KINLYTIC® UROKINASE

A US FDA APPROVED DRUG WITH A CLEAR & GROWING INDICATION

- Kinlytic® urokinase (formerly Abbokinase®) is an injectable thrombolytic or "clot-buster."
- Kinlytic is approved in the US and Canada to clear blood clots from intravenous catheters.
- Urokinase has treated over 4 million patients, with well-established efficacy and safety.
- Microbix® has a detailed and FDA reviewed plan to return Kinlytic to the lucrative US market.
- Microbix is well-qualified to direct this project for a committed strategic partner.

Urokinase is a naturally-occurring serine protease. Kinlytic is its low molecular weight form (LMW-UK), produced through a cost-effective cell culture process. It is efficient at clearing clots via enzymatic cleavage of fibrin, a major structural component of clots. Kinlytic is the only approved LMW-UK worldwide, providing both US and international sales potential.

CATHETER CLEARANCE MARKET OPPORTUNITY

- Over 7 million central venous catheters are used each year, with 25% blocked by clots[1].
- Catheters not cleared with a thrombolytic must be replaced, adding cost and patient risk.
- The US now endures a monopoly, held by Cathflo Activase® (Genentech's tPA).
- US Cathflo sales were $310 million in 2017 and are growing at ≥10% annually[2].
- Microbix believes 40% market share is attainable, for ultimate annual sales of >$200 million.
- Kinlytic production is well-understood, with a highly-attractive margin and cash flows.

1 – Dillon J.Clin. Oncol. 2004 2 - IMS data

PATHWAY BACK TO THE US MARKET

- Microbix owns all intellectual property associated with Kinlytic, including its regulatory approvals, cell banks and the reference standards used for prior commercial batches.
- Manufacturing will be re-established using qualified contract organizations (e.g., CMOs).
- Regulatory filing will be a supplement to the already approved NDA.
- The re-introduction plan has been discussed with FDA and will include analytical comparisons, animal PK studies and a bridging efficacy study in blocked catheters.
- The project will cost $18 million to FDA filing, based on 3rd party quotations and including all manufacturing, revalidations, a bridging study and filing fees.
- The full project has been designed to take 2 ½ years from start to supplemental (sNDA) filing with the US FDA.

PARTNER INVESTMENT AND RETURNS

- Kinlytic will become the sole alternative to the Cathflo monopoly in the US, providing pricing relief and ensuring security of thrombolytic supply to healthcare providers.[3]
- First-entrant generic and biosimilar precedents suggest that a modest price concession and updated product format will achieve significant and lasting market share for the indication.[4]
- Manufacturing is cost-efficient and enjoys high margins with the small amount (5,000 IU) of active ingredient needed for the indication. Current approved cells banks will support 7 years of manufacturing against plan.
- Marketing can be targeted to high-volume institutional users, requiring only a small specialty sales and training force, with no need for mass detailing or broad advertising
- US only sales over the ten years post introduction are estimated at over $1.4 billion, with a project IRR in excess of 80% and highly positive NPV under any reasonable cost of capital.

3 – IMS Data - Cathflo pricing has increased by approximately 6% every year. A major supply disruption occurred in 2013
4 – Hollis, Health Economics 11 (2002)

Microbix requires a partner capable of funding the full $18 million cost of the project over the 2½ -year term to filing and through re-launch. Of the total amount, only $1.7 million is required for the low risk and fast to execute bridging clinical study, the design of which has been discussed with FDA. Microbix requires a meaningful up-front payment and future success-dependent considerations. In turn, it can provide knowledge transfer or project management support. It is expected that proposals will detail such terms.

OTHER KINLYTIC MARKET OPPORTUNITIES

- In addition to a sustained US duopoly franchise for catheter clearance, re-launch might also be pursued in Canada, along with jurisdictions likely to recognize FDA approval.
- Current models only contemplate use in blocked catheters. A trial program to build on existing studies for prophylaxis of catheter-related complications, including systemic infection, could expand the label claim and double the market in catheter management.
- Following catheter-clearance, equivalency trials could be run in support of re-launch for the FDA-approved treatment of pulmonary embolism.
- Trial programs might likewise be conducted to register the previous off-label usages of Kinlytic, including deep vein thrombosis, peripheral arterial occlusion, stroke and in oncology.

FOR FURTHER INFORMATION, PLEASE CONTACT

MICROBIX

Torreya Partners
(212) 257-5806

Tom Bird, Partner
tom.bird@torreya.com

Microbix Biosystems Inc.
265 Watline Avenue
Mississauga, Ontario
L4Z 1P3
905-361-8910
www.microbix.com

Cameron Groome, CEO & President
cameron.groome@microbix.com

Kevin Cassidy, VP Biopharmaceuticals
kevin.cassidy@microbix.com