SHIELD THERAPEUTICS PLC

Improving Lives Together

Investor Presentation

9 March 2021

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Investment Highlights & Company Overview

Overview of Shield Therapeutics:

Revenue Generating Pharmaceutical Company Focused on the Treatment of Iron Deficiency

- **AIM-listed biotech company (STX.L)**
  - Market capitalization ~£46m (@8March2021)
- **Primary focus is on developing and commercializing Feraccru®/Accrufer®**
  - A novel oral treatment for treating iron deficiency (ID) in adults
  - Approved in the USA and EU
  - Commercialization out-licensed to:
    - Norgine (Q4 2018) – Europe, Australia and New Zealand - £11m upfront received
    - ASK Pharma (Q1 2020) – China, Taiwan, Hong Kong and Macau - $11.4m upfront received
  - Patent protection until 2035
  - £25m raised 26 February 2021 (subject to shareholder approval) to launch Accrufer® in the US
- **Development pipeline**
  - Late state asset - PT20 (phosphate binder to treat hyperphosphatemia)
  - Requires one phase 3 study to submit a MAA in Europe and NDA in the USA
- **Semi-virtual UK-based company**
  - Highly experienced management team in UK
  - US commercial team established to launch Accrufer

Investment Highlights

- Accrufer® is a novel, oral, FDA-approved, US launch-ready, high margin iron replacement therapy
- U.S. iron deficiency market is large and undertreated, with significant unmet needs beyond current treatments
- Accrufer has been proven in clinical studies in IBD and CKD patients to be both effective and well-tolerated, and broad label allows for application in other indications and patient populations including oncology, women's health and chronic heart failure
- FDA granted NCE status until June 2024 and there are multiple patents protecting Accrufer out to 2035
- US opportunity offers very substantial upside – potential for $100m US sales and substantial cash generation in 3rd year after launch with only modest market penetration

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Clinical Overview

Iron deficiency (ID)

- Iron is a key component of haemoglobin (Hb)
  - ID is the most common cause of anaemia (iron deficiency anaemia or “IDA”)

- ID is caused by malnutrition or bleeding and is associated with many diseases, in particular:
  - Inflammatory bowel disease (IBD) (e.g ulcerative colitis (UC), Crohn’s disease (CD)) , Chronic kidney disease (CKD), Womens’ health, Congestive heart failure (CHF), oncology, ageing
- Up to one third of the global population is affected by ID and IDA

Current Iron Deficiency Treatment Paradigm: Significant Unmet Need Remains

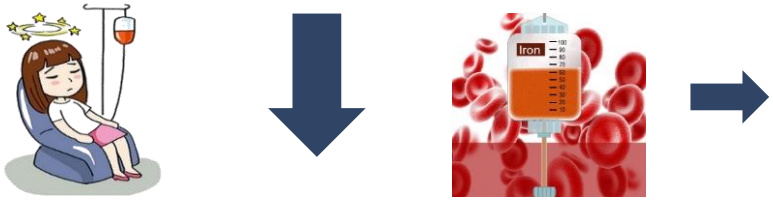
Patient diagnosed with iron deficiency

1st line treatment

- 80%+ of the Rx patient/unit volume comes from the orals which are primarily generic*
  - ~10m-11m TRx annually for oral products*

2nd line treatment

- >90% of the Rx market dollar volume comes from IV iron
  - Annual sales ~$1.2 billion*
  - 10 – 18% year on year growth*
- Comprised of primarily branded products including:
  - Injectafer®,Venofer®, Feraheme® & Monoferric®



Unmet Need

- **Oral:**
- Mostly salt-based iron compounds
  - \+ Inexpensive generics
  - \+ Convenient to take
  - – Poor tolerability in the gut
  - – Less efficient absorption
  - – Slower efficacy
  - – Poor compliance

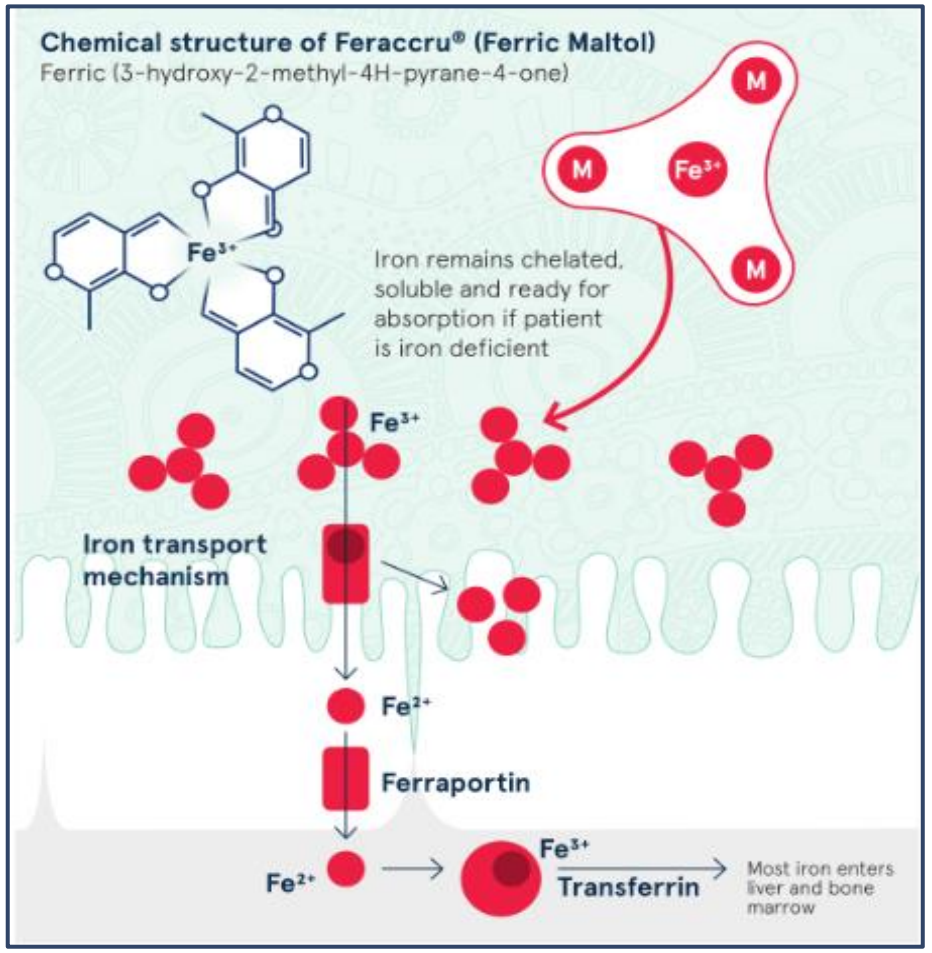
- **Intravenous (IV):**
- Used mainly in patients intolerant of oral therapies
  - \+ Increases iron levels quickly
  - \+ Better bioavailability/absorption
  - \+ No compliance issue
  - – Risk of iron overload
  - – Risk of allergic reaction
  - – Risk of infection
  - – Requires hospital administration
  - – Inconvenient
  - – Expensive

