

A close-up photograph of a person in a white lab coat and orange nitrile gloves holding a glass test tube containing a purple liquid. The background is blurred, showing other lab equipment like pipettes and a beaker with yellow liquid.

# **VIFOR PHARMA**

## **OCTAVIAN SEMINAR 2021**

14 JANUARY 2021

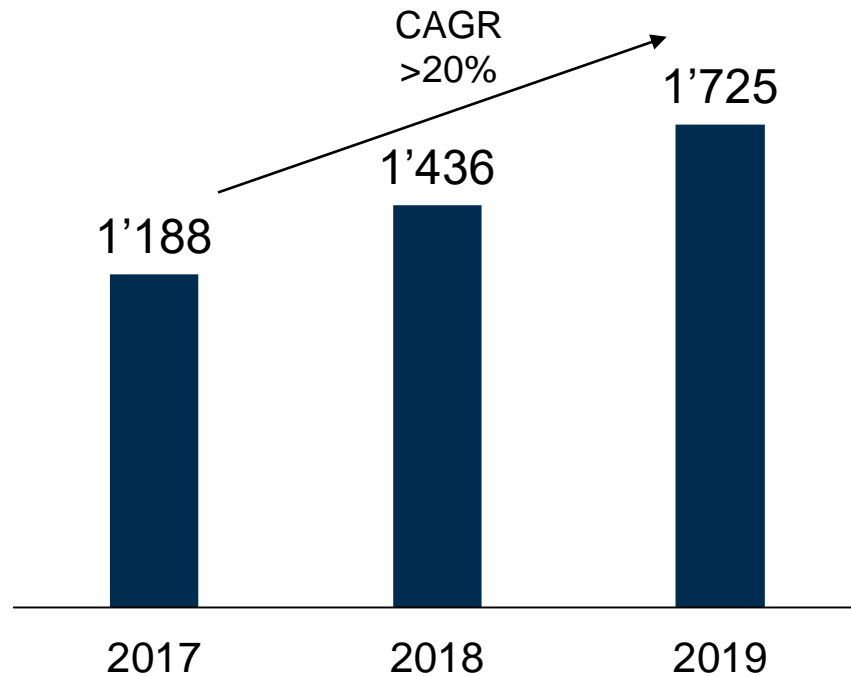
# STRONG TRACK RECORD

## NET SALES AND EBITDA GROWTH



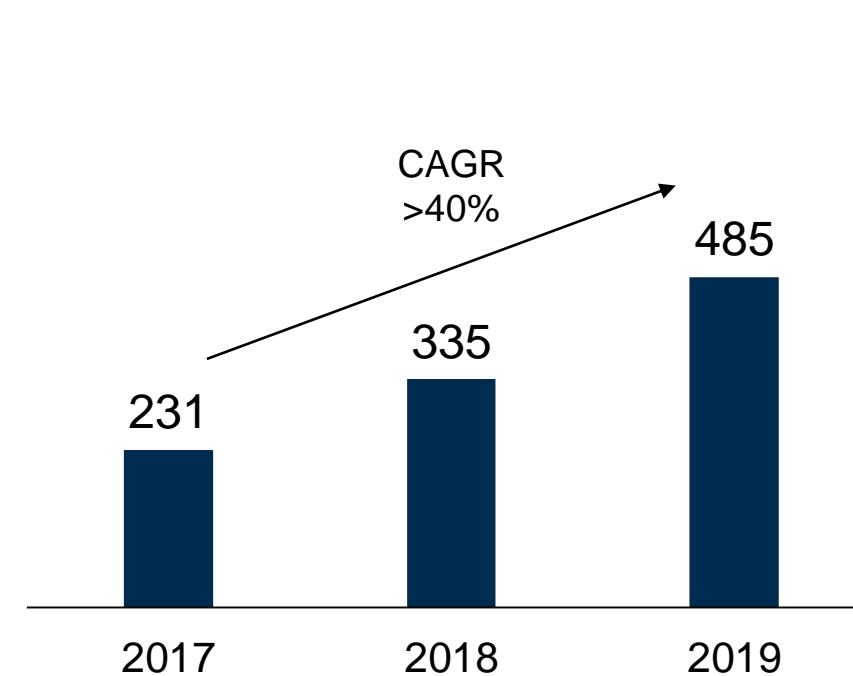
### NET SALES

IN CHF MILLION



### EBITDA

IN CHF MILLION



# STRONG TRACK RECORD

## GUIDANCE 2020<sup>1</sup>



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In 2020, net sales are expected to grow in the range of 5% at constant exchange rates, reported EBITDA is expected to grow in the range of 20%.



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1) Subject to no worsening of the situation due to COVID-19; full-year 2019 net sales and EBITDA excluding OM Pharma of CHF 1'725m and CHF 485m, respectively

# STRONG TRACK RECORD

## KEY ACHIEVEMENTS IN 2020



### CLINICAL TRIALS

- AFFIRM-AHF study of Ferinject® positive readout ✓
- KALM-2 phase-III study of Korsuva™ positive readout ✓
- INNO<sub>2</sub>VATE phase-III study of vadadustat positive readout ✓
- Recruitment in the phase-II study of VIT-2763 in beta-thalassemia started ✓

### MARKET ACCESS

- Ferinject® launched in Japan ✓
- China: Ferinject® and Veltassa® partnered & NDA submission for Ferinject® accepted ✓
- Avacopan filing accepted for review in Europe ✓
- Korsuva™ filed in the US ✓

### BUSINESS DEVELOPMENT

- In-licensing agreement with Cara Therapeutics for Korsuva™ extended ✓
- Worldwide rights<sup>1</sup> of ANG-3777 licensed from Angion Biomedica ✓
- Divestment of OM Pharma strengthens focus on key therapeutic areas ✓

1) Excluding China, Taiwan, Hong Kong and Macau; for all nephrology indications and congestive heart-failure

# LEADING PORTFOLIO IN TARGET THERAPY AREAS



	Iron deficiency	Nephrology	Cardio-renal
<b>Commercial products</b>			
<b>Pipeline products</b>	VIT-2763 <sup>1</sup>	Rayaldee <sup>®2</sup> Avacopan <sup>2</sup> Korsuva <sup>™2</sup> Vadadustat <sup>2 3</sup> ANG-3777 <sup>2</sup>	

