



Corporate Presentation

April 2021

DefenCath™: A potentially new standard-of-care in the prevention of catheter related blood stream infections

Forward-Looking Statements

This presentation contains certain statements that constitute forward-looking statements within the meaning of the federal securities laws. Statements that are not historical facts, including statements about our beliefs and expectations, are forward-looking statements. These statements are not guarantees of future performance and involve risks, uncertainties and assumptions that are difficult to predict. The forward looking statements in this presentation include statements about our business, including commercialization plans and potential markets for our products and product candidates, clinical trials, potential indications for our product candidates, development timelines, regulatory timelines and future events that have not yet occurred. Pharmaceutical and medical device development inherently involves significant risks and uncertainties, including the risks outlined in “Risk Factors” in our Annual Report on Form 10-K filed with the Securities and Exchange Commission and in “Risk Factors” in our Quarterly Reports on Form 10-Q filed with the Securities and Exchange Commission. Our actual results may differ materially from our expectations due to these risks and uncertainties, including, but not limited to, our dependence on the success of our lead product candidate DefenCath™, and factors relating to commercialization and regulatory approval thereof; unpredictability of the size of the markets for, and market acceptance of DefenCath™; the timing for regulatory approval of DefenCath™ in the U.S.; our need for and ability to raise sufficient capital; our ability to identify and enter into strategic transactions; intellectual property protection; retaining our stock’s listing on NASDAQ; research and development activities; competition; industry environment, and other matters. Any forward-looking statements included in this presentation are based on information available to us on the date of this presentation. We undertake no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

DefenCath™ is a Novel Product Targeting Substantial Market Opportunities

Novel Product Addressing a Significant Unmet Need in Multiple Clinical Indications

- DefenCath is a novel catheter lock solution with the potential to change the standard of care in several large markets – no current pharmacologic agent approved to prevent infections associated with central venous catheters (CVCs)
- DefenCath is intended initially for CVCs used by hemodialysis patients with kidney failure to reduce the risk of catheter related blood stream infections. Expanded label to be sought for use in CVCs used by oncology and total parenteral nutrition (TPN) patients

Substantial Market Opportunities

- Cost for treating all CRBSI episodes and their complications is up to \$2.7B – 250,000 CRBSIs per year in U.S.¹
- Large addressable markets for catheter-lock solutions in hemodialysis setting (~80MM catheter lumen locks per year²) and oncology/TPN (~150MM catheter lumen locks per year³) in U.S.
- Hemodialysis market can be addressed with a modest sized infrastructure (~50 individuals) given concentration of the dialysis clinics

Recently Received CRL from FDA

- Granted rolling submission and priority review of NDA by FDA based on data from LOCK-IT-100; FDA completed review by February 28, 2021 PDUFA date; FDA not able to approve at this time due to manufacturing deficiencies
- Fast track and QIDP designations granted by FDA
- 10.5 years of potential market exclusivity pursuant to New Chemical Entity, QIDP designation and pediatric exclusivity

Data Demonstrate Effectiveness and Safety

- LOCK-IT-100 trial of DefenCath demonstrated 71% reduction in the risk of occurrence of CRBSI in 795 hemodialysis subjects
- Safety profile comparable to heparin catheter lock solution, which is the current standard of care designed to prevent clotting, but not infections

Talented and Experienced Management Team

- Executive management team brings significant relevant commercial and clinical experience from large pharma
- Leadership team has launched >40 drugs in aggregate at prior companies

¹ Becker's Hospital Review

^{2/3} Market research commissioned by CorMedix from third party firm

CorMedix Senior Management Team

Khosro Baluch	Chief Executive Officer	  
Matt David, MD	EVP and Chief Financial Officer	    
Phoebe Mounts, PhD, JD	EVP and General Counsel	   
Paul Chew, MD	Chief Medical Officer	  
Jack Armstrong	EVP Technical Operations	    
Elizabeth Masson Hurlburt	EVP & Head of Clinical Operations	  

Targeting a Substantial Commercial Market Opportunity

- *No pharmacologic agents approved in the U.S. for the prevention of CRBSI in central venous catheters*
- *Total annual cost in U.S. for treating all CRBSI and their complications up to \$2.7B*
- *Multiple organizations are focused on reducing CRBSIs – CDC, NIH, CMS, IDSA, ASCO, ASPEN, among others****

