



Miromatrix and Baxter Announce Collaborative Research Agreement Aiming to Advance Care for Patients with Acute Liver Failure

- Combines Miromatrix's expertise in bioengineered organs with Baxter's leadership in critical care delivery and organ support therapies
- Includes intended Phase I clinical trial designed to generate key evidence to support additional therapeutic options for patients suffering from acute liver failure

EDEN PRAIRIE, Minn. and DEERFIELD, Ill., February 1, 2023 - Miromatrix Medical Inc. (NASDAQ: MIRO) and Baxter International Inc. (NYSE:BAX) today announced a collaborative research agreement to help support additional treatment options for patients with acute liver failure (ALF) in need of organ support therapies. As part of the collaboration, Miromatrix has created a new liver therapy called **miroliverELAP** that combines a Miromatrix single-use bioengineered liver with Baxter's **PrisMax** system. Miromatrix submitted an Investigational New Drug (IND) application for **miroliverELAP** to the U.S. Food and Drug Administration (FDA) in November 2022, which appears to be the first IND for a bioengineered organ. Miromatrix intends to commence a Phase I clinical trial using **miroliverELAP** to treat patients suffering from ALF, following FDA's decision that the trial may proceed. Baxter is both a collaborator and shareholder of Miromatrix.

"Miromatrix believes that **miroliverELAP** has the potential to save and improve the lives of ALF patients while simultaneously increasing the availability of livers for transplant into other patients," said Jeff Ross, Ph.D., Miromatrix CEO. "We are excited to be partnering with Baxter to pioneer this next generation innovation in acute care and liver disease."

ALF is a serious condition with limited clinical interventions. Over 50,000 people in the United States die from liver failure each year,ⁱ often because they cannot receive a liver transplant in time.ⁱⁱ However, the liver is capable of regenerating itself back to health in certain circumstances, making therapy to support the native liver during ALF highly clinically relevant. **MiroliverELAP** is designed to provide external support to the patient's native liver as a bridge-to-transplant or bridge-to-recovery, potentially helping to avoid a liver transplant. The **miroliverELAP** Phase I clinical trial will serve as a foundational building block to start generating evidence on how this pioneering therapy may help support patients with ALF.

Miromatrix's bioengineered liver is designed to replicate key functions of a human liver and is connected to Baxter's **PrisMax** system outside of the patient's body to create the **miroliverELAP** system. **MiroliverELAP** is designed to provide therapeutic support to ALF patients in hopes their native livers will regenerate themselves back to health. Baxter's **PrisMax** system is designed to help simplify delivery of continuous renal replacement therapy (CRRT) and other therapies, while providing hospitals the flexibility to meet the unique demands of the intensive care unit (ICU). As part of this collaboration, Baxter has created custom software and disposables to run the **miroliverELAP** treatments during the Phase I clinical trial.

"Baxter is focused on promoting continuous innovation to advance our organ support therapies and further elevate care for patients with ALF and other critical conditions," said Brian Tufts, Vice President, Acute Therapies at Baxter. "Combining Miromatrix's pioneering bioengineered organ technology with Baxter's expertise in critical care delivery and industry-leading **PrisMax** system has the potential to transform care for ALF patients."



About Miromatrix

Miromatrix Medical Inc. is a life sciences company pioneering a novel technology for bioengineering fully transplantable human organs to help save and improve patients' lives. The Company has developed a proprietary perfusion technology platform for bioengineering organs that it believes will efficiently scale to address the shortage of available human organs. The Company's initial development focus is on human livers and kidneys. For more information, visit miromatrix.com.

About Baxter

Every day, millions of patients, caregivers and healthcare providers rely on Baxter's leading portfolio of diagnostic, critical care, kidney care, nutrition, hospital and surgical products used across patient homes, hospitals, physician offices and other sites of care. For more than 90 years, we've been operating at the critical intersection where innovations that save and sustain lives meet the healthcare providers who make it happen. With products, digital health solutions and therapies available in more than 100 countries, Baxter's employees worldwide are now building upon the company's rich heritage of medical breakthroughs to advance the next generation of transformative healthcare innovations. To learn more, visit www.baxter.com and follow us on [Twitter](#), [LinkedIn](#) and [Facebook](#).

Intended Use for PrisMax in the U.S.

The **PrisMax** control unit is intended for:

Continuous Renal Replacement Therapy (CRRT) for patients weighing 20 kg or more with acute renal failure and/or fluid overload.

Therapeutic Plasma Exchange (TPE) therapy for patients weighing 20 kg or more with diseases where removal of plasma components is indicated.

All treatments administered via the **PrisMax** control unit must be prescribed by a physician.

Rx Only. For safe and proper use of the **PrisMax** device, refer to the full Instructions for Use.

Cautionary Statement Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical facts are forward looking statements of Miromatrix Medical Inc., including statements regarding the potential initiation of **miroliverELAP** clinical trials. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "outlook," "guidance," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. The forward-looking statements in this press release are only predictions and are based largely on Miromatrix's current business plans, expectations, and projections about future events and financial trends that Miromatrix believes may affect its business, financial condition, and results of operations. These forward-looking statements speak only as of the date of this press release and are subject to a number of known and unknown risks, uncertainties and assumptions, including, but not limited to, Miromatrix's history of significant losses, which it expects to continue; Miromatrix's limited history operating as a commercial company; Miromatrix's expectations with respect to the regulatory pathway of its product candidates, Miromatrix's ability to obtain regulatory approvals for such product candidates, and the anticipated effect of delays in obtaining any such regulatory approvals; Miromatrix's expectations with respect to preclinical and clinical trial plans for our product candidates, the results of such activities and the safety and efficacy of Miromatrix's product candidates; Miromatrix's ability to commercialize its product candidates; Miromatrix's ability to compete successfully with larger



competitors in its highly competitive industry; Miromatrix's ability to achieve and maintain adequate levels of coverage or reimbursement for any future products it may seek to commercialize; Miromatrix's expectations regarding its manufacturing capabilities; a pandemic, epidemic or outbreak of an infectious disease in the U.S. or worldwide, including the outbreak of the novel strain of coronavirus, COVID-19; product liability claims; Miromatrix's ability to establish and maintain intellectual property protection for its products, as well as its ability to operate its business without infringing the intellectual property rights of others; Miromatrix's ability to attract and retain senior management and key scientific personnel; and other important factors that could cause actual results, performance or achievements to differ materially from those expected or projected. For information identifying important factors that could cause actual results to differ materially from those anticipated in the forward-looking statements, please refer to the Risk Factors section of Miromatrix's Form 10-K filed with the U.S. Securities and Exchange Commission and any additional risks presented in its Quarterly Reports on Form 10-Q and its Current Reports on Form 8-K. Except as expressly required by applicable securities law, Miromatrix disclaims any intention or obligation to update or revise any forward-looking statements whether as a result of new information, future events or otherwise.

Miroliver and **miroliverELAP** are registered trademarks of Miromatrix Medical Inc. **Baxter** and **PrisMax** are registered trademarks of Baxter International Inc.

Miromatrix Investor Contact:

Greg Chodaczek
347-620-7010
ir@miromatrix.com

Miromatrix Media Contact:

Christina Campbell
612-280-0249
Christina@media-minefield.com

Baxter Investor Contact:

Clare Trachtman
224-948-3020

Baxter Media Contact:

Andrea Johnson
224-948-5353
media@baxter.com

ⁱ American Liver Foundation: [How Many People Have Liver Disease?](#)

ⁱⁱ American Liver Foundation: [Liver Transplantation](#)