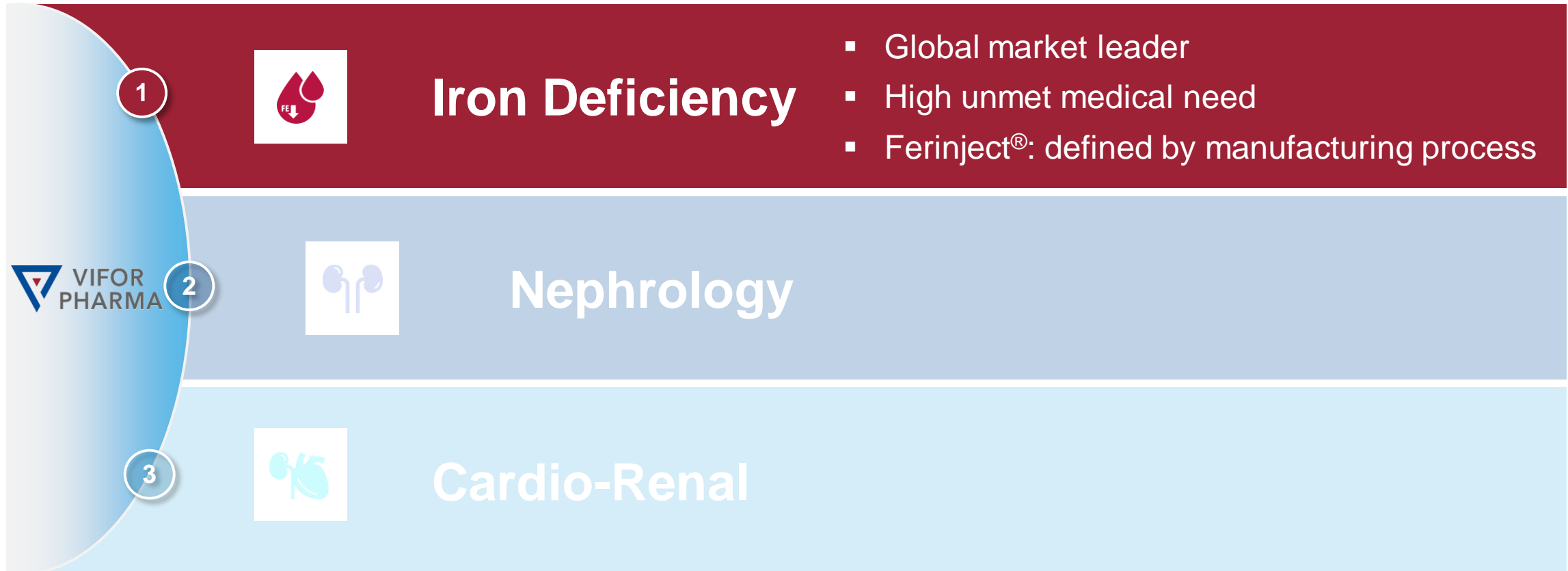
1) Restriction of iron availability, i.e. for treating non-transfusion-dependent thalassemia or sickle cell disease