Hemodialysis

- 2025 estimate of ~80MM catheter lumen locks and growing**
- Meets eligibility requirements for add-on payment (TDAPA*) outside of the ESRD bundle for at least the first two years

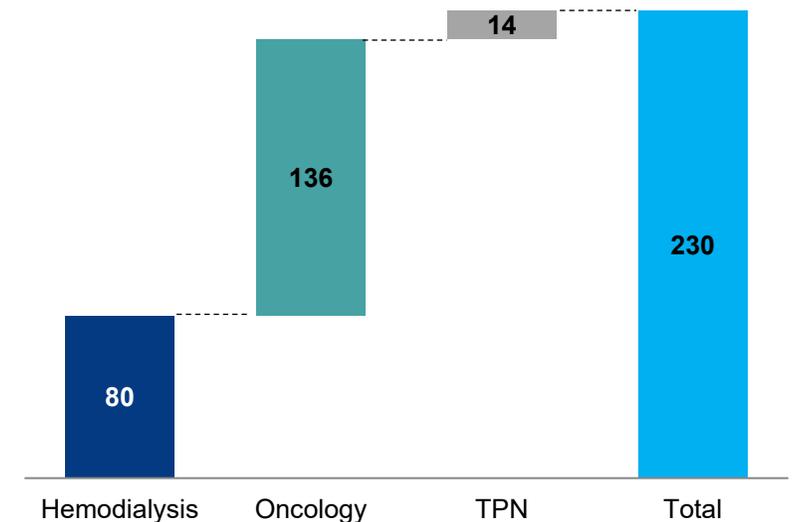
Oncology

- 2025 estimate of ~136 million catheter lumen locks**
- Immunocompromised patients at elevated risk of CRBSIs
- ~95% of patients treated for their cancer in out-patient settings, most with favorable ASP+ reimbursement

TPN

- 2025 estimate of ~13 million catheter lumen locks**
- Patients receiving TPN at home are at very high risk of infections

Estimated 2025 Market for Catheter-Lock Solutions
(lumen locks, annually)**



* TDAPA: Transitional Drug Add – On Payment Adjustment

** Source: Market research commissioned by CorMedix from third party firm

***Note: Centers for Disease Control and Surveillance (CDC), National Institutes for Health (NIH), Centers for Medicare and Medicaid Services (CMS), Infectious Disease Society of America (IDSA), American Society of Clinical Oncology (ASCO), American Society of Parenteral and Enteral Nutrition (ASPEN)

DefenCath™/Neutrolin® is an Anti-Bacterial and Anti-Fungal Catheter Lock Solution Designed to Prevent CRBSIs and Clotting

- *Used to fill catheter lumens when they are not in use to prevent microbial growth and clotting*

DEFENCATH / NEUTROLIN PROPRIETARY FORMULATION

- **Heparin 1000 U/ml** (anti-coagulant)
- **Taurolidine – 1.35%** (anti-infective)
- **Citrate – 3.5%** (pH buffer)

NEUTROLIN/DEFENCATH REGULATORY STATUS

- **In the EU, Neutrolin** is regulated as a medical device and is CE Marked for commercial distribution in the EU and other jurisdictions
- **In the US, DefenCath** is regulated as a New Drug; New Drug Application has been submitted and accepted for filing by FDA
- For medical professionals, catheter instillation of **Neutrolin/DefenCath** is consistent with current practice of using heparin, but with an added benefit of an anti-infective
- Broad antimicrobial activity, including gram-negative and gram-positive bacteria, multi-drug resistant bacteria, as well as fungi
- No demonstrated development of antimicrobial resistance in laboratory studies



LOCK-IT-100 – Pivotal Clinical Trial Design

DESIGN

- Phase 3, multicenter, double-blind, randomized (1:1), active control (heparin)
- Event-driven: 56 CRBSI events required to complete the study; 28 CRBSI events at Interim Analysis met pre-specified efficacy endpoint without safety concerns and Data Safety Monitoring Board recommended early termination
- Statistical power based on minimum treatment effect of 55% vs. the control arm

OBJECTIVE

- Demonstrate the efficacy and safety of Defencath as a catheter lock solution for the prevention of CRBSI and the incidence of treatment-emergent adverse events compared to heparin standard of care

