Press Release

Microbix and Zydus Cadila reach agreement to market Urokinase, a critical care therapy in North America

AHMEDABAD, January 6, 2012

Microbix Biosystems Inc. (TSX: MBX), a biotechnology company commercializing novel technologies and Zydus Cadila, a global pharmaceutical company headquartered in India, today reported that they have signed a Letter of Intent to market the Thrombolytic drug, Urokinase in the North American markets. The estimated market size for Urokinase use in the U.S. alone is expected to touch $400 million by 2020 between three indications: pulmonary embolism, catheter clearance and catheter prophylaxis. The same active pharmaceutical ingredient can be used in new and even larger indications in oncology and ophthalmology.

Urokinase, a successful thrombolytic drug, was first approved in the U.S. in 1978 for pulmonary embolism (blockage in the arteries supplying blood to the lungs) and coronary occlusion (blockage in the vessels which carry blood to the heart). It was used substantially off label for dissolving large peripheral thrombi (clotting in the arteries which supply blood to the limbs) in arms and legs, and until 1998 it was the standard of care for catheter clearance where it is used to re-establish flow in occluded biomedical catheters. Over 4 million patients have been treated successfully with Urokinase. Many physicians remain loyal to Urokinase due to the drug’s superior and well-documented safety profile as well as cost and efficacy. The drug was withdrawn from the market for 3 years from 1999 to 2002 for reasons unrelated to product performance. Urokinase was acquired by Microbix in 2008 which has since then stepped up efforts to re-introduce the drug in North America.

William J. Gastle, Chief Executive Officer, Microbix Biosystems said: "Microbix has been the champion of Urokinase and we are committed to returning this life saving therapy to physicians and patients. We have been investing to rebuild this franchise including manufacturing infrastructure, raw materials, and technical expertise, in addition to acquiring the approved NDA’s for both Canada and the US markets. With Zydus, we now have a strong commercial partner to help us realize our objective."

The Ontario-based, Microbix Biosystems Inc., specializes in the development of biological technologies and markets virology and biological products worldwide. The company’s expertise ranges from influenza vaccine manufacturing, an animal reproduction technology for semen sexing, and to a virology products business supplying to diagnostic and pharmaceutical companies worldwide.

Pankaj Patel, Chairman and Managing Director of Zydus Cadila said, “We have been investing in novel technologies, particularly in the area of biotechnology and have also been exploring partnerships to bring critical care therapies to the marketplace. Microbix’ Urokinase strengthens our critical care portfolio and enhances our ability to globalize our capabilities”.

Zydus Pharmaceuticals USA Inc., the group’s subsidiary in the US is ranked 12th amongst the top generic companies in the US. 51 million prescriptions are dispensed with Zydus generics in the US annually. The company is among the top 3 players in the US market for 9 out of the 10 products marketed.
In the last two years Microbix reported that the discussions on Urokinase have been underway with various potential industry partners. The terms of the agreement between both the companies requires Zydus to provide the funding needed to re-launch the drug in the US and Canada, including an initial commitment, plus milestone based payments. Microbix will also receive a milestone payment upon reaching a certain sales target and will be guaranteed a margin plus earn a royalty fee based on sales. Zydus will receive an option on the rights to all future indications including in the areas of oncology and ophthalmology.

Gastle added, “The immediate impact will include the financial support and regulatory expertise that Zydus will bring to implementing the business plan for re-launching the drug. Zydus has very experienced regulatory staff that will assist Microbix in guiding the file through the FDA and Health Canada”. The Companies expect a definitive agreement to be signed early in 2012. The anticipated timeline for approval is late 2014.

One of the key opinion leaders on Urokinase is Dr. Ken Ouriel former Chairman, Division of Surgery at the Cleveland Clinic and former Senior V-P, International Operations, Presbyterian Hospital, New York, stated, "Urokinase was our workhorse agent for dissolving clots within arteries and veins until it became unavailable. Physicians felt very comfortable with its margin of safety and would welcome its long-overdue return to the marketplace”.

In October 2011 Microbix received approval for a Base Shelf Prospectus to help fund its product development pipeline including Urokinase. The consummation of this agreement will reduce the need for funds to be raised and, consequently, the Prospectus will be amended to reflect Zydus’ funding for Urokinase.

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About Microbix Biosystems

Microbix Biosystems Inc. specializes in the development of biological technologies and markets virology and biological products worldwide. The Company has intellectual property in large market products including a FDA approved biotherapeutic drug, a proprietary vaccine technology and an animal reproduction technology. Microbix supplies customers in the U.S. Europe, and Asia. Established in 1988, Microbix is headquartered in Mississauga, Ontario, Canada. Visit www.micribx.com or contact: William J. Gastle, CEO, (416) 234-1624 x 230; or James Long, CFO, (416) 234-1624 x 265.

About Zydus Cadila

Zydus Cadila is an innovative global pharmaceutical company that discovers, develops, manufactures and markets a broad range of healthcare products. The group’s operations range from API to formulations, animal health products and cosmeceuticals. Headquartered in the city of Ahmedabad in India, the group has global operations in four continents spread across USA, Europe, Japan, Brazil, South Africa and 25 other emerging markets. The group has been one of the fastest growing healthcare companies in recent years and reported 41% growth in profits for 2010-11. Revenues were in excess of US$ 1 billion. In its mission to create healthier communities globally, Zydus Cadila delivers wide ranging healthcare solutions and value to its customers. With over 13,500 employees worldwide, a world-class research and development centre dedicated to discovery research and eight state-of-the-art manufacturing plants, the group is dedicated to improving people’s lives. For further information: Visit http://www.zyduscadila.com/
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