2) In-licensed products

3) Subject to certain conditions and limited to the US dialysis market

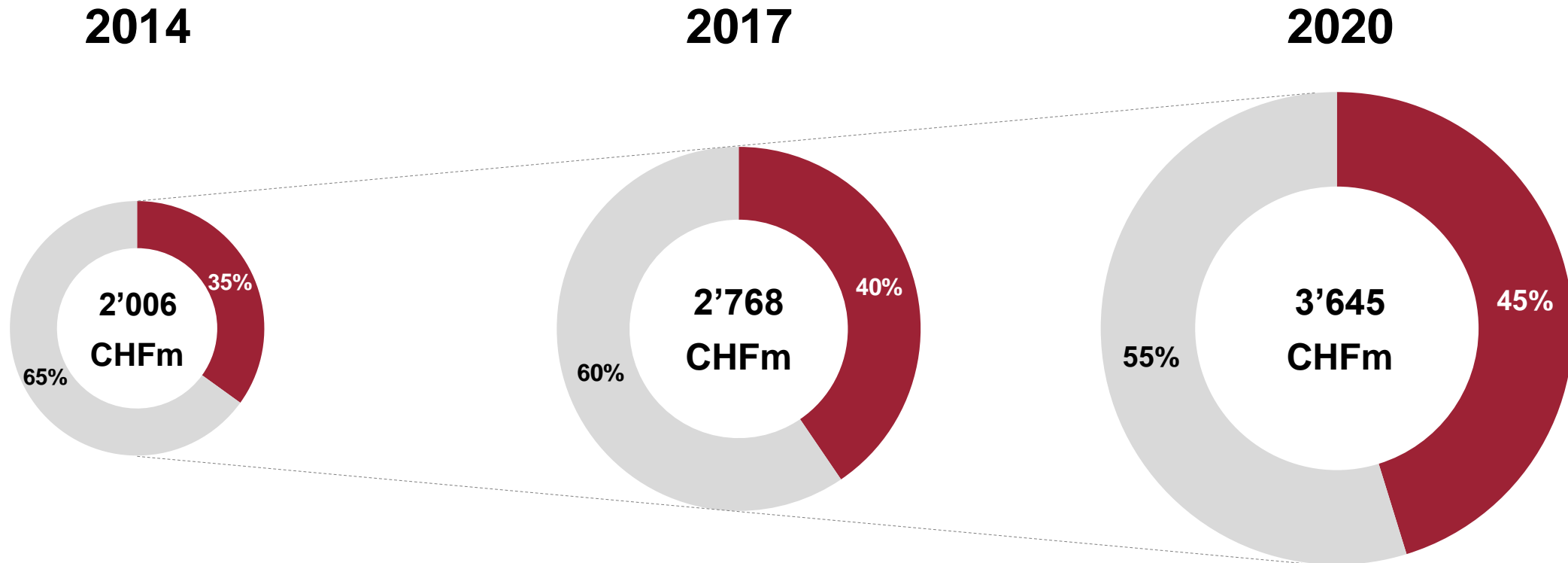
# VIFOR PHARMA STRATEGIC FOCUS

## THREE AREAS AS BASIS FOR FUTURE GROWTH



# IRON DEFICIENCY – MARKET OVERVIEW

## DRIVING OVERALL MARKET GROWTH

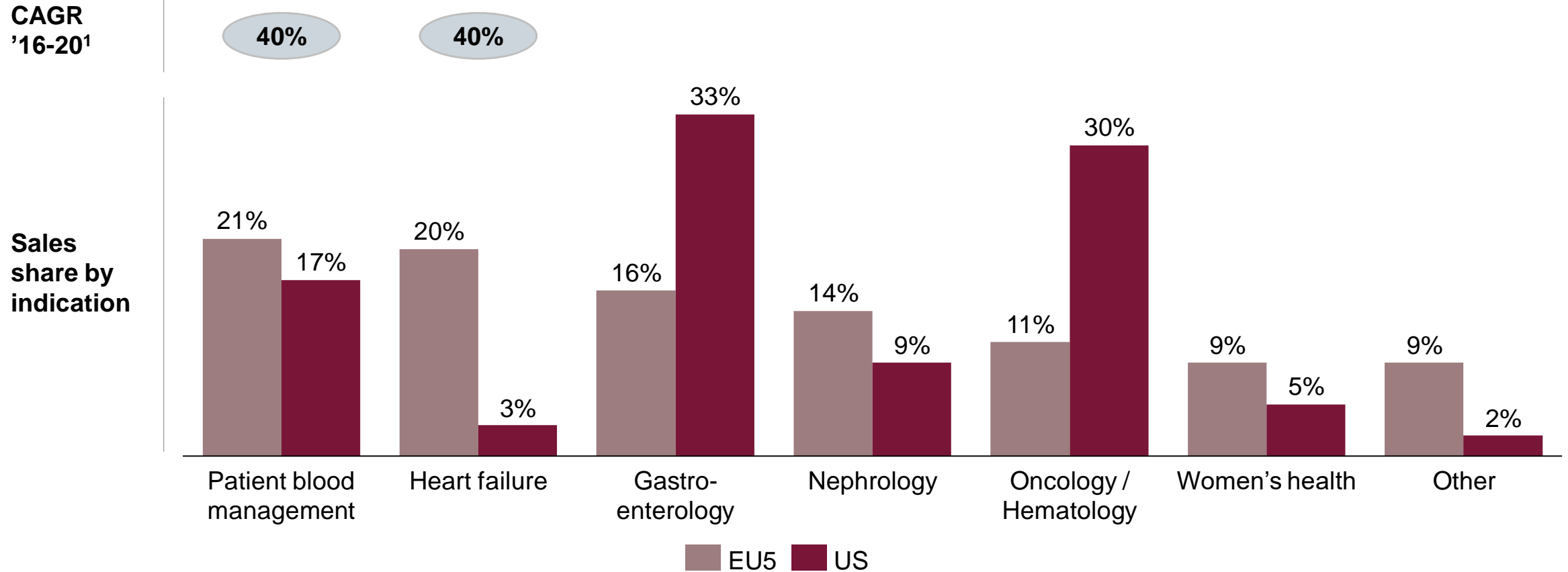


■ Ferinject<sup>®</sup>/Injectafer<sup>®</sup>, Venofer<sup>®</sup> and Maltofer<sup>®</sup>

Source: quarterly IQVIA<sup>™</sup> MIDAS<sup>®</sup> panel, GERS, Insight Health, DLI, moving annual total Q3-2020. Average 2019 exchange rates have been applied

# IRON DEFICIENCY – FERINJECT® INDICATIONS

## INDICATIONS SPLIT DRIVEN BY REGIONAL FOCUS



1) Pre-COVID-19 year-over-year growth rate as per end of Q1 2020

Source: quarterly IQVIA™ MIDAS® panel, GERS, Insight Health, moving annual total Q2 2019-20 in 100mg equivalents; EU5: Germany, France, Italy, Spain and the United Kingdom