* US market data

Accrufer® (Ferric Maltol) is Uniquely Positioned to Address Unmet Needs in Iron Deficiency Patients

- **Accrufer® is a low dose (30mg BID) oral formulation of a non-salt complex of Fe^{3+}, which is stable in the GI tract:**
  - Other oral irons are salts, and require the Fe to dissociate to be absorbed
  - This leads to formation of insoluble products in the GI tract, causing intolerance in patients, which is one of the main reasons behind discontinuation/dissatisfaction with oral therapy
- **The Fe^{3+} in Accrufer® remains in complex with maltol until absorbed and iron is delivered into the bloodstream where it binds to transferrin:**
  - Maltol is metabolised and excreted in urine
  - Unabsorbed Accrufer® passes through the digestive system in the benign complex and is excreted in feces
- **Accrufer® is a well tolerated, oral iron replacement therapy, with its long-term efficacy profile comparable to that of IV iron replacement therapy**
- **An Accrufer® pack contains 1 month's supply**

Accrufer® Mechanism of Action

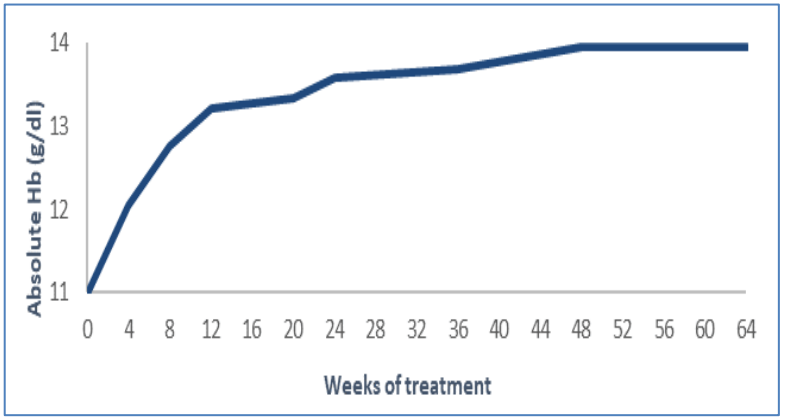


Accrufer® has Established a Robust Efficacy and Safety Profile in IBD and CKD Patients

Accrufer®'s Pivotal Phase 3a Trials Summary

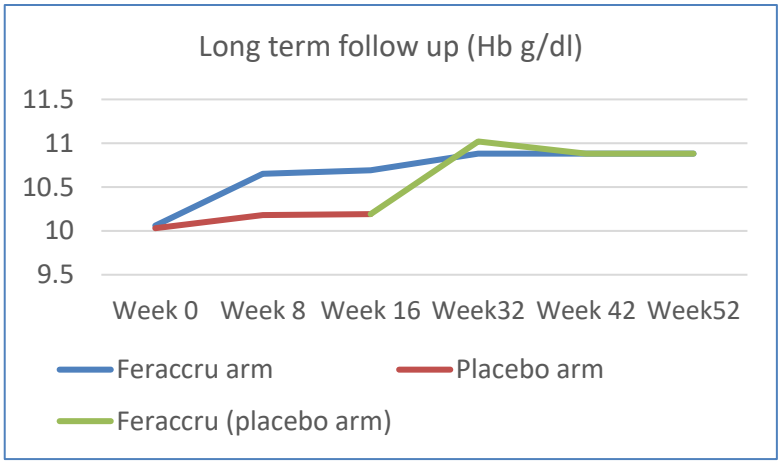
Phase 3a AEGIS-IBD (UC & CD):

- Phase 3 clinical study designed to investigate the efficacy and safety of ferric maltol compared with placebo in patients with UC or CD who have had an inadequate response, or had been intolerant to previous oral iron products for IDA:
  - Accrufer® delivered highly relevant and rapid 2.3g/dL rise in hemaglobin (Hb) inside 12 weeks, with 1g/dL increase in only 4 weeks
  - With chronic therapy, anemia did not reoccur, and iron indices continued to improve
  - Majority of adverse events were related to IBD status; low incidence of other adverse events



Phase 3a AEGIS-CKD (Non-Dialysis) Study:

- Phase 3, randomized, placebo controlled, prospective, multicenter study with ferric maltol for treatment of IDA in subjects with CKD:
  - Statistically significant change in Hb was observed across all analyses (ITT, mITT and PP), and in all sensitivity analyses at both week 8 and 16
  - Change in ferritin, TSAT and serum iron from baseline statistically significant at weeks 4, 8 and 16, and consistent with changes seen in AEGIS-IBD studies
  - Hb levels increased and were maintained over 52 weeks
  - Good safety profile and tolerability



Health Economics-Based Phase 3bTrial: AEGIS H2H Study

Phase 3b head-to-head, non-inferiority study compared the efficacy and safety of Accrufer® vs. Injectafer® IV* (ferric carboxymaltose or FCM) at 12 weeks in IBD patients with IDA and hemoglobin as low as 8.0g/dL. Primary endpoint was either 2g/dL increase in Hb OR normalization of Hb at week 12. An open label extension arm went through 52-weeks. ***Although trial did not demonstrate non-inferiority at the 12-week time point (which was the primary endpoint)***, a reanalysis confirmed similar clinically meaningful efficacy and safety as seen in the Phase 3a trials.

