



## The University of Texas Health Science Center at Houston joins Biomerica's InFoods® Irritable Bowel Syndrome ("IBS") Diagnostic-Guided Therapy ("DGT") clinical trial

- InFoods® Diagnostic-Guided Therapy is designed to identify patient-specific foods that, when removed from the diet, may alleviate an individual's IBS symptoms
- Approximately 45 million Americans suffer from IBS<sup>1</sup>

IRVINE, CA--(June 29, 2020) - Biomerica Inc. (NASDAQ: [BMRA](#)) today announced it has signed a definitive agreement with the University of Texas Health Science Center at Houston ("UTH") to join the clinical trial for Biomerica's new InFoods® diagnostic-guided therapy, designed to alleviate Irritable Bowel Syndrome (IBS) symptoms. The University of Texas Health Science Center at Houston is the fifth large medical center to be part of the InFoods® clinical trial which includes: Mayo Clinic, Beth Israel Deaconess Medical Center Inc., a Harvard Medical School Teaching Hospital, Houston Methodist and the University of Michigan as primary enrollment centers. UTH can now begin enrollment of patients in this trial.

It is estimated that over 45 million Americans suffer from IBS and the symptoms are often triggered by consumption of specific foods (which are unique in each sufferer). The total cost (direct + indirect) of IBS has been estimated at \$30 billion annually in the United States. IBS is a common condition that can substantially impair physical and mental well-being of a patient and a person's ability to function both at home and in the workplace.

A clinical lab version of the InFoods® IBS DGT product is being used in this clinical trial. However, the Company is also working to develop a point-of-care version of the InFoods® IBS DGT product that would potentially allow physicians to perform the test in-office using a finger stick blood sample. The point of care version would allow physicians to be reimbursed for administering the test. A billable CPT code that can be used by both clinical labs and physicians' offices is already available for the InFoods® IBS products. Market research conducted by a leading, independent, pharmaceutical, marketing research firm, determined that over 70% of physicians surveyed would utilize the InFoods® DGT to treat their IBS patients without reimbursement and over 90% would utilize it with reimbursement.

Importantly, the InFoods® DGT can be used without or in conjunction with current IBS pharmaceuticals to potentially improve patient outcomes. Since the InFoods® product is a diagnostic-guided therapy and not a drug, it has no drug-type side effects.

The current endpoint clinical trial is expected to be completed in approximately 6 months. However, due to the novel coronavirus' impact on the U.S.'s healthcare system, it may take longer. If all goes as expected, Biomerica plans to commence the final pivotal trial several months thereafter, which is needed for submission to the FDA for final clearance. The endpoint trial stratifies enrollment by the three main IBS subclasses (IBS-Constipation, IBS-Diarrhea and IBS-Mixed). The clinical study design has already received a non-significant risk determination from the FDA.

Dr. Brooks D. Cash, Chief of Gastroenterology, Hepatology, and Nutrition at the University of Texas Health Science Center at the Texas Medical Center, stated, "We are excited about the potential impact this can make for IBS patients and excited to be part of the clinical trial group for InFoods® IBS. The product is novel in that it is addressing a root cause of IBS with a non-pharmaceutical therapy, yet can be combined with current pharmaceutical therapies to improve outcomes."

Zackary Irani, Chief Executive Officer of Biomerica, commented: "IBS remains a major burden for up to 45 million people in the United States who desperately seek some form of medical advancement providing relief. We believe our approach, supported by a Scientific Advisory Board comprised of the leading minds in the IBS medical community, is differentiated by focusing on one possible root cause of IBS compared to simply treating symptoms."

#### **About Biomerica (NASDAQ: [BMRA](#))**

Biomerica, Inc. ([www.biomerica.com](http://www.biomerica.com)) is a global biomedical technology company that develops, patents, manufactures and markets advanced diagnostic and therapeutic products used at the point-of-care (in home and in physicians' offices) and in hospital/clinical laboratories, for detection and/or treatment of medical conditions and diseases. The Company's products are designed to enhance the health and well-being of people, while reducing total healthcare costs. Biomerica primarily focuses on gastrointestinal and inflammatory diseases where the Company has multiple diagnostic and therapeutic products in development.

