



## Mayo Clinic joins Biomerica's InFoods® Irritable Bowel Syndrome ("IBS") Diagnostic-Guided Therapy clinical trial.

- Biomerica also announces its first Japanese patent has been granted for its InFoods® IBS Diagnostic Guided Therapy technology
- InFoods® Diagnostic-Guided Therapy is designed to identify patient-specific foods, that when removed from the diet, alleviate an individual's IBS symptoms
- Approximately 45 million Americans suffer from IBS<sup>1</sup>

IRVINE, CA--(June 1, 2020) - Biomerica Inc. (NASDAQ: [BMRA](#)) today announced they have signed a definitive agreement with Mayo Clinic to join the clinical trial for Biomerica's new InFoods® diagnostic-guided therapy (DGT), designed to alleviate Irritable Bowel Syndrome (IBS) symptoms. Mayo Clinic is joining Beth Israel Deaconess Medical Center Inc., a Harvard Medical School Teaching Hospital, Houston Methodist and the University of Michigan as primary enrollment centers for this study. Mayo Clinic can now begin enrollment of patients in this trial.

Biomerica has added several new, large medical centers and groups to assist with accelerating completion of the endpoint trial and to participate in the subsequent pivotal trial needed for final FDA clearance. Biomerica continues to add leading gastrointestinal ("GI") physicians operating in world-renowned centers to the InFoods® IBS clinical study, who are potential users and advocates for this product once cleared by the FDA.

Biomerica also announced today that the Japanese Patent Office has issued Biomerica's first Japanese patent pertaining to the Company's InFoods® family of products that allow for a revolutionary new treatment option for patients suffering from IBS and several other disease states. Specifically, this patent (JP,6681907,B) contains numerous claims that broadly cover a product that enables physicians to identify patient-specific foods (e.g. pork, milk, shrimp, broccoli, chickpeas, etc.), that when removed from the diet, may alleviate or improve an individual's IBS symptoms including, but not limited to, constipation, diarrhea, bloating, pain and indigestion. It is estimated that about 19 million people in Japan suffer from IBS.

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 product is being used in this clinical trial. However, the Company is also developing InFoods® IBS DGT as a point-of-care product that allows physicians to perform the test in-office using a finger stick blood sample. 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 seventy percent (70%) of physicians surveyed would utilize the InFoods® DGT without reimbursement and over 90% would utilize it with reimbursement.

Importantly, the InFoods® DGT can be used without or in conjunction with current 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 clinical trials are randomized, double-blinded, and placebo-controlled. Beth Israel Deaconess Medical Center Inc., a Harvard Medical School Teaching Hospital, has completed its enrollment of patients for this endpoint study but will continue to participate in the final pivotal trial once that commences

This clinical endpoint 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). There is currently no FDA cleared therapy for IBS-Mixed. The study design has already received a non-significant risk determination from FDA.

Zackary Irani, Chief Executive Officer of Biomerica, commented: "We are excited to have Mayo Clinic join the InFoods® IBS trial. IBS patients who desperately seek symptom relief will be the beneficiaries of this revolutionary disruptive technology. Also, we are pleased to have additional countries issue patents with broad claims that acknowledge the novel and innovative attributes of this technology platform that can be used to help patients that suffer from IBS and many other diseases."

#### **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 focus is 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 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; 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.

## 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 Caroline Canavan, Joe West, and Timothy Card