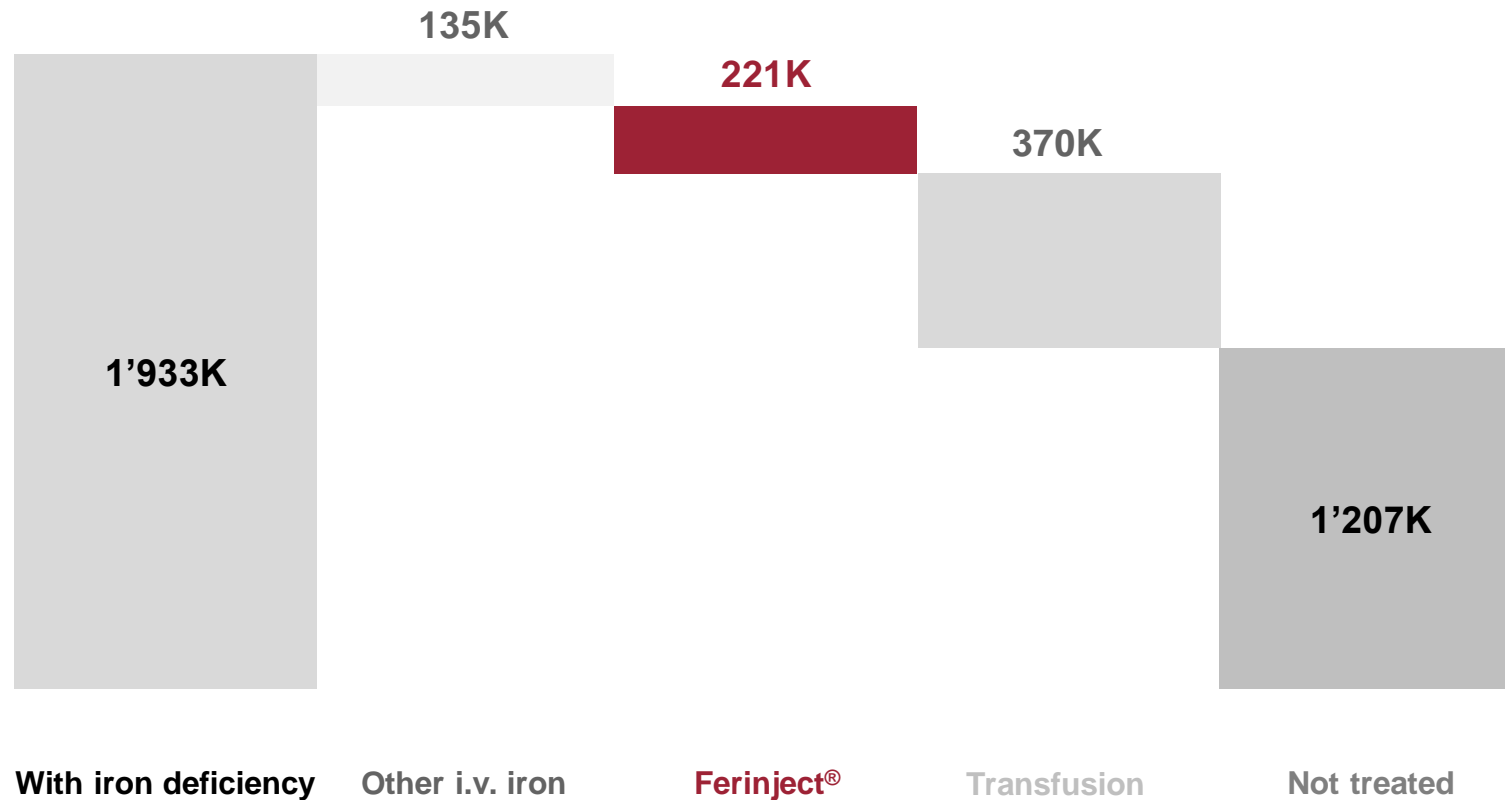


# IRON DEFICIENCY – FERINJECT® PBM<sup>1</sup> EUROPE

## MAJOR GROWTH OPPORTUNITY



### PATIENT DROP-OFF – EU5



- PBM strongly supported by World Health Organization
- Estimated savings per patient of CHF 850 vs usual care<sup>2</sup>
- Additional real world evidence data expected in 2021

Source: Vifor Pharma analysis, 2019, countries included: DE, ES, FR, IT, UK

1) Patient Blood Management

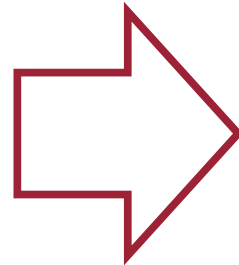
2) Froessler B, et al. Risk Manag Health Policy 2018;11:77–82;

# IRON DEFICIENCY – FERINJECT® MOLECULE

## NANOMEDICINES – LARGE AND COMPLEX STRUCTURE



IRON CARBOHYDRATE  
COMPLEX



### NANOMEDICINES

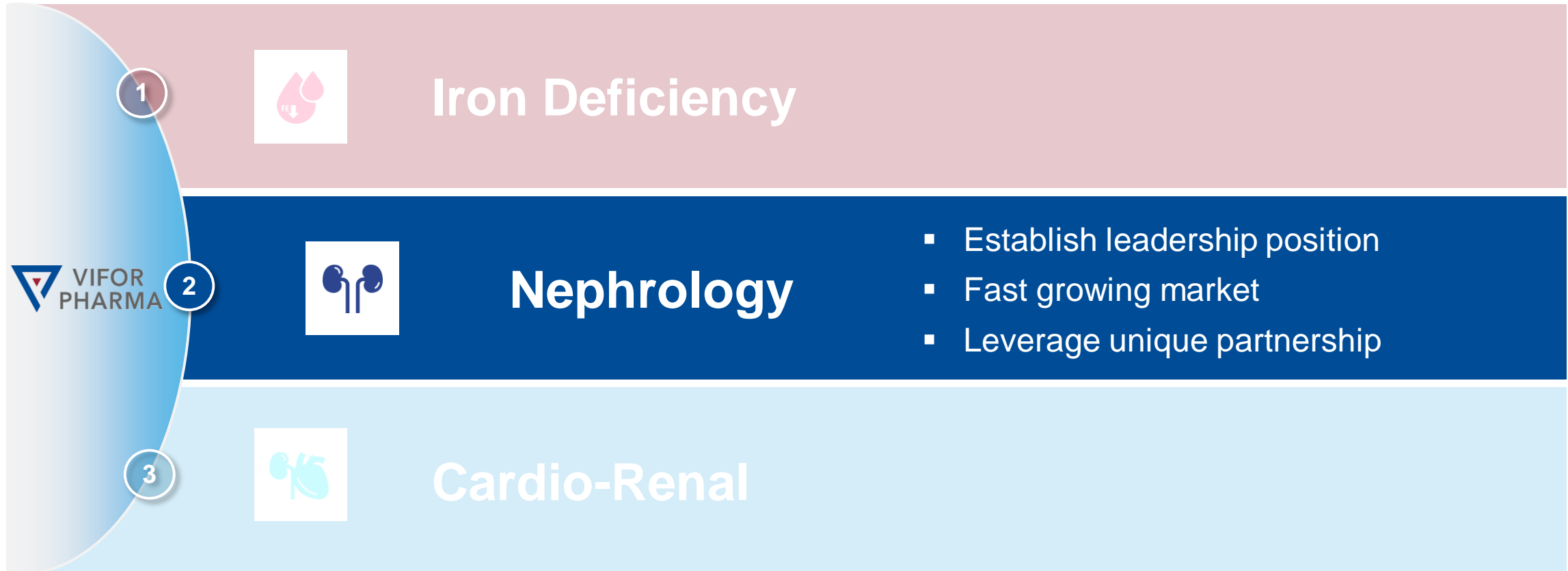
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- Ferinject® and Venofer® are nanomedicines
- These are large and complex molecules, **defined by their manufacturing processes**
- Any potential **copy** of a nanomedicine will inevitably have **small differences**
- Scientific evidence shows that small changes can lead to clinically meaningful differences<sup>1</sup>
- US & EU: specific regulatory requirements

1) Rottembourg et al. Nephrol Dial Transplant 2011; 26: 3262–3267, M.L. Aguera, A. Martin-Malo, M.A. Alvares de Lara et al. Nefrologia 2014;34(S1), abstr 319

