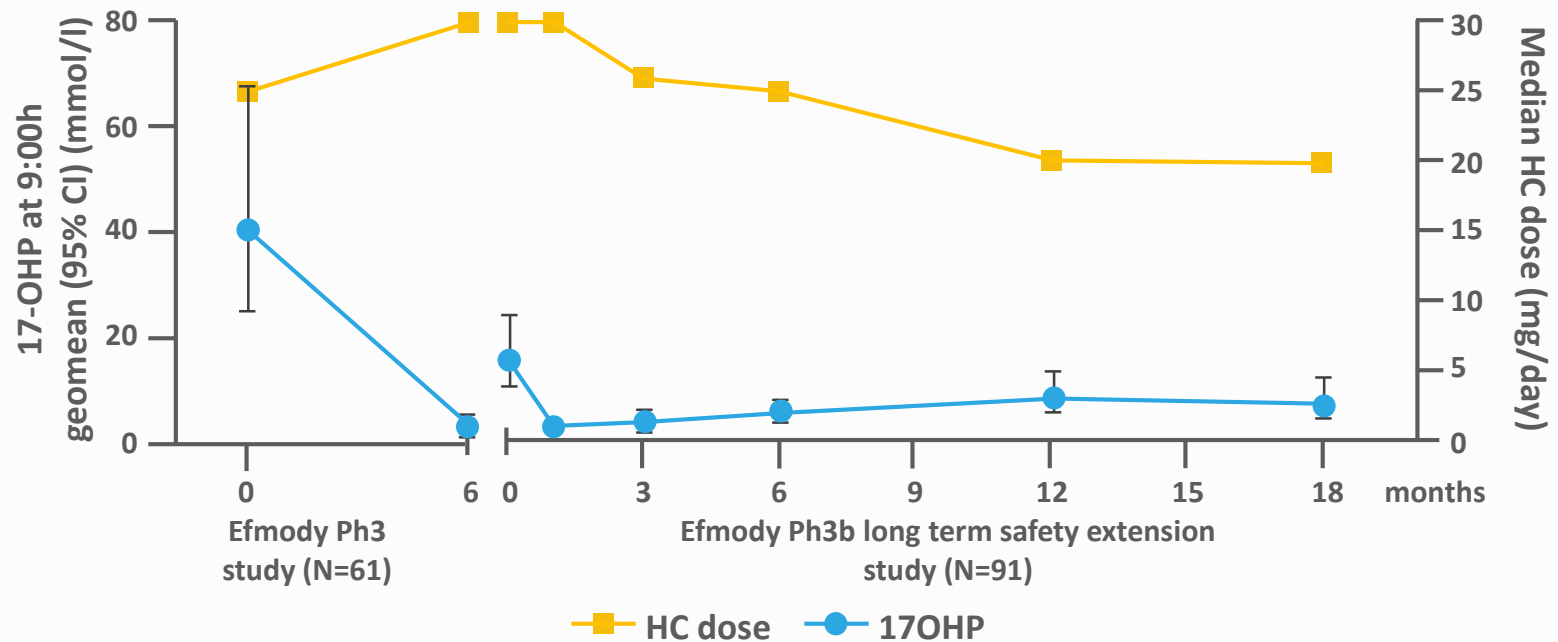


1. European Public Assessment Report (European Medicines Agency 2021).

Androgen Control in Adults With a Reduction in Steroid Dose



Efmody®



- Despite the primary endpoint being missed, titration during Phase 3 led to similar doses to published cohort studies¹ but better control
 - (90% vs 50%, 09:00 17-OHP <36 nmol/l)
- In the long-term extension study, good disease control was maintained at a reduced daily dose that approximates physiological cortisol release
 - After 18 months the median daily dose was 20 mg
 - 80% of patients had 17-OHP <36 nmol/l at 09:00

Adapted from Merke et al., JCEM 2021.

1. Arlt et al., JCEM 2010; data on file.

Global Presence Through Expanded Partnerships

Efmody®

Europe¹



Approval: Received May 2021

Launch: September 2021

European marketing commercial infrastructure
& supply chain: Existing

Marketing & distribution agreement: Benelux
& Nordics²: Consilient

UK



Approval: Received July 2021

Launch: September 2021

UK marketing commercial infrastructure &
supply chain: Existing

Rest of the World

China



License Agreement: Citrine Medicine

Australia & New Zealand



**Marketing & Distribution
Agreement:** Chiesi

Israel



**Marketing & Distribution
Agreement:** Medison

Turkey



**Named Patient Distribution
Agreement:** Er-Kim

1. Reflects launch in the European Economic Area.

2. Nordic Countries = Finland, Denmark, Norway, Sweden, Iceland; Benelux Countries = Belgium, the Netherlands, Luxembourg.