The Private Securities Litigation Reform Act of 1995 provides a "safe harbor" for forward-looking statements. Certain information included in this press release (as well as information included in oral statements or other written statements made or to be made by Biomerica) contains statements that are forward-looking, such as statements relating to the efficacy of the Company's tests, the rapidity of testing results, pricing of the Company's test kits, commencement of FDA clinical trials, completion of clinical trials, favorable outlook pertaining to clinical trial outcomes, the FDA's acceptance of clinical trials data, clearance from the FDA for the Company's products to be sold in the US, receipt of regulatory approvals for the Company's products to be sold outside of the US, demand for domestic US and international orders, availability of the Company's test kits, and patent protection on the test technology. Such forward-looking information involves important risks and uncertainties that could significantly affect anticipated results in the future, including, without limitation: results of studies testing the efficacy of the Company's test; regulatory approvals necessary prior to commercialization of the Company's test and or therapy; availability of the Company's test kits; capacity, resource and other constraints on our suppliers; the Company's ability to effectively manufacture the test kit once approved for sale; dependence on our third party manufacturers; dependence on international shipping carriers; governmental import/export regulations; demand for our tests or therapy; competition from competitors that have significantly more financial and other resources available to them; governmental virus control regulations that make it difficult or impossible for the company to maintain current operations; regulations and the Company's ability to obtain patent protection on any aspects of its test technology. Accordingly, such results may differ materially from those expressed in any forward-looking statements made by or on behalf of Biomerica. Additionally, potential risks and uncertainties include, among other things; fluctuations in the Company's operating results due to its business model and expansion plans, downturns in international and/or national economies, the Company's ability to raise additional capital, the competitive environment in which the Company competes and will be competing, the impact of the coronavirus on the Company's operations, revenues and the completion of the clinical trials, the and the Company's dependence on partners and strategic relationships. The Company is under no obligation to update any forward-looking statements after the date of this release.

We are susceptible to a widespread outbreak of an illness or other health issue, such as the recent 2019 CoV-19 Coronavirus (“Covid-19 Virus”) outbreak first reported in Wuhan, Hubei Province, China in December 2019 and subsequently spreading throughout the world resulting in hundreds of thousands of confirmed cases worldwide and many deaths. The outbreak of the Covid-19 Virus has caused the various governments, including the U.S., to implement quarantines, various restrictions on travel causing airlines to suspend international and certain domestic flights, and shelter in place orders. Governments have also implemented work restrictions that prohibit many employees from going to work, and for businesses that are allowed to remain open, many employees are electing to remain at home to avoid spread of the disease. As a result of this Covid-19 Virus outbreak and potential future pandemic outbreaks, the Company faces significant risks including, but not limited to; a) supply chain disruptions making it difficult for the Company to order and receive materials needed for production of its products, and needed to ship finished products to our end customers, b) loss of contract and customers from the financial strains or other disruptions they are experiencing as a result of the pandemic, c) financial risks pertaining to receivables due from customers that may fall into insolvency or otherwise be unable to pay their bills, d) government responses including orders that make it difficult to remain open for business, restrict imports of raw materials or exports of finished goods, refuse to allow the Company’s product to be licensed for sale in their countries, and other seen and unforeseen actions taken by government agencies, e) absenteeism or loss of employees at our Company, or at our partner’s companies, due to health reasons or government restrictions, that are needed to develop, validate, manufacture and perform other necessary functions for our operations, f) equipment failures, loss of utilities and other disruptions that could impact our operations or render them inoperable, g) litigation or government actions against the Company pertaining to existing products or new products sold by the Company that are directed at limiting or treating the spread of the pandemic outbreak, h) a local or global recession or depression that could harm the international banking system, limit demand for all products including those made by the Company, and many other seen and unforeseen events and circumstances, all of which could negatively impact the Company.

## CONTACT INFORMATION

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<sup>1</sup> The epidemiology of irritable bowel syndrome. Clin Epidemiol. 2014; 6: 71–80. doi: 10.2147/CLEP.S40245  
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