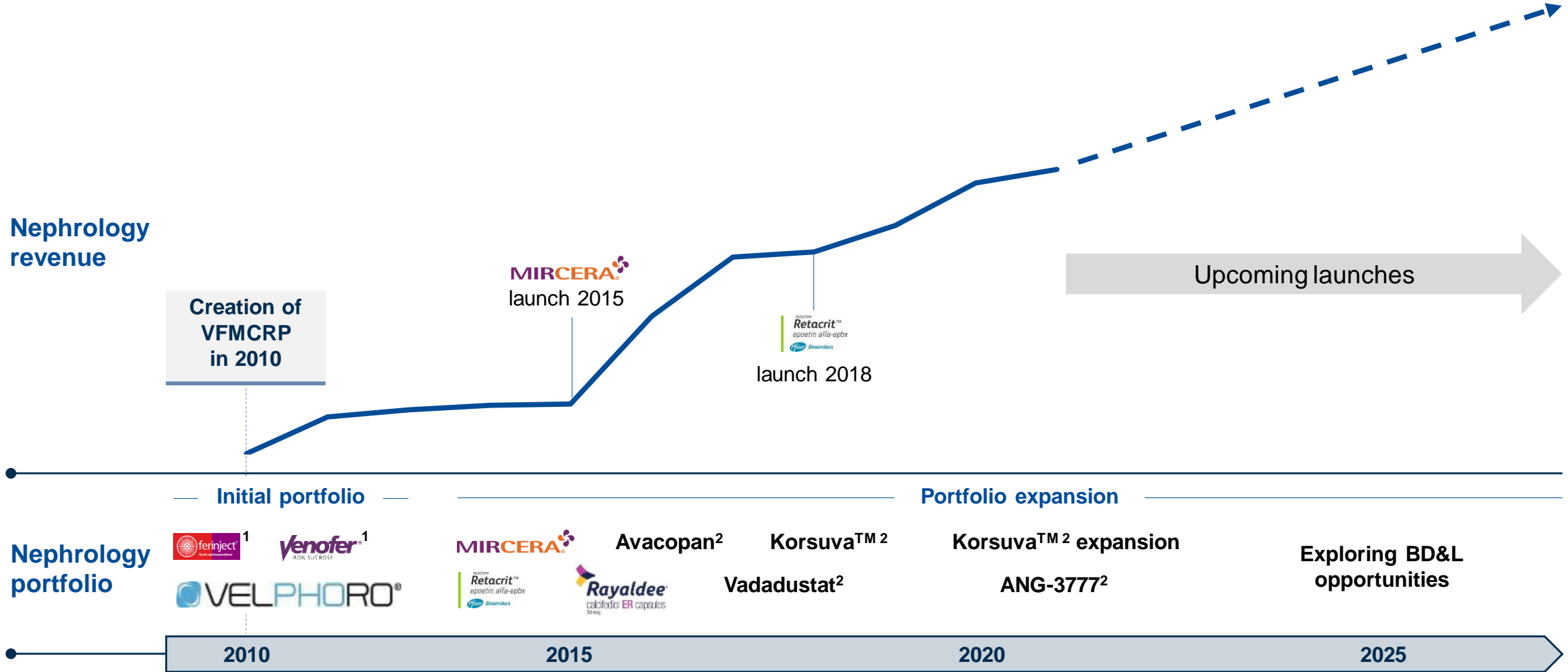
# VIFOR PHARMA STRATEGIC FOCUS

## THREE AREAS AS BASIS FOR FUTURE GROWTH



# NEPHROLOGY – PORTFOLIO OVERVIEW

## CONTINUING TO ESTABLISH LEADERSHIP POSITION



1) Sales in chronic kidney disease

2) Pipeline products

# NEPHROLOGY OPPORTUNITIES

LARGE AND GROWING MARKET WITH HIGH UNMET MEDICAL NEED



## COMMERCIAL

- Iron deficiency
- Anaemia
- Diabetic kidney disease
- Hyperphosphatemia
- Hyperkalemia

## PIPELINE

- Uremic pruritus
- ANCA associated vasculitis
- Secondary hyperparathyroidism
- Cardiac surgery associated acute kidney injury
- Delayed graft function
- C3G

## BD&L OPPORTUNITIES

- CKD progression drivers
- CKD associated complications
- Dialysis related complications
- Acute kidney injury
- Transplantation

# NEPHROLOGY – PARTNERSHIP WITH FMC<sup>1</sup>

## UNIQUE EXPERTISE AND PATIENT ACCESS



### STRONG IRON AND PHARMA EXPERTISE

- Clinical development
- Manufacturing, regulatory and market access experiences
- Global commercial presence

55%  
Stake



### Global leadership in nephrology through:

- Combination of strengths
- Optimal sourcing of innovation
- Access to patient data & faster clinical trial execution
- Improving outcomes via treatment algorithms



### GLOBAL LEADER IN DIALYSIS

~350'000  
patients



>52 million  
dialysis treatments p.a.