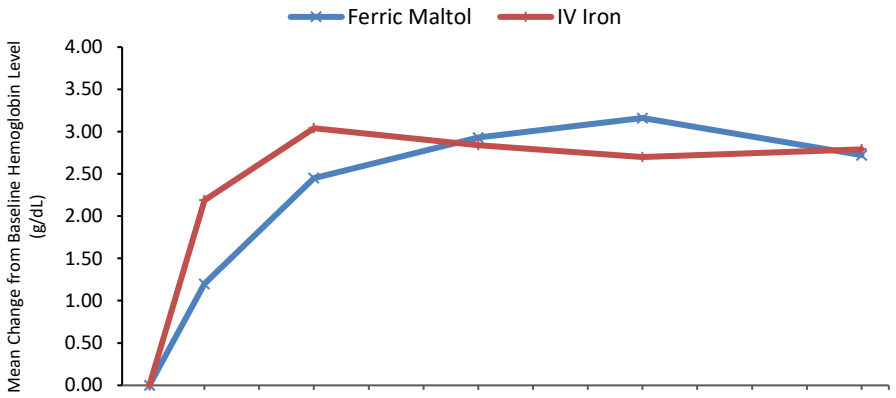
By week 12 (first phase):

- Accrufer demonstrated a clinically meaningful increase in Hb levels:
  - Mean increase in Hb levels:
    - Accrufer: 2.45 g/dL & Injectafer: 3.04 g/dL
- Percent of patients who had responded to treatment (as previously defined) by week 12:
  - Accrufer: 67% & Injectafer: 84%
- 82% of IV patients received more than one infusion during the first 12-weeks of the study

Long term phase (using the ITT results):

- At weeks 24, 36 and 52, the mean increases in Hb levels in those patients still being monitored :
  - Accrufer: 2.93 g/dL, 3.16 g/dL and 2.72 g/dL
  - Injectafer: 2.84 g/dL, 2.70 g/dL and 2.79 g/dL
- 58% of the Injectafer patients who were monitored from the week 12 visit required at least one further IV infusion

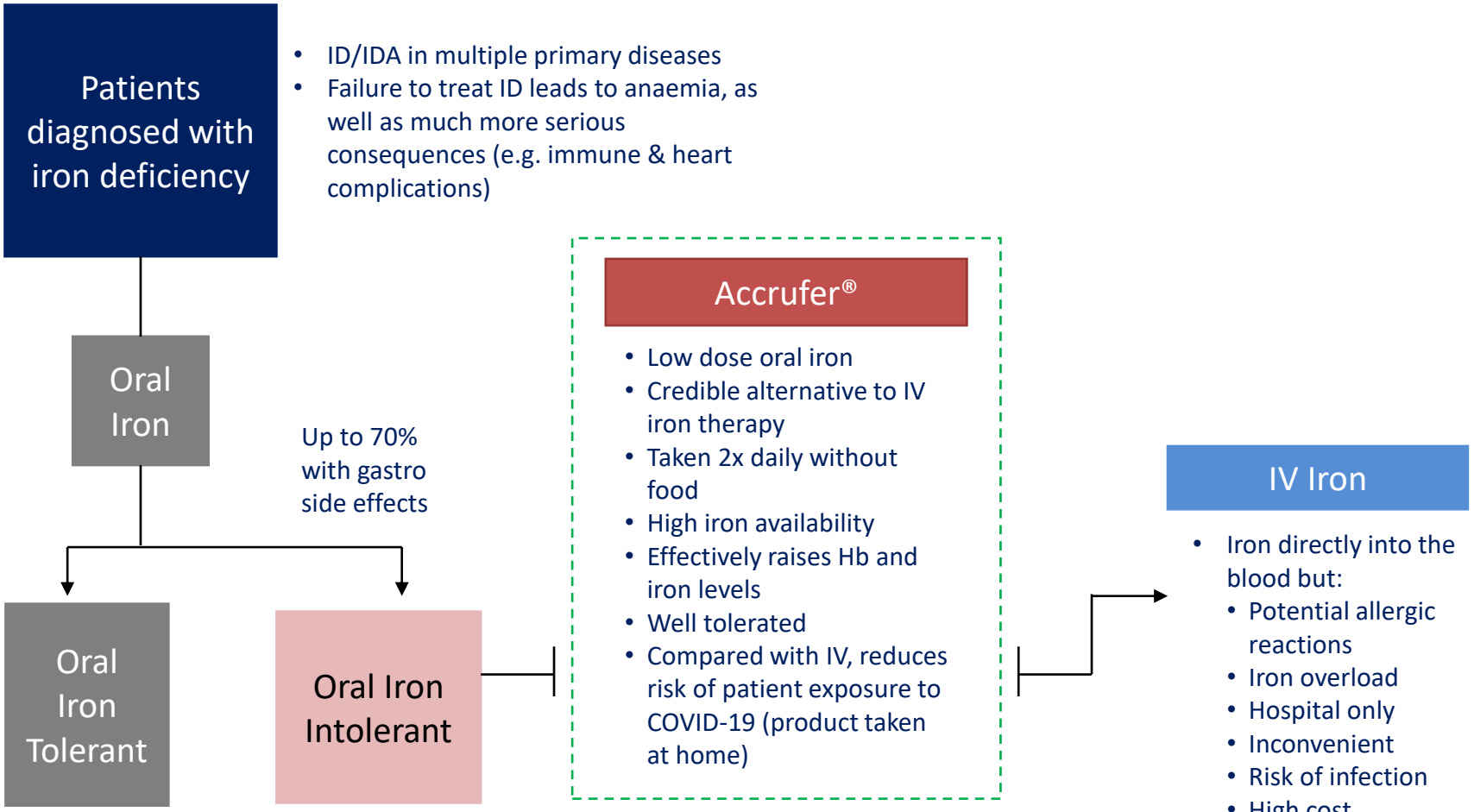
Mean Change from Baseline Hb Concentration rise seen in the ITT population



Number of eligible patients:						
Ferric maltol	125	123	115	92	72	61
IV FCM	125	121	118	91	67	56

* Injectafer/Ferinject global in-market sales 2019 ~$1bn – source Vifor March 2020 Analyst Presentation

Accrufer® in the Treatment Algorithm Can Address Both Oral and IV Segment of the Market



With a broad indication, Accrufer® can target multiple therapy areas

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US Market Overview & Opportunity