Efmody®: New Treatment Option for Adolescents and Adults with Classic CAH

Efmody®



Efmody® twice daily approximates physiological cortisol rhythm



Steroid dose reduction after 18 months of treatment



Significantly improved morning biochemical control of 17-OHP (surrogate) at 6 months of treatment



Efmody® was well tolerated. No serious adverse events occurred

Pivotal Phase 3 study for CAH to start Q4, 2021



Special Protocol Assessment (SPA)¹

- Confirmed by the FDA in July 2021
- Provides agreement that the Phase 3 trial design adequately addresses objectives that would support the regulatory submission for drug approval

CONnect:

- A randomized, double-blind, active-controlled, Phase 3 study of Chronocort® compared with immediate-release hydrocortisone replacement therapy in participants aged 16 years and over with congenital adrenal hyperplasia

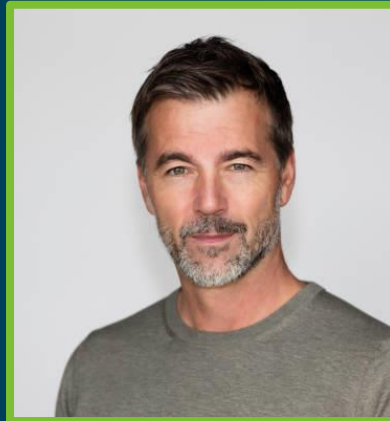
CONnect study design







- Pivotal Phase 3 study for US and will also act as the registration study in Japan
- Primary endpoint is biochemical responder non-inferiority of Chronocort® vs twice daily immediate release hydrocortisone after 52 weeks randomized treatment
- Secondary endpoints include responder analysis to glucocorticoid dose, female and male indicators of fertility, body weight, waist circumference and quality of life measures
- Successful completion of pivotal study entitles patients to enter safety extension study
- 150 congenital adrenal hyperplasia patients
- Up to 50 global study centers planned (US, Japan, France, and Turkey)
- CRO appointed; ethics and regulatory submissions imminent for Q4, 2021 start

1. Special Protocol Assessment Guidance for Industry (2018).

DITEST™

1st Oral, Native Testosterone Product
For Male Hypogonadism



	Patient Needs	<ul style="list-style-type: none"> • Primary hypogonadism: low serum testosterone due to chromosomal defects or direct testicular injury • Secondary hypogonadism: disease (e.g., Prader–Willi) or direct injury to the hypothalamus or pituitary gland (e.g., tumors, radiation)
	Market Size	<ul style="list-style-type: none"> • Targeting the ca. >\$5bn male hypogonadism market • Estimated to affect 4–5 million males in the US
	Product/Innovation	<ul style="list-style-type: none"> • Uses native (i.e., unmodified) testosterone • Delivery method has potential to mimic the natural rhythm of testosterone • Proprietary oil-based formulation
	Patent	<ul style="list-style-type: none"> • Granted worldwide patents to 2030 (composition of matter) • Potential patent protection until 2040 (method of treatment and medical use)
	In-Place Marketing Expertise	<ul style="list-style-type: none"> • Developing strategy to create own commercial infrastructure in the US
	Pipeline/Expansion Opportunities	<ul style="list-style-type: none"> • Potential to expand to pediatric and other indications

DITEST™: Innovative Oral, Native Testosterone Therapy for Male Hypogonadism

Proprietary, Oil-Based Formulation



No meal requirements



Avoids risk of exposure to others, including women and children, from topical formulations



Gels and creams are facing regulatory pressure and safety concerns from the FDA¹



**No painful injections²
No irritating skin patches³**

1. FDA requirement for Testim® and AndroGel® 1% (2015) to have black box warning regarding transference.

2. Shoskes et al Translational Andrology and Urology (2016).

3. Schnabel et al Clinical Endocrinology (2007).

DITEST™: Phase 1 Proof-of-Concept Achieved



DITEST™



Achieved testosterone levels within normal healthy young male range; levels less variable than seen with comparator (oral testosterone undecanoate)



Levels of the potent testosterone derived androgen, dihydrotestosterone (DHT), were lower than with testosterone undecanoate



