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RIKEN Medical Technology Seed Development at M3 Group

Artificial Dura Mater "DuraBeam<sup>TM</sup>" Production and Distribution Approval in Japan

M3, Inc. (Headquarters: Tokyo, Japan; CEO: Itaru Tanimura; URL: <a href="https://corporate.m3.com/en/">https://corporate.m3.com/en/</a>; "M3" below) has announced that TamaBio (Headquarters: Tokyo, Japan; CEO: Makoto Sawada; "TamaBio" below), a subsidiary established in last April based on the dominant patent held by RIKEN, Japan. (Headquarters: Saitama, Japan; President: Hiroshi Matsumoto; URL: <a href="http://www.riken.jp/en/">http://www.riken.jp/en/</a>; "RIKEN" below). has received approval from the Ministry of Health, Labour and Welfare (MHLW) for the production and distribution (Class IV) of "DuraBeam" in Japan.

"DuraBeam<sup>TM</sup>" was developed by TamaBio as a part of the M3 Seeds Rocket
Business upon acquiring the dominant patent for the technology to specially process
artificial dura mater with polymer resin, researched by RIKEN. Currently, various artificial
organs including artificial dura mater are in development as medical devices in forms such
as implants, to establish alternatives to the patients' kinematic and biological body functions
lost through accidents and surgery. However, post-surgery infections, adhesions, and
various adverse events are problems being faced in the clinical space. "DuraBeam<sup>TM</sup>"
developed by TamaBio was designed incorporating expert surgeon opinions to overcome

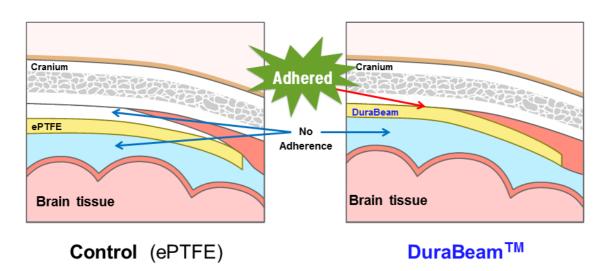
these issues and is expected to offer high biocompatibility, shortened surgery times, and lower infection risk.

TamaBio aims to further develop the technology of specially processing polymer resin, to promptly deliver the product for use as practical generic technology to patients in need. The CEO, Makoto Sawada, has had extensive experience in regulatory affairs, such as leading a major medical device company as its Director of the regulatory Department, and founding a regulatory affairs consulting firm. We will pursue the R&D and business development of this technology by maximizing his expertise and M3 group's development and regulatory support capabilities. Going forward, we look to developing artificial organs other than artificial dura mater in overseas markets as well.

Through the seeds investment subsidiary M3i, Inc. (Headquarter: Tokyo, CEO: Kazuhiro Umeda, "M3i" below), M3i has provided comprehensive business management support from the early stages of business initiatives planning of TamaBio in the form of management resource provision, regulatory planning consult, advice from pharmaceutical, chemical, and material technology advisors, and business structure development, while also injecting capital as a co-founder and founding investor.

Through the M3i Seeds Rocket Business initiatives, M3 will endeavor to fill global Unmet Medical Needs (medical needs of patients with currently un-curable diseases) with least delay, to produce pharmaceutical, device, and regenerative products that are truly appreciated by patients.

## ■ "Durabeam<sup>™</sup>" Utilization Image



■ Total Domestic Addressable Market

Estimated annual number of open brain surgeries: 77,000 (Extrapolated from 6,463 surgeries in September, Ministry of Health 2015 Report)

■ Comment from the CEO of TamaBio, Makoto Sawada

The research for this product's technology began 20 years ago at RIKEN. Durabeam<sup>™</sup> is the result of endless research efforts contributed by researchers and clinical physicians. With the support of everyone at numerous cooperative companies, the approval we have received today from the MHLW for the production and distribution of this product is truly a gift. Any person or part missing would have prevented it from being born into the world as a medical device. This technology has potential applications not only for neurosurgery, but also within cardiovascular surgery, gastrointestinal surgery, and various other surgical areas, and I am convinced that it holds the key to saving millions of patient lives across the globe.

- Comment from the Director of RIKEN Cluster for Industry Partnerships, Akihiro Fujita

  I am delighted that artificial dura mater based on research conducted at RIKEN has gained approval for production and distribution. I anticipate that there will be important medical applications.
- TamaBio Overview

Founded: April 2016 (M3 subsidiary)

Address: Akasaka Intercity 10th floor, 1-11-44 Akasaka, Minato-ku, Tokyo 107-0052

Employees: 9 (including directors)

CEO: Makoto Sawada