# Houston Methodist (part of Texas Medical Center) to start patient enrollment for Biomerica's InFoods® Irritable Bowel Syndrome (IBS) diagnostic guided therapy clinical trial.

- Texas Medical Center is the largest medical complex in the world with 10 million patient encounters per year and a 1,345-acre campus (50 million square feet of developed facilities)
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- InFoods® Diagnostic Guided Therapy (DGT) 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[1]

IRVINE, CA--(January 07, 2020) - Biomerica Inc. (NASDAQ: BMRA) today announced that Houston Methodist (part of Texas Medical Center, the largest medical complex in the world) will start enrollment for the clinical trial of its new InFoods® diagnostic-guided therapy (DGT) to alleviate Irritable Bowel Syndrome (IBS) symptoms. Houston Methodist will join Beth Israel Deaconess Medical Center Inc., a Harvard Medical School Teaching Hospital, and the University of Michigan as primary enrollment centers for this study.

The InFoods® endpoint trial is expected to be completed before 2020. Biomerica is now in the process of adding several new large medical groups (including Houston Methodist) to assist with accelerating the endpoint trial and participate in the subsequent pivotal trial needed for final FDA clearance. Further, by adding large world-renowned centers to its trials, Biomerica continues to grow the number of leading gastrointestinal (GI) physicians using the InFoods® IBS product during the trials and once FDA clearance is received.

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 patient well-being and a person's ability to function both at home and in the workplace.

The patented Biomerica InFoods® IBS product is designed to allow 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 constipation, diarrhea, bloating, abdominal cramps, pain and indigestion. The InFoods® IBS point-of-care product is being developed to allow physicians to perform the test in-office using a finger stick blood sample. A

clinical lab version of the product is being used in this clinical trial. A billable CPT code that can be used by both clinical labs and physicians' offices is already available for InFoods® IBS products. Market research conducted by a leading independent pharmaceutical marketing research firm determined that seventy percent (70 %) of physicians surveyed would use the InFoods® DGT without reimbursement and 90% would use it with reimbursement.

Importantly, the InFoods® DGT can be used without or in conjunction with current pharmacotherapy 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. The University of Michigan will continue to enroll patients in this endpoint trial along with Houston Methodist and others.

This clinical endpoint trial is expected to be completed in approximately 9 months. If all goes as expected, Biomerica is looking to commence the final pivotal trial a few 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 thrilled to have Houston Methodist commence patient enrollment for the InFoods® IBS trial. As part of the Texas Medical Center, the world’s largest medical complex, we expect Houston Methodist to significantly accelerate the completion of this endpoint trial and play a significant role in the final FDA InFoods trial. IBS patients who desperately seek symptom relief will be the beneficiaries of this revolutionary disruptive technology. We are also very pleased to be working with leading experts in functional GI disorders that have been the primary investigators in clinical studies for many of the leading drug therapies for IBS. We plan to continue to add leading medical centers to the InFoods trials.”

**About Biomerica (NASDAQ: BMRA)**

Biomerica, Inc. (www.biomerica.com) is a global biomedical company that develops, manufactures and markets advanced diagnostic products used at the point-of-care (in home and in physicians' offices) and in hospital/clinical laboratories for the early detection 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 products for Gastrointestinal Disease, Diabetes and esoteric testing.

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 intended launch dates, sales potential, significant benefits, market size, prospects, new products, commencement of FDA clinical trials, completion of clinical trials, favorable outlook, new distributors, expansion, increases in productivity and margins, expected orders, leading market positions, anticipated future sales or production volume of the Company, the launch or success of product and new product offerings. Such forward-looking information involves important risks and uncertainties that could significantly affect anticipated results in the future, and accordingly, such results may differ materially from

those expressed in any forward-looking statements made by or on behalf of Biomerica. The potential risks and uncertainties include, among others, 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 will be competing, and the Company's dependence on 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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[1] The epidemiology of irritable bowel syndrome
Clin Epidemiol. 2014; 6: 71–80. . doi: 10.2147/CLEP.S40245
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