No serious adverse events seen

DITEST™: Key US Inflection Points



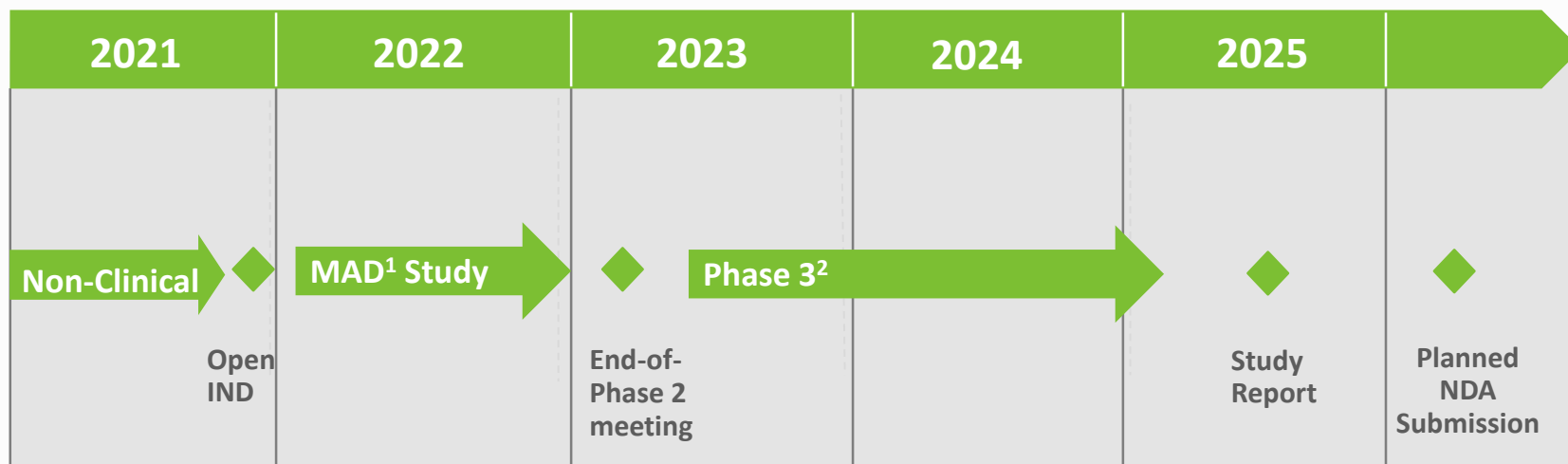
DITEST™

Pre-IND meeting with FDA successfully concluded

- A pre-Investigational New Drug (IND) meeting was completed with the FDA during the period which confirmed that DITEST™ can progress to an NDA via the abbreviated 505(b)(2) route

Investigational New Dossier (IND) submission during Q4, 2021

- IND package preparation, including non-clinical studies, in progress
- IND submission set for Q4, 2021 to allow a Phase 1 multiple ascending dose study to start in the US shortly thereafter in early 2022; CRO appointed and study site ready to go









1. Multiple Ascending Dose study. 2. Subject to further FDA approval and further funding (or partnering).

Outlook

Outlook for 2021 / 2022

Approval of Efmody® by the MHRA in UK	Q3 2021	✓
Conclude Special Protocol Assessment (SPA) for Chronocort® in US	Q3 2021	✓
First commercial launch of Efmody® in Europe	Q3 2021	✓
Start Chronocort® AI line extension study in Europe	Q4 2021	
Start Chronocort® Phase 3 Study in US	Q4 2021	
Submission of DITEST™ IND in US	Q4 2021	
Capital markets day planned	Q4 2021	
Start DITEST™ Multiple Ascending Dose study in US	Q1 2022	

Investment Summary

	Global Markets	<ul style="list-style-type: none">• \$9.6bn market opportunity• Revenue-generating• Initial target: >\$3bn cortisol deficiency market
	Specialists in Rare Endocrine Disorders	<ul style="list-style-type: none">• Initial focus on unmet patient needs in adrenal insufficiency (AI), congenital adrenal hyperplasia (CAH) and hypogonadism
	In-Place Marketing Expertise	<ul style="list-style-type: none">• Established direct sales force in key territories in Europe• Forging commercial partnerships globally
	Pipeline Expansion	<ul style="list-style-type: none">• Line extension opportunities to related indications• Earlier pipeline product maturing• Potential to expand through in-licensing opportunities
	Strong Commercial Exclusivity	<ul style="list-style-type: none">• Robust protection in key markets• Granted patent exclusivity for lead products until 2034 + orphan drug designation¹ and regulatory exclusivity and patents
	Experienced Management	<ul style="list-style-type: none">• Established record in biotech, pharma, & financial sectors• World-recognized leader in endocrinology

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Diurnal Group plc

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APPENDIX

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Selected Historical Financial Information¹