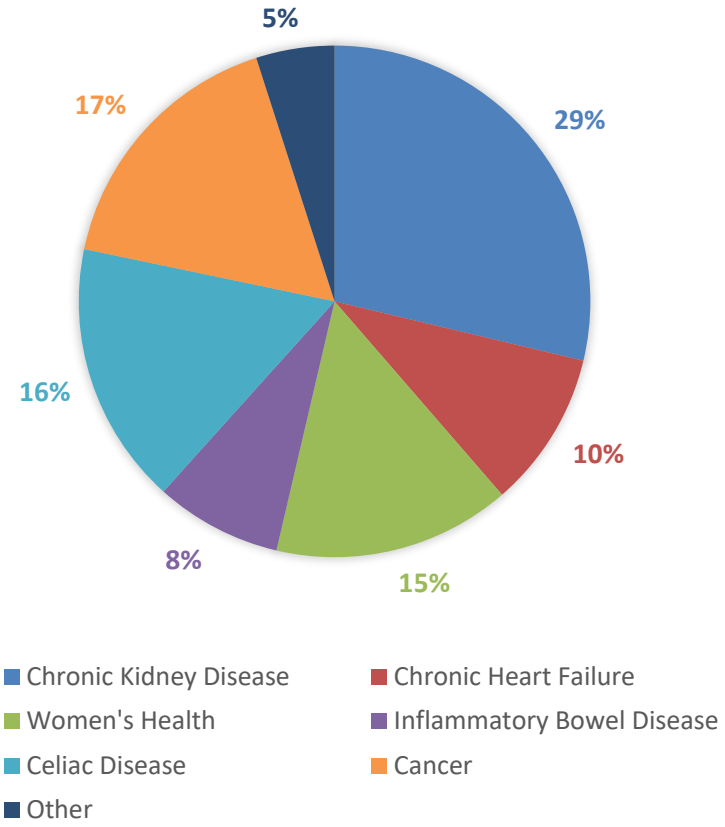
Accrufer® Market Opportunity Overview

- **Iron deficiency is a large, diverse and undertreated market**
  - ~10 million ID patients in US: ~5 million patients treated annually for IDA
  - Existing 1st line therapies are poorly tolerated iron salts: ~10-11 million TRx annually
  - 2nd line therapy is intravenous (IV) iron which is inconvenient for patients with expensive administration costs
    - ~ 2.3 million doses yearly
    - Annual IV iron sales ~$1.2 billion
- **There is a significant and well-documented unmet market need for an effective, well-tolerated oral iron option**
- **Payer research indicated Accrufer should have few restrictions & non-preferred formulary status at tested price points ensuring good patient access**
- **Competitive brands have seen sales +/- $100M within 5 years of launch despite less-than-favorable product profiles**
  - Auryxia® (ferric citrate) is an oral iron salt tablet with annual sales of ~$111M. Product is limited to non-dialysis CKD (IDA) and dialysis CKD (control of serum phosphate levels) with daily dosing ranging from 3 to 12 tablets
- **COVID-19 is changing healthcare delivery and recommendations for the care of at-risk patients**
  - Increased use of telemedicine
  - Recommendations to consider home treatments and/or switching patients from IV to oral therapies to minimize exposure

Iron Deficiency is a Serious and Prevalent Disease

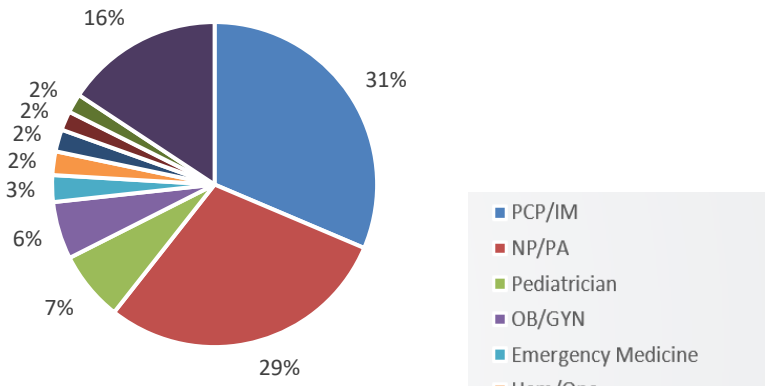
~10M Patients Are at Risk for Iron Deficiency Across Multiple Therapeutic Areas in US

- **Chronic Kidney Disease (CKD)**
  - 37m patients (dialysis & non-dialysis)
  - ~50% of patients at risk
  - ~2.5m patients have Stage 3 or 4 CKD with IDA
- **Women's Health**
  - 1 in 5 women of childbearing age
  - Heavy uterine or post partum bleeding
- **Gastrointestinal Disorders**
  - Inflammatory Bowel Disease (IBD)
    - Affects up to 36%-76% of patients
  - Celiac Disease
    - 10%-20% of patients at risk
- **Oncology**
  - Solid tumors & hematological malignancies
  - 32%-60% of cancer patients at risk
- **Cardiology**
  - 17% of chronic heart failure patients maybe affected

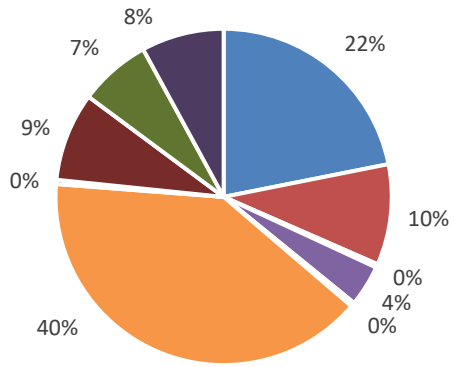


Large Number of HCPS Writing for Oral Iron but a Much Smaller Number Writing for IV Iron

Total Number of HCPs Writing Oral Iron by Specialty (n=~460,000)



Total Number of HCPs Writing IV Iron by Specialty (n=~11,500)



Target the Highest Rx Writers and Most Productive Specialties* for Oral Iron (D8-D10)