>4'000  
clinics

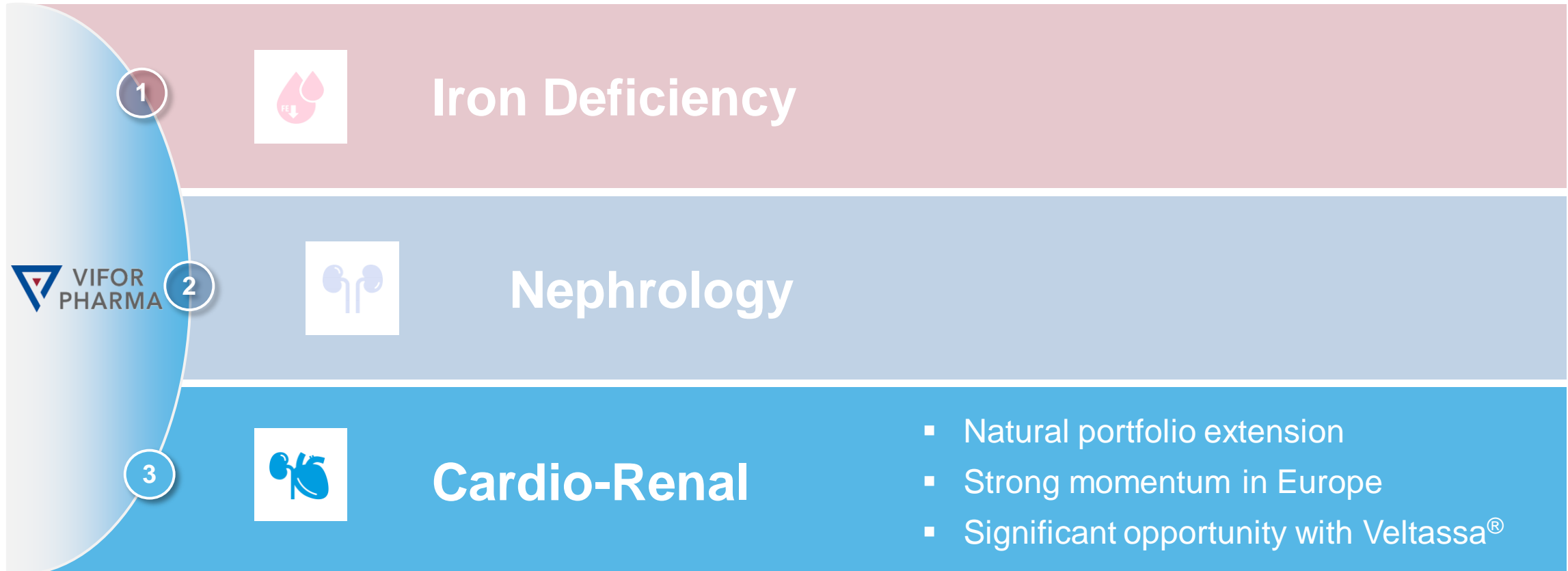


45%  
Stake

1) Fresenius Medical Care

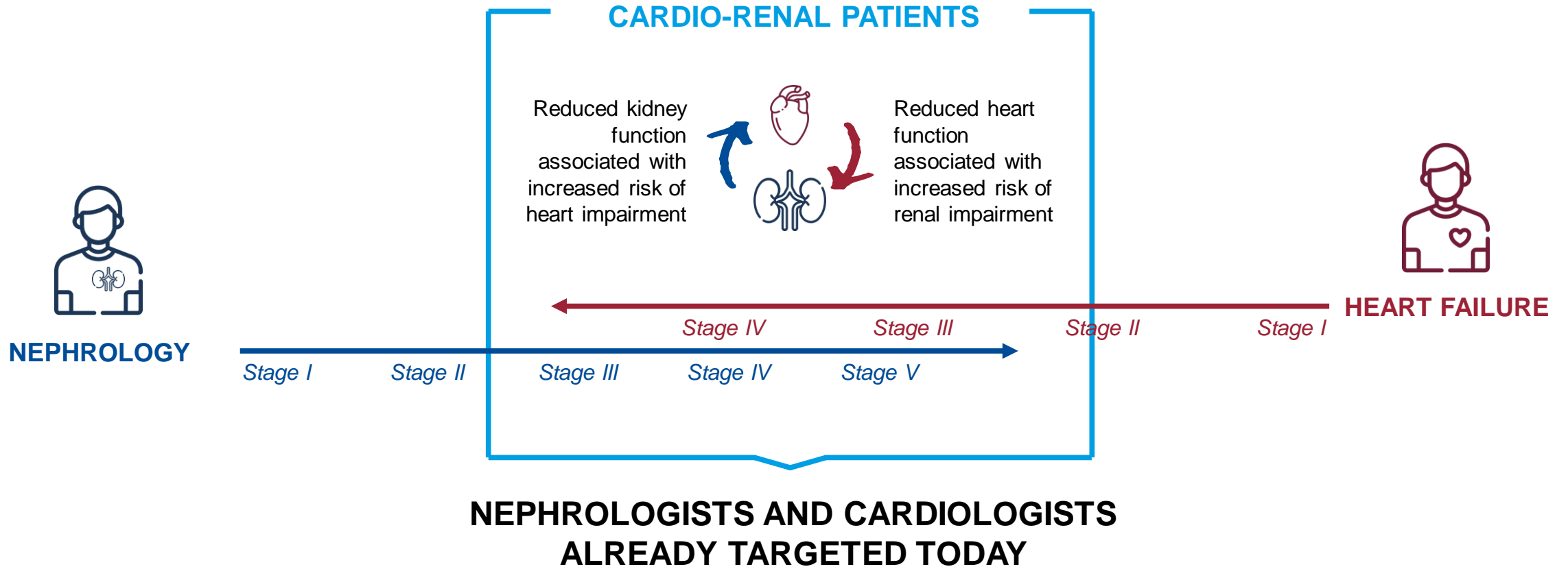
# VIFOR PHARMA STRATEGIC FOCUS

## THREE AREAS AS BASIS FOR FUTURE GROWTH



# CARDIO-RENAL – PATIENT POPULATION

## NATURAL EXTENSION OF OUR THERAPY AREA FOCUS





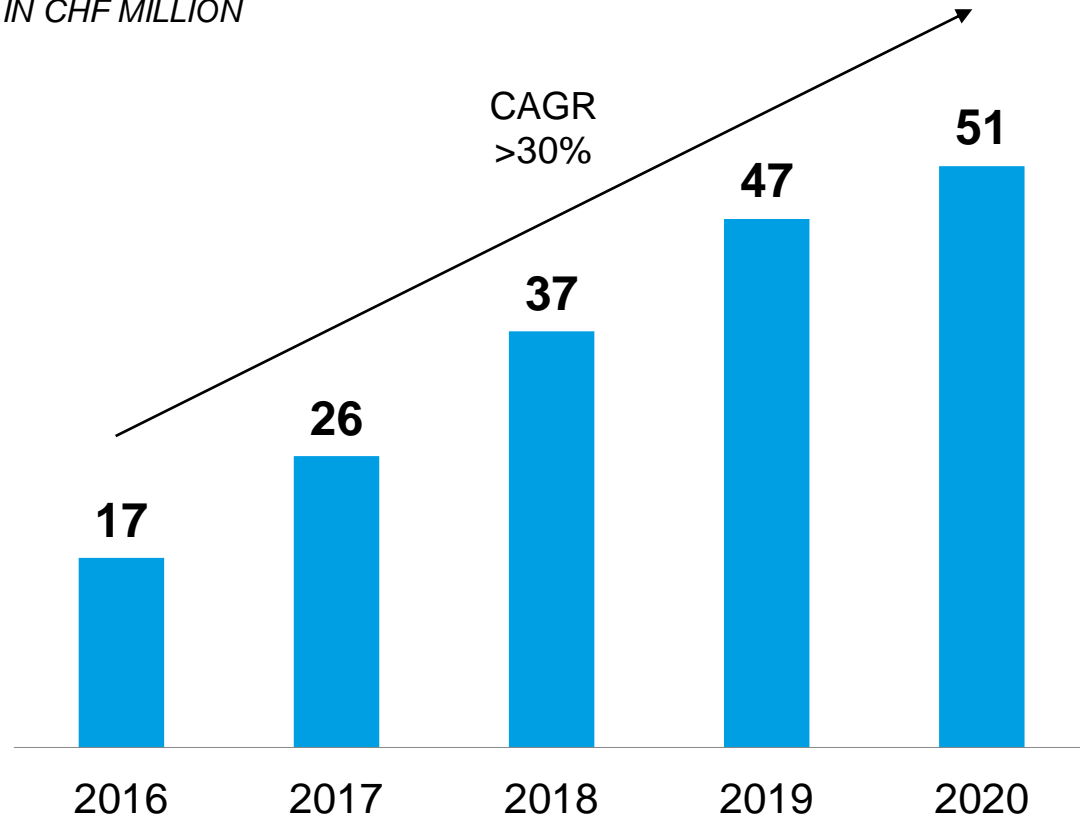
# CARDIO-RENAL – FERINJECT® EUROPE

## SIGNIFICANT GROWTH MOMENTUM



### IN-MARKET SALES IN HEART FAILURE – EU5

IN CHF MILLION



- ESC guideline recommendation since 2016
- Leverage strong clinical data
- ESC guideline update expected in 2021
- Market opportunity over CHF 450m