PRIMARY ENDPOINT

- Time to occurrence of CRBSI

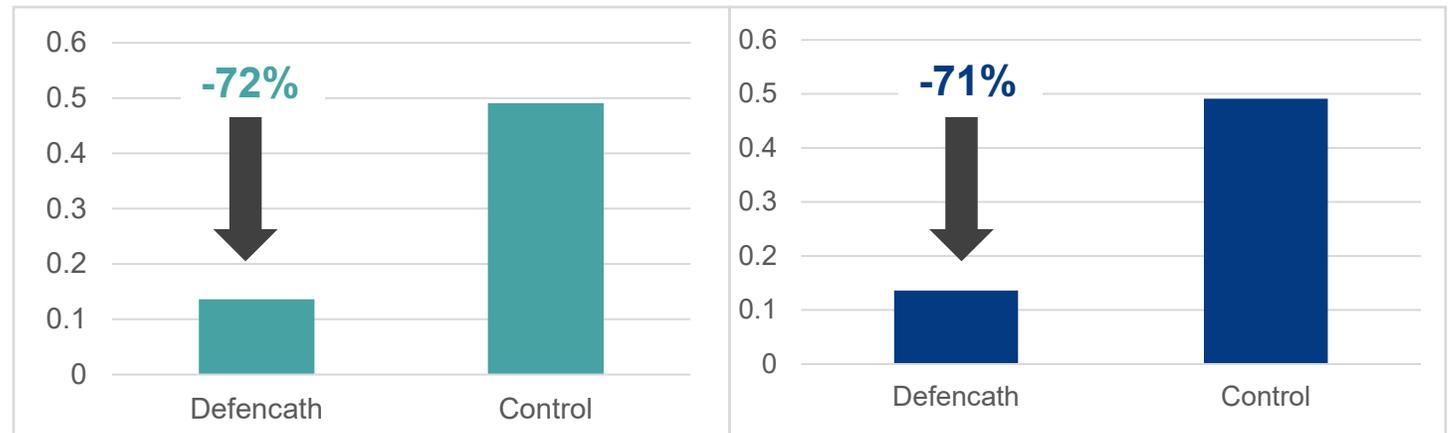
SECONDARY ENDPOINTS

- Loss of catheter patency
- Catheter removal for any reason

Phase 3 LOCK-IT-100 – Topline Results

- ✓ Primary endpoint met – highly statistically significant efficacy
- ✓ Secondary safety endpoints met - no statistically significant differences between DefenCath (D) & Heparin (H) control arm for loss of catheter patency and catheter removal

	Interim Analysis	Full Study
Total CRBSIs (D / H)	28 (6 D / 22 H)	41 (9 D / 32 H)
Total Subjects	653	795
DefenCath Reduced CRBSIs	72%	71%
DefenCath (heparin control) Event Rates*	0.136 (0.491)	0.133 (0.465)
p-value	0.0034	0.0006



*Event Rate is per 1,000 Catheter-Days

Phase 3 LOCK-IT-100 – Conclusions

01

LOCK-IT-100, a landmark study, showed that in ESRD subjects with hemodialysis via a central venous catheter, DefenCath catheter lock solution significantly reduced catheter-related bloodstream infections by **71% (p=0.0006) in 795 patients** (9 D, 32 H).

02

Compared to heparin, there was **NO statistically significant difference** in either catheter removals for any reason (p=0.42) or loss of catheter patency (p=0.12).

03

Treatment-emergent serious adverse events were **infrequent and similar** between DefenCath and Heparin arms.

DefenCath Regulatory Status

- DefenCath NDA was filed and supported by data from LOCK-IT-100 as substantial evidence of safety and effectiveness
 - Priority review of the NDA was granted; goal of 6 months vs. standard review period of 10 months
 - February 28, 2021 PDUFA
- Also requested NDA approval pursuant to Limited Population Pathway for Antibacterial and Antifungal Drugs (21st Century Cures Act), if needed to provide FDA with additional flexibility for NDA approval based on the single study of LOCK-IT-100
- Received a Complete Response Letter (CRL) from FDA that indicated the need to (1) resolve deficiencies at third-party manufacturing facility, where a pre-approval inspection could not be conducted due to the pandemic and (2) conduct a manual extraction study to confirm volume in DefenCath vials
 - Draft labeling for Limited Population of patients with kidney failure receiving hemodialysis via CVC pursuant to LPAD
- Met with FDA to align on proposed manual extraction study and discuss resolution of deficiencies identified at third-party manufacturing facility
 - CorMedix to continue to work through items needed in order to resubmit the DefenCath NDA