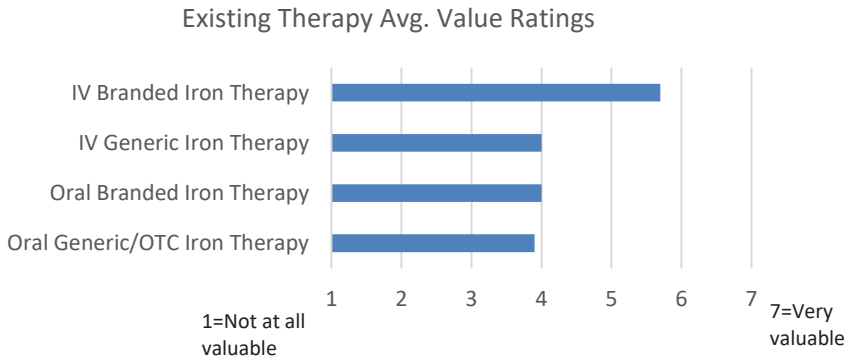
- ~11,000 Rx writers account for 30% of TRx (D8-D10)
  - Represent only ~3% of total target writers
  - Average 252 TRx per year per writer
    - D1-D7 writers average only 15 TRx
  - Almost 100 “super writers”
    - 1,000+ TRx annually
- **Therefore, ~ 60 sales reps can cover 80%+ of the target list**

* Target HCP Specialties Defined as: Gastroenterologists, Hematologists/Oncologists, OB/GYNs, Nurse Practitioners & Physician Assistants and PCPs (including FPs, GPs, PCPs and IMs)

Market Research[1] & Competitor Data[2] Confirm the Unmet Need

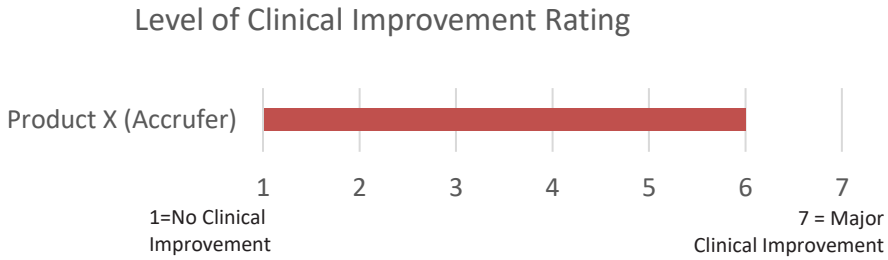
Physicians believe there is an unmet need in the market…..

- Iron replacement therapy is generally considered an area of unmet need
- Key needs are effectiveness and GI tolerability



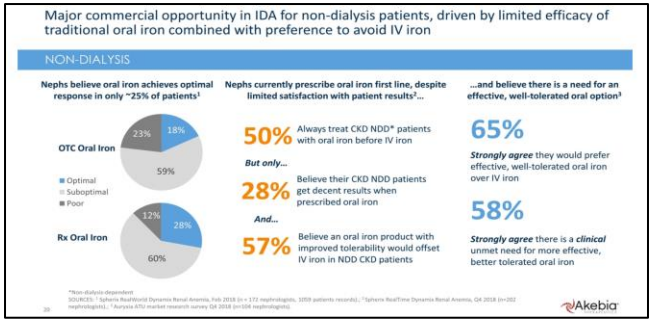
….and see Accrufer® as delivering a high level of clinical improvement over existing therapies

- Accrufer® was viewed favorably as a clinically meaningful improvement
  - Good **tolerability** profile and **efficacy** data are key benefits
  - Potential first line use if allowed by insurance plans



Competitors have also outlined the need for an effective, well tolerated oral option

- Auryxia® (Akebia) tablets, completed market research for IDA in non-dialysis CKD patients, demonstrated a clear unmet need for a better oral iron



1. MME: Accrufer PRMA Opportunity for United States. June 2020. 8 physicians (3 Nephrologists, 3 Gastroenterologists, 2 OB/GYN and 2 Hematology/Oncology)
2. Akebia Therapeutics 2019 Current Report 8-K dated January 7, 2019

Accrufer®'s Unique Product Profile Make it an Ideal Iron Replacement Therapy for Higher Risk ID/IDA Patients – *Especially During COVID-19*

COVID-19 & At-Risk Patient Populations

Underlying Medical Conditions & Other Risk Factors
Asthma
Chronic Kidney Disease being treated with dialysis
Chronic Lung Disease
Diabetes
Hemoglobin Disorders
Immunocompromised
Liver Disease
People aged 65 years and over
People in nursing homes or long-term care facilities
Serious Heart Conditions
Severe Obesity

Includes:
- Cancer
- CKD
- Use of immunosuppressant drugs for conditions such as Crohn's disease or Ulcerative colitis

Many ID/IDA patients also have an underlying condition making them more susceptible to COVID-19 including:

- Chronic Kidney Disease
- Cancer
- Heart Failure
- Those taking immunosuppressant drugs for IBD related conditions
- The Elderly

COVID 19 is changing healthcare delivery and recommendations for the care of at-risk patients

- Increased use of telemedicine
- Taking extra precautions for clinic visits
- Consider providing home treatments
- Switching patients from IV to oral therapies to minimize exposure
- Nearly 1 in 3 chronically ill patients report being afraid to leave their home because of COVID-19

AstraZeneca, Roxadustat – HIF - PH Inhibitor: "A Rising Tide Lifts All Boats"

- Roxadustat expected to launch in US market in 2021 (subject to FDA approval)
- Roxadustat is a first-in-class, **orally administered** small molecule hypoxia-inducible factor-prolyl hydroxylase (**HIF-PH)** inhibitor that promotes erythropoiesis by increasing endogenous production of erythropoietin.
- HIF PH inhibitors improve iron regulation, and down regulate hepcidin (thereby overcoming the negative impact of inflammation on hemoglobin synthesis and red blood cell production).
- **Key Point:** Iron is NOT REPLACED or replenished with the use of HIF-PH Inhibitors (or earlier ESA products) but rather it simply becomes more readily available or accessible.
- Iron replacement therapy still has an important role even with hypoxia-inducible factor prolyl hydroxylase inhibitor treatment, but perhaps more so via oral products such as Accrufer™.