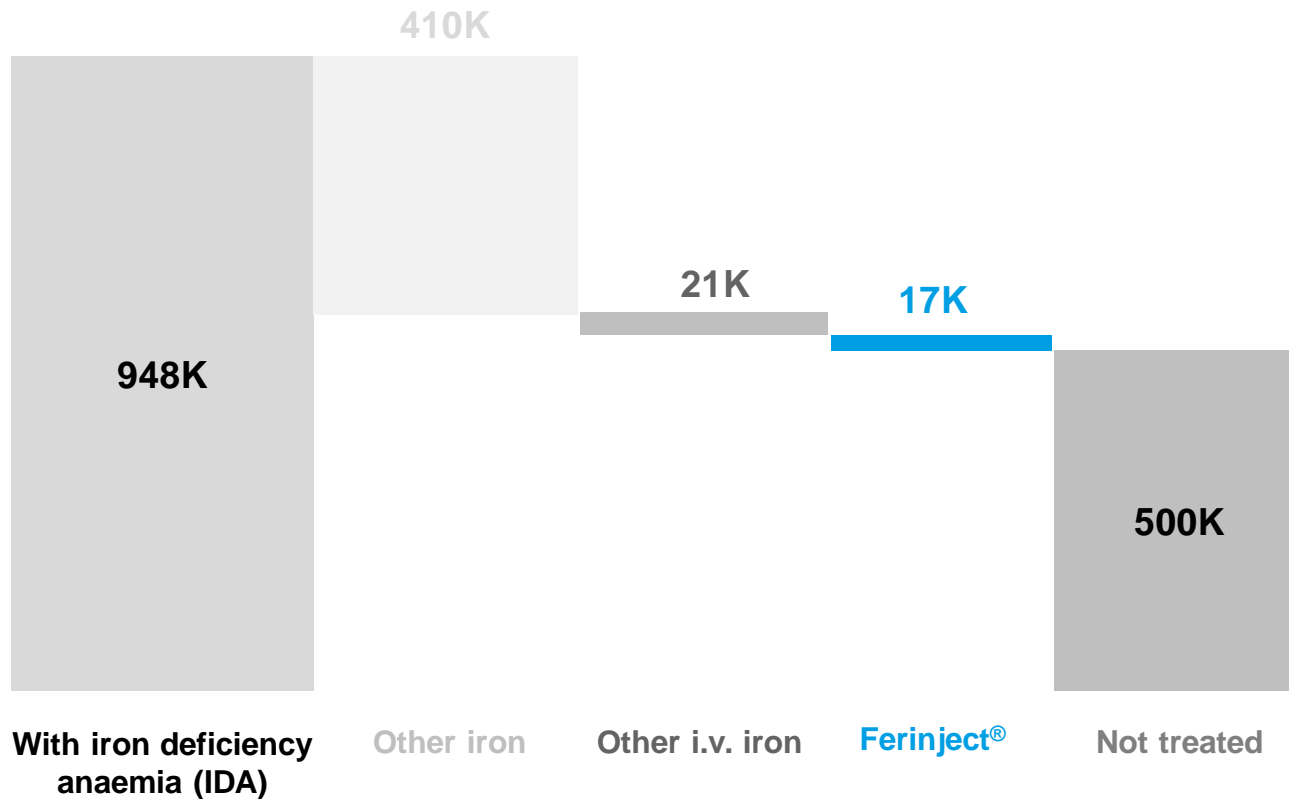
EU5: Germany, France, Italy, Spain and the United Kingdom      ESC = European Society of Cardiology  
Source: IQVIA™ hospital ward data, NVI, Pharmafakt, DN sales, Farma&Cia, APDD, Q2-2020

# CARDIO-RENAL – INJECTAFER® US

## MAJOR UNADDRESSED GROWTH OPPORTUNITY



### HFrEF<sup>1</sup> PATIENT DROP-OFF – US



- Injectafer® label extension based on FAIR-HF & AFFIRM-AHF in 2021/22
- US guideline update in 2022
- Further label and guideline strengthening following HEART-FID study in 2023/24
- US market opportunity over USD 1 billion

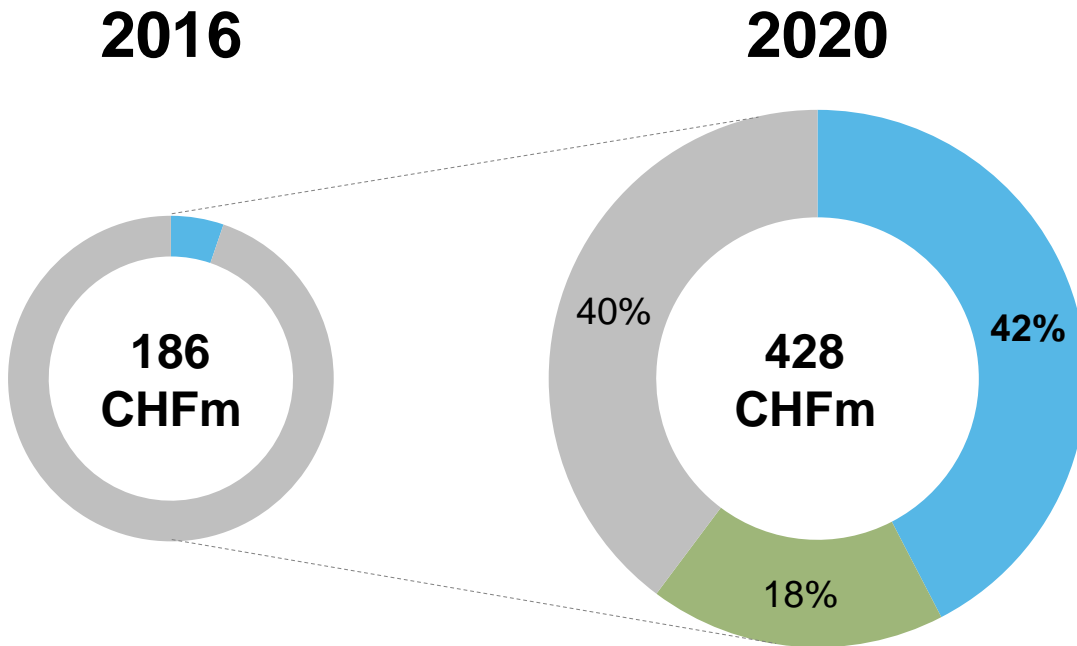
1) Heart failure with preserved ejection fraction  
 Source: interviews with US HF specialists, ZS analysis on claims, ATU research, scientific papers

