





FORWARD-LOOKING STATEMENTS

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Sigyn CardioDialysis™



A First-in-Industry Device to Address Cardiovascular Disease, the Leading Cause of Global Deaths





- ➤ Objective of CardioDialysisTM is to extend the lives of individuals with progressive cardiovascular disease (CVD)
- Mechanism simultaneously reduces the bloodstream presence of cholesterol-transporting lipoproteins and inflammatory molecules that drive CVD progression
- Deployed on the same dialysis machine infrastructure that extends the lives of individuals with end-stage renal disease (ESRD)





- Leading cause of death worldwide, responsible for nearly 1/3 of annual fatalities
- ➤ Reduction of Major Adverse Cardiovascular Events (MACE) is the primary clinical endpoint of CVD therapies
- Market for MACE reduction therapies estimated at \$150-200 billion





- Statins (Lipitor, Crestor, Zocor, etc.) that target LDL-C reduction are leading class of CVD drugs that reduce MACE by <u>25-35%</u>
- ➤ Lipoprotein Apheresis (LA) devices (Kaneka Liposorber, Fresenius DALI, MONET) that reduce the bloodstream presence of LDL-C and Lp(a) report MACE reductions of 55-98%

Note: LA treatments are limited to specialized apheresis centers. As an example, Liposorber administration is limited to fewer than 60 locations in the U.S.







Sigyn CardioDialysis™ An Emerging Strategy to Reduce MACE

- Targets LDL-C and Lp(a) reduction (proven to significantly reduce MACE)
- Simultaneous reduction of inflammatory molecules that drive CVD progression
- Deployed on dialysis machines already located in 7,500+ U.S. Dialysis Clinics





Sigyn CardioDialysisTM An Emerging Strategy to Reduce MACE

- Highly Efficient Processes the bloodstream~15 times during a four-hour treatment
- Immense Capacity Incorporates a formulation of adsorbent components with ~200,000 M² of surface area (50 acres) to remove CVD targets



An Opportunity to Transform the Dialysis Industry

- > Extending the lives of end-stage renal disease (ESRD) patients has quantifiable value to the dialysis industry
- ➤ CardioDialysisTM establishes a pathway to treat CVD in the general population, which is the focal point of Lipoprotein Apheresis
- We envision today's kidney dialysis clinics as being "Renal and CardioDialysis Treatment Centers" in the future



CVD in End-Stage Renal Disease (ESRD) Dialysis Patients

- 550,000+ ESRD patients receive ~85 million dialysis treatments in the U.S. each year
- ➤ Annual mortality rate is ~20%
- > Cardiovascular Disease (CVD) is the leading cause of ESRD patient deaths
- Endotoxemia, concurrent inflammation, and Lp(a) accumulation increases the incidence of MACE



Two Organizations Dominate The U.S. Dialysis Industry



38% Market Share



37% Market Share



The Value of Extending ESRD Patient Lives





~\$1 billion of added revenue per Company for each month of extended life



The Value of Reducing ESRD Patient Hospitalizations





~\$250 million of recouped revenues per Company for each week of reduced hospitalization



Sigyn CardioDialysisTM Clinical Plan

- Investigation Device Exemption (IDE) drafted for FDA submission
- > Feasibility study protocol to enroll 12-15 ESRD subjects at three site locations
- ➤ Sigyn CardioDialysisTM to be administered in series with regular dialysis treatments
- Primary endpoint is safety / secondary endpoints LDL-C & Lp(a) reduction / quantification of endotoxin and inflammatory cytokine levels
- > Study completion sets stage for ESRD subject pivotal study and establishes a potential pathway to initiate cardiovascular disease studies in the general (non-ESRD) population



Question?

How would a cardiovascular disease treatment be valued if it reduced Major Adverse Cardiovascular Events (MACE) in the general population?

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