"Although erythropoiesis-stimulating agents (ESAs) are the mainstay of anemia treatment, concomitant iron supplementation is often required. "

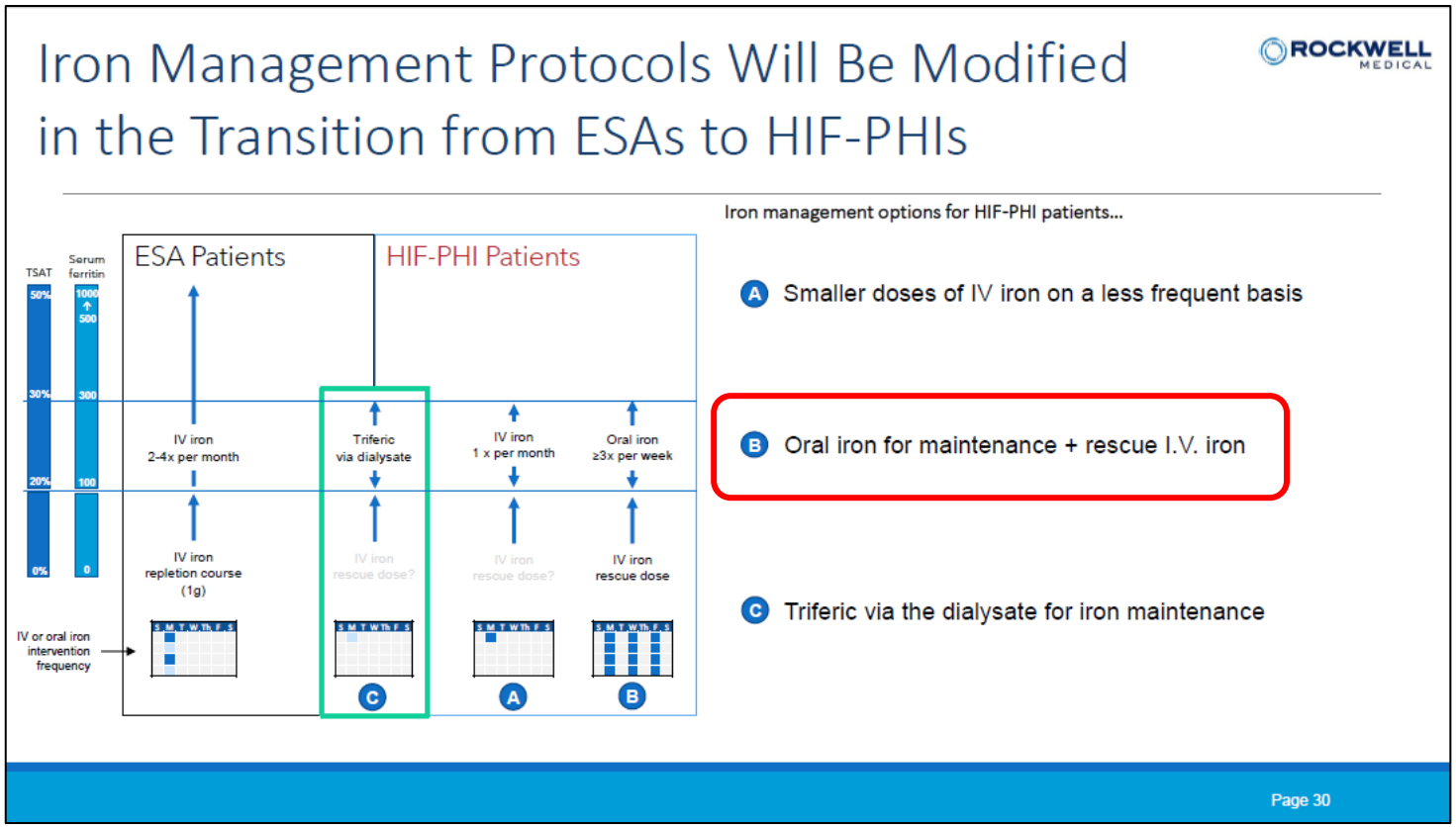
Anne Marie Liles; *Review: Intravenous Versus Oral Iron for Treatment of Iron Deficiency in Non-hemodialysis-dependent Patients With Chronic Kidney Disease.* Am J Health Syst Pharm. 2012;69(14):1206-1211.

"The results showed that the change from baseline was similar in iron-replete and depleted patients receiving Roxadustat… while the results were positive, iron therapy will still play an important role with hypoxia-inducible factor prolyl hydroxylase inhibitors."

Mark E. Neumann; *Roxadustat effective in patients with CKD even with iron depletion.* Reporting from National Kidney Foundation Spring Clinical Meetings: March 30, 2020