Marketing Exclusivity and Intellectual Property

MARKET EXCLUSIVITY

- **Upon approval, 10.5 years of potential market exclusivity**
- Designated an Investigational New Drug by FDA
- New Chemical Entity (NCE) Status – **5 years of exclusivity**
- Designated as Qualified Infectious Disease Product (QIDP) – additional **5 years of exclusivity**
- Approval for pediatric use would provide additional **6 months of exclusivity**

INTELLECTUAL PROPERTY PORTFOLIO

- Patent portfolio consists of:
 - 7 issued U.S. patents and 17 pending U.S. patent applications
 - 14 issued foreign patents and 45 pending foreign patent applications
- Additional patent applications to be filed to cover any additional related subject matter developed

DefenCath Pricing Will be Supported by its Clinical Benefit and Economic Benefits to the Healthcare System

Several factors currently being assessed to derive pricing include:

1

In the US, will be the first approved antimicrobial catheter lock solution

2

Facilities and patients involved in at-risk arrangements involving coordination of care

3

Clinical benefit of preventing life-threatening infections

4

Reductions in CRBSIs (inpatient and outpatient costs)

5

CRBSI-related complications reduced

6

Antibiotic use and potential for microbial resistance decreased

7

Fewer missed dialysis days

- Pricing will be supported by the offsets DefenCath provides to the broad economic burden on the U.S. healthcare system linked to CRBSIs
- Preliminary work completed; detailed analysis ongoing

Medicare (CMS) Accounts for ~90% of ESRD Reimbursement and is Very Focused on Quality of Care

ESRD PPS has quality measures as part of its reimbursement methodology

Coverage

Medicare coverage kicks in

- Ensures dialysis care for all patients
- Includes commercial insurance after a period of time

Quality of Care Measures

- Medicare rates all dialysis facilities on quality of care measures that are publicly available
- Measures include infection rates, hospitalizations
- Medicare is incorporating **additional** patient ratings on each dialysis facility to drive additional quality

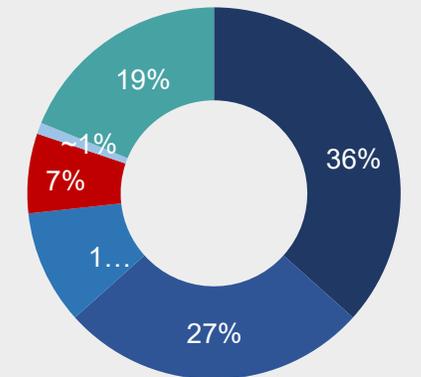
More Choice

Medicare Advantage

- Medicare Advantage (MA) becomes an available choice for all dialysis patients starting in 2021
- ESRD programs through MA typically provide additional covered services

Medicare has a special reimbursement program to encourage innovation called TDAPA – Transitional Drug Add-on Payment Adjustment

Payer Mix for Dialysis Patients



- Medicare FFS
- Medicare & Medicaid Dual Eligible
- Medicare Advantage
- Group Commercial
- Other Secondary Coverage
- Other Primary Coverage

DefenCath Reimbursement Opportunity Through TDAPA

Under new regulations effective January 2020, New Chemical Entities (NCEs) are eligible for CMS reimbursement outside the bundle under the TDAPA* program

- The intent of the TDAPA is to facilitate beneficiary access to certain new renal dialysis drugs or biological products by allowing payment for these products while the necessary utilization data are collected
- CMS will pay for the drug or biological using a TDAPA for at least 2 years – If the injectable or intravenous **product is used to treat or manage a condition for which there is not an existing ESRD PPS functional category**
- If approved under TDAPA, reimbursement of DefenCath would be calculated based on its average selling price

Drugs with TDAPA Designation

- Parsabiv® (Amgen)
- Sensipar® (Amgen)



- Both Amgen products received TDAPA extension **beyond** the 2 year mark
- Parsabiv **remains** in TDAPA
- Sensipar was terminated when generic became available

* TDAPA (Transitional Drug Add – On Payment Adjustment) allows for facilitation of beneficiary access to certain qualifying, new injectable or intravenous products by allowing payment for these drugs and biologicals while the necessary utilization data is collected.