£000	Year ended 30 June 2021	Year ended 30 June 2020	% change
Revenue	4,371	6,313	-31%
Cost of sales	(779)	(668)	+17%
Gross profit	3,592	5,645	-36%
Research and development expenditure	(6,915)	(4,625)	+50%
Selling and distribution expenses	(5,236)	(4,135)	+27%
Administrative expenses	(3,056)	(2,904)	+5%
Other gains - net	15	627	n/a
Operating loss	(11,600)	(5,392)	+115%
Net financial income	62	114	-46%
Taxation	1,489	1,206	+23%
Loss for the period	(10,049)	(4,072)	+147%
Net cash used in operating activities	(10,662)	(4,809)	+122%
Net cash generated by financing activities	28,762	10,670	+170%
Closing cash and cash equivalents	34,037	15,434	+121%

1. Year-end results to 30 June 2021.

Key Investors

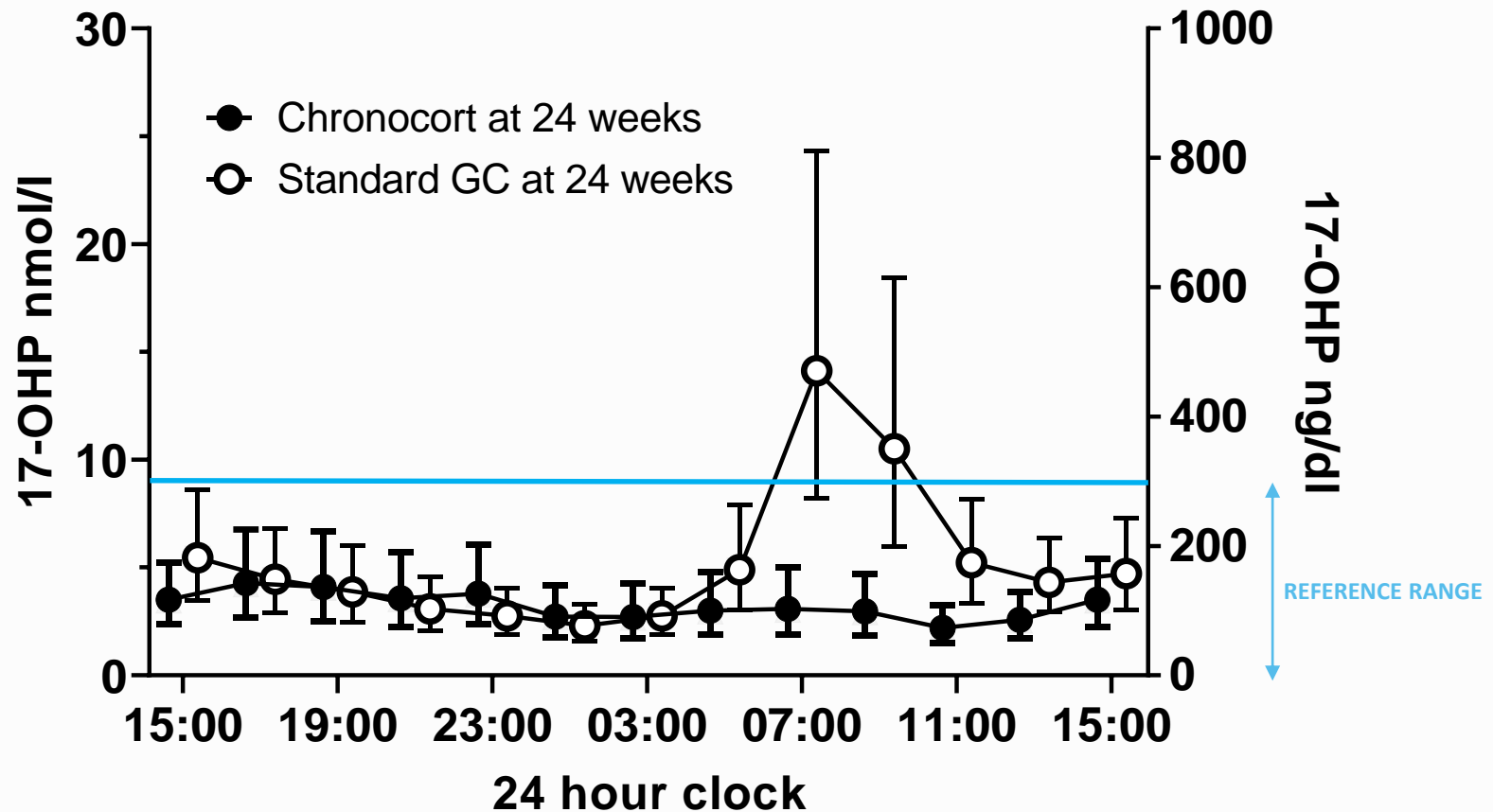


Achieved Significantly Better Control of 17-OHP in the Period 07:00-15:00



Efmody®

Although primary endpoint of superior androgen control over standard of care over 24-hours not met