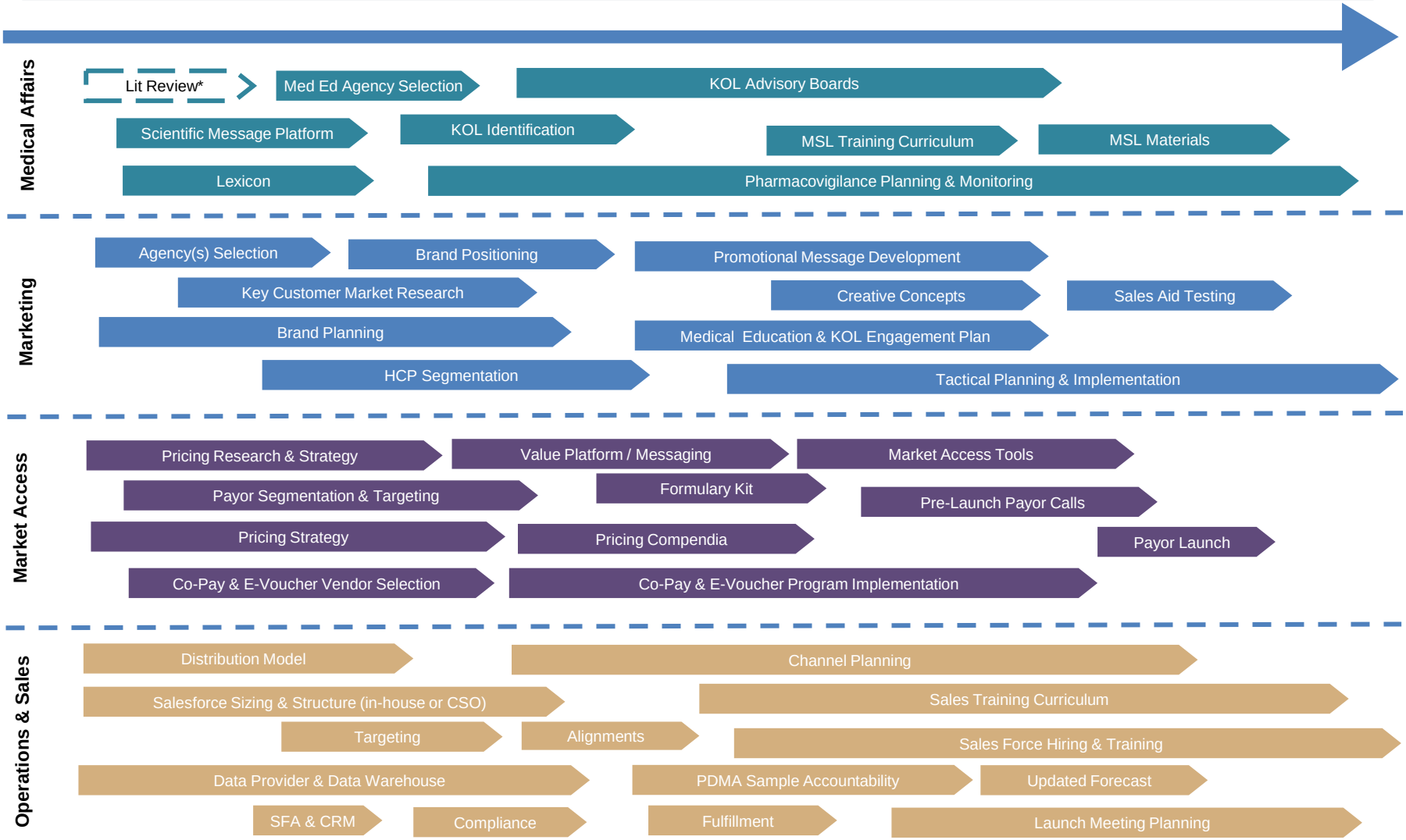
As Roxadustat and Other HIF PF Inhibitors Prepare to Launch, IV Iron Therapies Are Anticipating Changes to the Overall Iron Management Protocols

Rockwell Medical (distributor of Triferic® solution and powder) presented three potential iron management options for HIF-PHI patients. (slide below taken from Rockwell Medical's August 2020 Investor Presentation)



Triferic® (ferric pyrophosphate citrate) solution and powder are indicated only for HDD-CKD patients. Triferic® is administered through the dialysate (mixed with the bicarbonate).

Planning for a Successful US Launch of Accrufer®:
Major Work Streams in Process



Representative of major work streams for overall launch. It is not meant to provide an exact timing of project initiation or completion.

Creating HCP Awareness and Driving Demand in a COVID-19 Environment

Multiple industry studies are reporting a decline in live sales rep interactions and more time being dedicated to "remote" engagements

- **Bain & Company "Post–COVID-19, Doctors Want Both In-Person and Virtual Visits with Sales Reps" June 2020**
  - Prior to COVID, 75% of HCPs preferred in-person pharma rep visits
  - Post-COVID, 60% of HCPs prefer less in-person pharma rep visits and more virtual engagements
- **Medical, Marketing & Media "Back to the Future: Pharma and HCP Engagement Post-Pandemic" June 2020**
  - 47% of physicians are turning to on-line research to replace information they had previously received from a field sales rep
- **Non-personal promotion expected to play a large part of Accrufer's HCP educational efforts**
  - Digital tactics
    - Media/Social Media
    - Search Engine Optimization
    - Peer-to-peer webinars
  - Virtual Detailing

Prior Market Research with US Payers

Qualitative Market Research with Payers, June 2020

- **10 payers representing 200m+ lives**
  - Included national traditional payers, national and regional PBMs, and payers who covered commercial, Medicare and Medicaid
- **Objective: to understand current iron treatment management, Accrufer® value impressions, and expected coverage and restrictions at tested price points**

Market Research Summary

Accrufer® is expected to have few restrictions and non-preferred formulary status at tested price points

- **Very low overall priority is given to managing the iron replacement therapy category**
- **Commercial coverage of current branded therapy:**
  - IV iron replacements are covered and are largely unmanaged
- **Medicare coverage of current branded therapy:**
  - IV iron access is more tightly managed with pre-certification to protect against double-payment
- **Orally administered therapy with better GI tolerability is the key unmet need perceived by payers being addressed by Accrufer**
- **Accrufer® was viewed favorably:**
  - Improved GI tolerability/absorption profile
  - Oral route of administration
  - Predictable dosing regimen

1. MME: Accrufer PRMA Opportunity for United States. June 2020. 10 payers (2 large national traditional payers, 2 national PBMs, 2 regional Blues, 2 regional PBMs, 1 regional IDN, and 1 regional traditional payer

Accrufer® US sales potential

Sales estimates generated by management consultants/3rd parties support the potential for Accrufer® sales to exceed $100m from the third year following launch and to reach $300m-$400m by years 5-6

- At approximately $1,000 per patient per year (assuming 4 packs per year, $250 net price per pack[1])…
- …net sales of $100m pa equate to 100,000 patients treated or 400,000 prescriptions
  - only 2% of 5 million US IDA patients treated annually

Substantial cash generation potential

- 90% gross margin, after manufacturing costs and Vitra[2] 5% royalty
- Year 3 US SG&A costs forecast to be ~$40m-$45m
- Expect to take 15-18 months from launch to breakeven on monthly basis

1. Net sales expressed after assumed 50% gross to net deductions
2. Vitra Ltd was original owner of ferric maltol IP and is entitled to a 5% royalty on net sales under terms of 2010 agreement

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Europe/China

Paediatric study

Intellectual Property

Feraccru® in Europe & China

Europe

Licensed to Norgine (September 2018)

- £11m upfront received
- Sales royalties 25%-40% (Shield pays cost of goods)
- Sales milestones – up to €50m
- On market in Germany, UK, Scandinavia and Belgium
- 2020 sales volumes in Germany/UK up 70% vs 2019 - £0.7m royalties
- Norgine using Head-to-Head Phase III study results to reconfirm pricing & reimbursement strategy in France, Italy and Spain