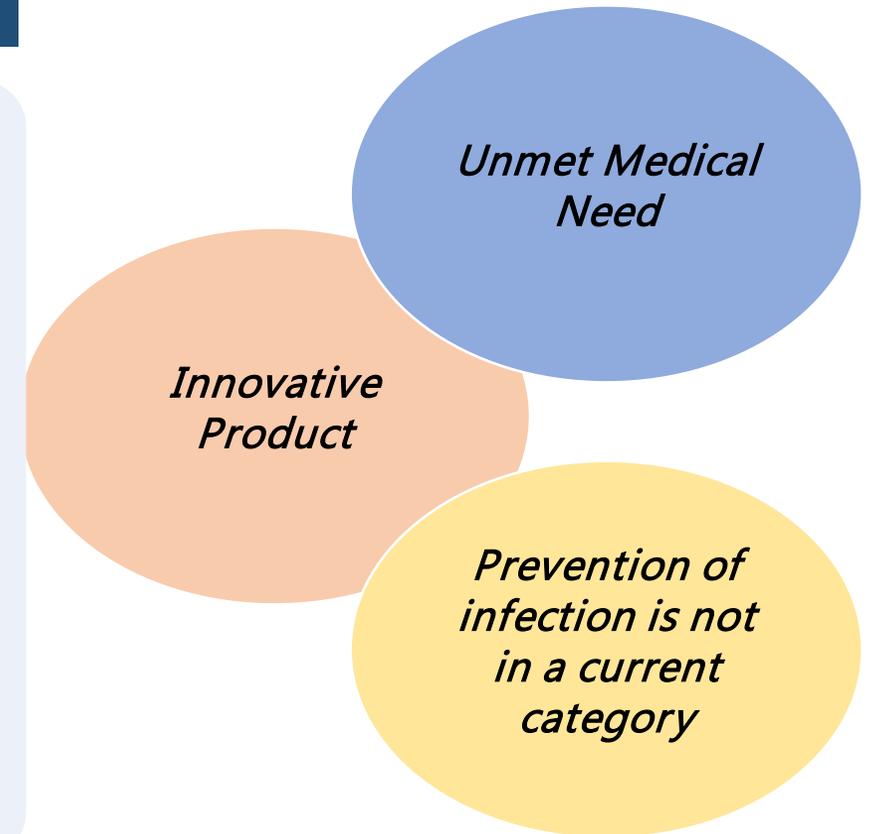
**ESRD PPS (End Stage Renal Disease Prospective Payment System)

*** Frequent catheter use for administration of drugs

CorMedix Believes DefenCath is Eligible for and Will Obtain TDAPA

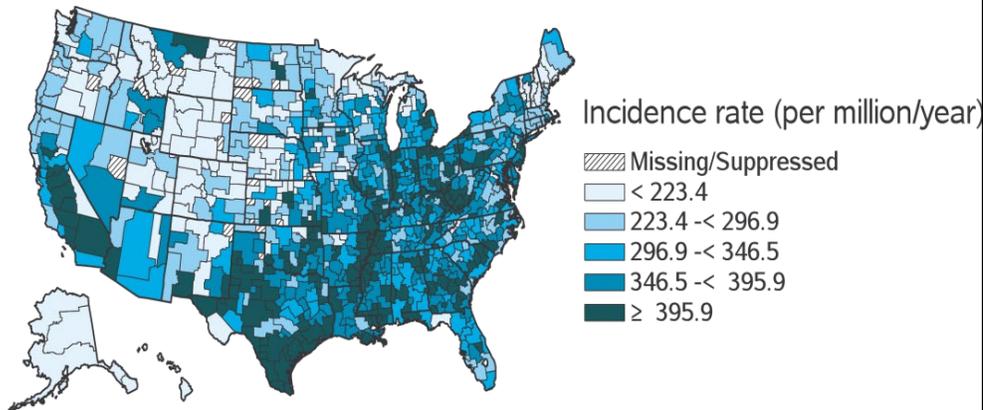
Highlights of Rationale to Support TDAPA

- ✓ *FDA Fast-Track Designation*
- ✓ *FDA Designated as Qualified Infectious Disease Product (QIDP)*
- ✓ *No standard of care has been established to prevent CRBSIs in hemodialysis patients*
- ✓ *Prevention is important as chronic use of anti-infectives increase potential for development of drug resistance*
- ✓ *Meets criterion of being a new renal dialysis product used to treat or manage a condition associated with ESRD*
- ✓ *Infections are the 2nd leading cause of death in patients with ESRD and CVCs are a significant risk factor for infection-associated mortality*



Commercial Execution Can Be Accomplished With a Highly Focused Organization

Map of the standardized incidence rate of ESRD, by Health Service Area, in the U.S. population, 2012 - present



Data Source: Special analyses, USRDS ESRD Database. Standardized to the age-sex-race distribution of the 2011 US population. Special analyses exclude unknown age, sex, HAS and unknown/other race. Values for cells with 10 or fewer patients are suppressed. Abbreviation: ESRD, end-stage renal disease

* In US, the largest dialysis providers include: DaVita, Fresenius, US Renal Care, Dialysis Clinic Inc., and American Renal Associates.