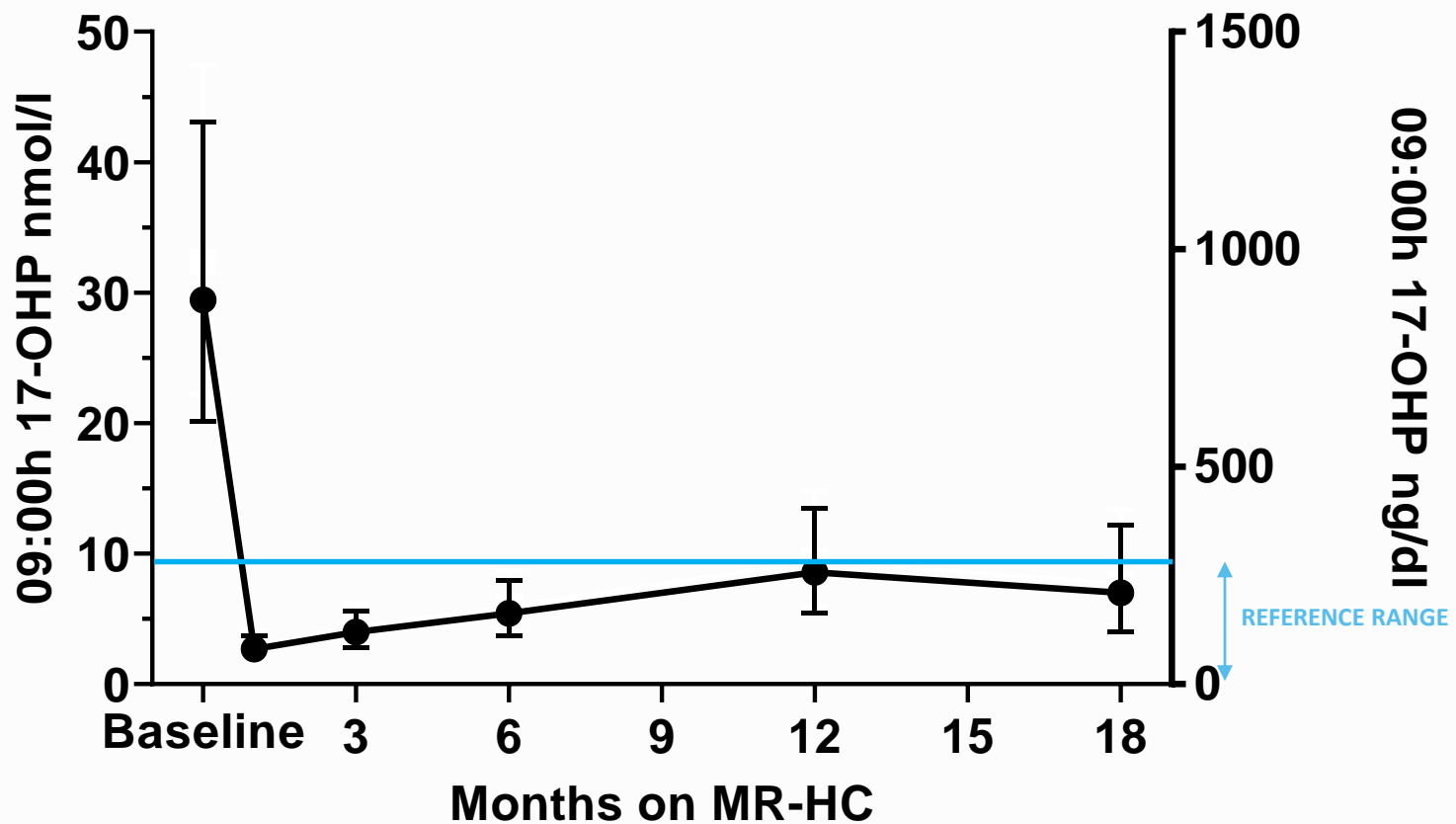


Achieved Sustained Control of Androgens for 18 Months

Efmody® achieved sustained control of androgens for 18 months on lower doses of steroid than normally used to treat Congenital Adrenal Hyperplasia



Efmody®



Median Dose (mg)

30

26

25

20

20

20

Source: Adapted from Merke et al. JCEM (2021).