China

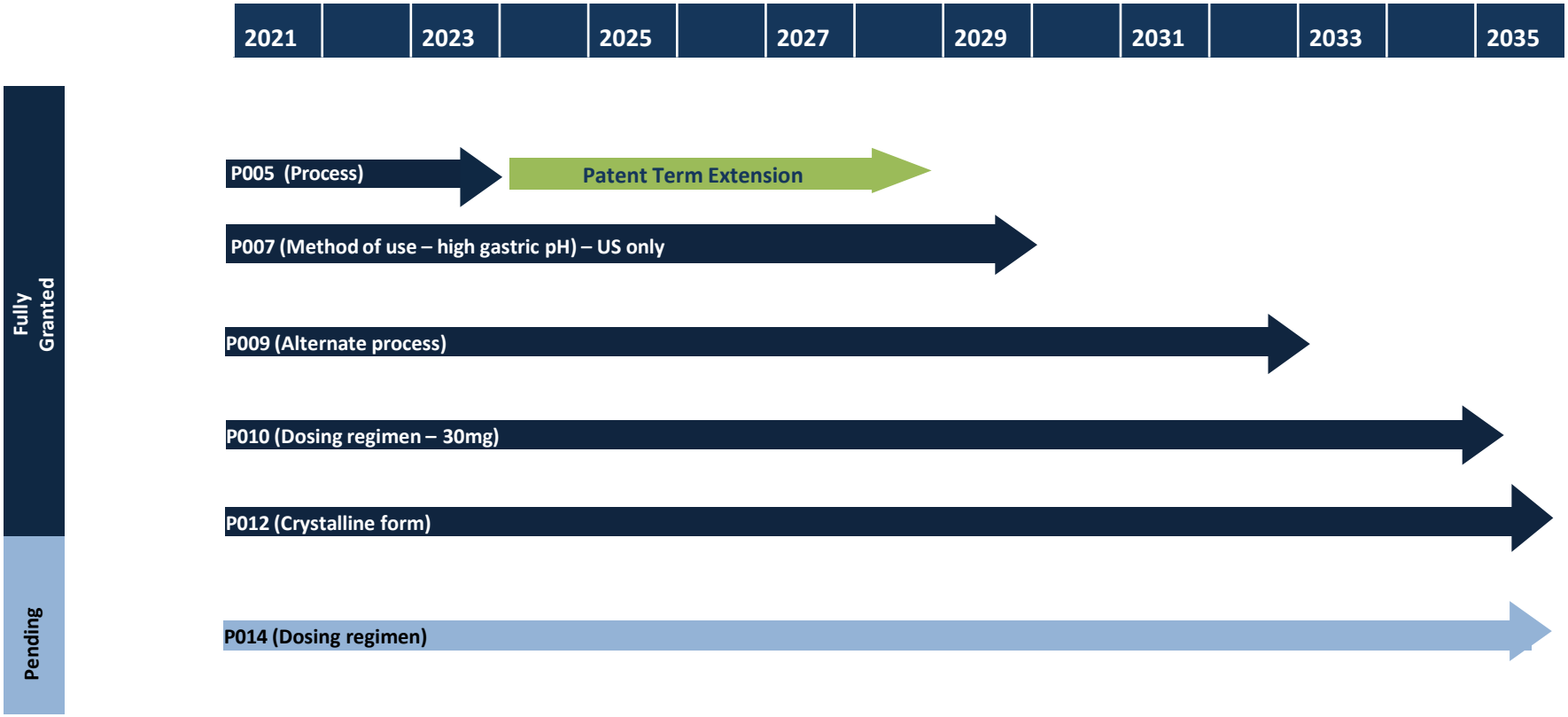
Licensed to ASK Pharm (January 2020)

- $11.4m upfront received
- IND application submitted - likely to require only one Phase III 12-week study in 120 IBD patients
- Potential approval & launch in 2023
- $11.4m milestone due on approval
- Sales royalties 10%-15% (ASK pays cost of goods)
- Sales milestones – up to $40m

Paediatric study

- A post-approval requirement of both EMA and FDA is to evaluate safety and tolerability (primary end points) of Feraccru®/Accrufer® in infants, children and adolescents
  - Secondary endpoints include change in Hb concentration and achieving Hb concentration within normal range by Week 12
- A liquid formulation has been developed and been tested in healthy adult volunteers for equivalence with the capsule (Stage 1)
  - Stage 1 Clinical Study Report (CSR) is expected by end February 2021
- The main study (Stage 2) is expected to start recruiting 110 subjects in Summer 2021
- Stage 2 forecast to cost around £4.5m and take 2- 2½ years
- Successful outcome expected to lead to label expansion to include children

Accrufer® / Feraccru® Patent portfolio



- Orange Book listed patents are P007, P010, P012.
- Patent Term Extensions have been applied for patents P005, P007, P009, P010, P012, Shield would elect to extend patent P005 if PTE granted.

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Cash Forecast
&
Use of Proceeds

Cash requirement, sources and use of proceeds

Cash requirement

- The Group's cash flow forecasts, including the US launch of Accrufer® and the paediatric study, show that the Group should start to breakeven on a monthly basis within 15-18 months after launch
- $30m-$40m should provide the finance necessary to reach the breakeven point

Fundraise announced 26 February 2021

- £25m placing + up to £4m open offer ($35m-$40m) equity
- Subject to shareholder approval (general meeting 18 March 2021)

Use of proceeds

- Bulk of GBP proceeds will be converted into US$ to avoid FX risk
- US launch costs will include sales representatives, market research and data analysis, marketing spend and other US operational costs
- The paediatric study and other non-US expenditure will be funded out of gross margin generated by US and Norgine revenues

Shareholder loan facilities

- The shareholder loan facilities announced on 10 December 2020 and confirmed on 29 January 2021 will be cancelled on completion of fundraise

Investment Highlights

- Accrufer® is a novel, oral, FDA-approved, US launch-ready, high margin iron replacement therapy
- U.S. iron deficiency market is large and undertreated, with significant unmet needs beyond current treatments
- Accrufer has been proven in clinical studies in IBD and CKD patients to be both effective and well-tolerated, and broad label allows for application in other indications and patient populations including oncology, women's health and chronic heart failure
- FDA granted NCE status until June 2024 and there are multiple patents protecting Accrufer out to 2035
- US opportunity offers very substantial upside – potential for $100m US sales and substantial cash generation in 3rd year after launch with only modest market penetration

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