# CARDIO-RENAL – VELTASSA®

## SIGNIFICANT OPPORTUNITY WITH EXISTING PRESCRIBERS



### IN-MARKET SALES



■ Veltassa® ■ Sodium zirconium cyclosilicate ■ Other potassium binders

### KEY CHARACTERISTICS

- Calcium-based, non-absorbed
- 52-weeks data available
- Acute & chronic usage

### KEY FOCUS



- Build awareness
- Establish clinical differentiation
- Improve pull-through
- DIAMOND study is significant growth accelerator and “differentiator”

Source: monthly IQVIA™ MIDAS® panel, GERS, InsightHealth, DLI, moving annual total Q3-2020. Average 2019 exchange rates have been applied.

# PROVEN BD&L CAPABILITIES & STRONG PIPELINE

## KEY UPCOMING LAUNCHES AND DATA READOUTS



PRE-CLINICAL	PHASE 1	PHASE 2	PHASE 3	PRE-COMMERCIAL	LIFE CYCLE MANAGEMENT
<p><b>NephThera</b> <i>(Kidney fibrosis)</i></p>		<p><b>VIT-2763</b> <i>(Ferroportin inhibitor)</i></p> <p><b>ANG-3777<sup>1</sup></b> <i>(CSA-AKI)</i></p>	<p><b>ANG-3777<sup>1</sup></b> <i>(DGF)</i></p>	<p><b>Royaldee<sup>®</sup> 1</b></p> <p><b>Korsuva<sup>™</sup> 1</b></p> <p><b>Avacopan<sup>1</sup></b></p> <p><b>Vadadustat<sup>1</sup></b></p>	<p> <b>HEART-FID<sup>2</sup></b></p> <p> <b>DIAMOND</b></p>

BD&L = Business development and licensing  
1) In-licensed products

DGF = Delayed graft function      CSA-AKI = Cardiac surgery associated acute kidney injury  
2) Study conducted by our US partner Daiichi Sankyo

# AVACOPAN

## NEW STANDARD OF CARE IN ANCA-AV



### Sustain remission

statistically superior at 52 weeks

### Reduce glucocorticoid toxicity

vs. standard of care

### Orphan and rare renal disease

around 50k patients in Europe

## Avacopan<sup>1</sup>



### Global rights

excl. US

### Launch in Europe in ANCA-AV

end 2021 / early 2022

### Potential in further indication

including C3G and HS

ANCA-AV = Anti-neutrophil cytoplasmic antibody-associated vasculitis  
1) In-licensed product

C3G = C3 glomerulopathy

HS = Hidradenitis suppurativa

# KORSUVA™ (CR845/DIFELIKEFALIN) INJECTION

## INNOVATION IN CKD-ASSOCIATED PRURITUS



**Standard of care with poor efficacy**  
and/or unfavorable safety profile

**~40% of ESRD patients**  
moderate to severe CKD-aP

**No approved treatment**  
in the US and Europe

**Korsuva™ 1**



**Global rights**  
excl. Japan and South Korea

**Launch in the US in end of 2021**  
followed by Europe in early 2022

**Leverage commercial organisation**  
established presence in dialysis

1) In-licensed product

# ANG-3777

## EXPANDING LEADERSHIP ON THE NEPHROLOGY CHAIN



**First small molecule**  
hepatocyte growth factor mimetic

**Global rights<sup>2</sup>**  
in DGF and CSA-AKI

**~110k patients with CSA-AKI**  
US and EU5 combined

**ANG-3777<sup>1</sup>**  
angion

**~15k patients with DGF**  
US and EU5 combined

**Phase-II study in CSA-AKI**  
read out in Q2 2021

**Phase-III study in DGF**  
read out in end of 2021

DGF = Delayed graft function  
1) In-licensed product

CSA-AKI = Cardiac surgery associated acute kidney injury  
2) Excluding China, Taiwan, Hong Kong and Macau

# VIT-2763 (FERROPORTIN INHIBITOR) TARGETING RARE BLOOD DISORDERS



Oral small molecule



Blocks iron transport to the blood



Mechanism similar to hepcidin

## BETA THALASSEMIA

## SICKLE CELL DISEASE

Unmet need

Transfusion burden and iron overload

Pain crisis and organ damage

Addressable patients<sup>1</sup>

Approx. 25'000

Approx. 150'000

Phase-II status

Expected completion in H2 2021

Study initiation expected in 2021

1) US and EU combined estimate



## MARKET ACCESS

- Ferinject<sup>®</sup> approval in China
- Korsuva<sup>™</sup> launch in the US & approval in Europe
- Avacopan approval in Europe
- Avacopan & Korsuva<sup>™</sup> partnering in China
- Vadadustat filing in the US by our partner Akebia Therapeutics, Inc.

## CLINICAL TRIALS

- VIT-2763 phase-II readout in beta thalassemia in H2 2021
- ANG-3777 phase-II readout in CSA-AKI in Q2 2021
- ANG-3777 phase-III readout in DGF in Q4 2021

## BD&L

- At least two in-licensing deals, product acquisition or corporate transactions

# KEY INVESTMENT HIGHLIGHTS



- Strong track record of profitable growth and resilient cash flow generation
- Global leadership in growing iron deficiency & iron deficiency anaemia markets
- Global leadership in nephrology empowered by unique FMC<sup>1</sup> partnership
- Proven BD&L capabilities and “partner of choice” in nephrology
- Positioned to unlock attractive high-growth opportunities in cardio-renal area
- Delivering material pipeline and international expansion opportunities
- Highly experienced leadership team

1) Fresenius Medical Care

# CONTACT INFORMATION



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## Investor relations

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**Colin Bond**  
Chief Financial Officer

**Phone:** +41 58 851 83 53

**Email:** [colin.bond@viforpharma.com](mailto:colin.bond@viforpharma.com)



**Julien Vignot**  
Head of Investor Relations

**Phone:** +41 58 851 66 90

**Email:** [julien.vignot@viforpharma.com](mailto:julien.vignot@viforpharma.com)



**Laurent de Weck**  
Investor Relations Senior Manager

**Phone:** +41 58 851 80 95

**Email:** [laurent.deweck@viforpharma.com](mailto:laurent.deweck@viforpharma.com)

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