An initial commercial organization of ~50 people can provide adequate coverage for launch into hemodialysis:

- There are ~7,600 dialysis facilities, ~10,000 nephrologists
- However, 2,500 to 3,000 dialysis facilities provide ~ 70% of the opportunity
- 5 large dialysis organizations* account for >85% of the dialysis patients; central decision making
- Top 15 states account for ~ 70% of the patients
- CorMedix is laying the groundwork for building a commercial team to prepare for a launch in HD

The geographic concentration of ESRD along with the clear identification of dialysis facilities and corporate owners allows for targeting and efficient deployment of resources (sales reps, medical affairs and market access)

Label Expansion Into Other CVC Areas Provides Opportunities; Oncology has Compelling Dynamics

- There are multiple natural extension opportunities for DefenCath beyond hemodialysis catheters
- Among these, Oncology represents a compelling market opportunity¹
 - Largest number of catheter locks
 - Immunocompromised patients – risk for CRBSI can be 4.5x higher than in hemodialysis patients
 - Potential to avoid delays in chemotherapy and prolonged hospital stays
 - High oncologist interest
 - Favorable pricing dynamics
- CorMedix aims to obtain NDA approval DefenCath in hemodialysis patients and conduct studies for oncology and TPN in a post-approval setting (safety data focus)

Patient Population	Estimated Patients (2019)	Share with Central Venous Catheters	Market: # of CLS per year 2025
Hemodialysis	~565K	~20%	80m
Oncology	~6M*	~25% - 60%**	136m
Total Parenteral Nutrition	~300K Discharges + 26K home TPN	~100%	14m

¹ Source: Market research commissioned by CorMedix using a third party

Manufacturing Overview: Supply Chain Substantially Completed; Launch Quantities in Production

- Successfully concluded technical transfer and validation of the drug product manufacturing process, which has enabled production at 2 different manufacturing locations
 - Company has DMF for taurolidine; production process has been validated
- API (taurolidine and heparin) sourced from U.S./European manufacturers under contract and is shipped to drug product manufacturer, located in Europe
 - Multiple heparin suppliers available for sourcing
 - No Chinese-sourced heparin in supply chain
- Drug product manufacturer produces unlabeled vials in bulk packaging and these are shipped to U.S. for labeling and packaging; stored to be sold by 3PL
- Launch quantities are already in production
- Additional CMO, likely U.S.-based, anticipated for drug product manufacturing; required to meet anticipated demand
- Costs of production, shipment, and labelling/packaging expected to result in gross margins typical of pharmaceutical products

Financial Highlights

KEY STATISTICS

- Exchange: NASDAQ Global Market
- Common Stock: 38.0 million shares as of 3/25/2021
- Market cap: ~\$350 million

BALANCE SHEET

- Pro forma Cash*: \$87.8 million as of 12/31/2020
- Debt: None

* Inclusive of net proceeds from recent ATM issuance.

CorMedix Key Highlights

DefenCath is a Novel Product Addressing a Significant Unmet Medical Need

Seeking Approval in Lead Indication in Kidney Failure Patients Receiving Hemodialysis via CVCs

Potential for 10.5 Years of Market Exclusivity

Data Demonstrate Effectiveness and Safety for Preventing CRBSI in Hemodialysis

Substantial Market Opportunities in Hemodialysis; Further Upside in Oncology and TPN Markets

Senior Leadership with Significant Experience Bringing Drugs to Market

A photograph of a hospital room. In the foreground, a man in a white lab coat is seen from the back, looking towards a female nurse in blue scrubs who is wearing a white surgical mask and blue gloves. She is attending to a male patient lying in a hospital bed. The patient is wearing a white hospital gown. In the background, there is a window with blinds, a curtain, and a piece of medical equipment with a monitor and an IV drip hanging from a stand.

Thank you

A potentially new standard-of-care in the prevention of central venous catheter infections, decreasing hospitalizations and death