GID BIO completes Phase IIb clinical trial, successfully meeting endpoints and two-year safety results, to support regenerative cellular implants as treatment for knee osteoarthritis

Louisville, Colo. – **September 30, 2019** - GID BIO announced today that it has completed its first pivotal Phase IIb clinical trial using an FDA-approved study design, and successfully met all endpoints with two-year safety follow-up for treatment of knee osteoarthritis (OA) using autologous stromal cells. The trial demonstrated a significant reduction in pain for the responder group, and no serious or device-related adverse events after two years. This milestone clears a path to proceed toward a second pivotal Phase III clinical trial for its SVF-2 technology and point-of-care (POC) therapy.

"This study demonstrated that results for the treatment groups were statistically significant relative to a placebo control," said William W. Cimino, Ph.D., CEO of GID BIO. "This first pivotal study of our SVF-2 device and POC therapy showed that 88 percent of subjects responded greater than placebo at one year, with a median 87 percent improvement in pain, stiffness and function. The data supports the initiation of our second pivotal study to further evaluate the efficacy and safety of the technology and cellular therapy."

The GID technology isolates and concentrates stromal cells from a small sample of the patient's adipose tissue. Stromal cells play an essential role in the body's natural healing response, which is a complex and highly coordinated interplay among different types of cells and the soluble factors they produce. This healing process is different than a drug, which is a synthetic chemical compound with no dynamic or reactive ability to participate in the healing process.

With a cellular therapy approach, patients do not need joint replacement surgery or medications for knee pain. Instead they receive an injection of a cellular implant made with their own cells. The entire procedure is minimally invasive and completed in less than two hours.

Bruce Bunnell, Ph.D., professor, director of the Tulane Center for Stem Cell Research & Regenerative Medicine, says, "There is potential for GID's device and therapy to be a tremendous benefit to patients. The right types of healing cells are extracted to control inflammation in patients with osteoarthritis. These cells work better than any other cells or drug currently available. Once FDA-approved and widely available, most patients will likely want to use their own healing cells rather than other drugs or surgical options."

"Our treatment has a potential significant societal impact in terms of minimizing patient suffering and lost workplace productivity. An FDA-approved therapy, proven to be safe and effective, that addresses symptoms of knee osteoarthritis would dramatically transform the treatment for this serious condition due to less procedure and recovery time, less pain and less cost," said Dale Tomrdle, vice president of finance and operations for GID BIO. "Given there are more than several million hyaluronic acid and corticosteroid injections performed annually[2], coupled with more than 700,000 TKR (total knee replacement) surgeries annually, GID's cellular therapy could help ease the $200 billion annual healthcare burden[3] for osteoarthritis."

"We have been actively engaged with the FDA from the very beginning and anticipate enrolling our first subjects at approximately10 sites in an FDA-approved second pivotal study in the near future. If we can repeat the efficacy and safety results obtained in the first trial, then a stromal cell-based therapy will become a substantial alternative for treating OA of the knee," noted Cimino.

About OA

OA is the leading cause of adult disability, with 14 million people in the USA with OA of the knee[1]. Adults suffer from OA, primarily due to an aging population and an increasing prevalence of obesity. The combination of direct medical costs, pain and suffering, and loss of workplace productivity elevates OA to a major socioeconomic problem for health systems, the economy, and suffering patients. As the most common type of arthritis, OA is characterized by the destruction of articular cartilage and structural changes in underlying bone, which contribute to pain and loss of joint function. Current knee OA treatment options for patients are pain medication, joint injections, and total knee replacement.

About GID SVF-2 and POC Therapy

GID technology has reduced a Good Manufacturing Practices (GMP) cell-processing facility to a single disposable device for scalable point-of-care cell processing. The technology uniquely isolates, concentrates and extracts harvested stromal cells from a patient's own tissue sample. The cellular implant is administered by injection in a physician's office under ultrasound guidance. The American Medical Association granted GID two new CPT class III codes that will become effective January 2020, a step toward Medicare reimbursement.

About GID BIO

GID BIO develops next generation cellular therapies for degenerative musculoskeletal, dermal, and organ specific diseases, making cellular medicine possible for everyone. GID's SVF-2 device and POC therapy harnesses the innate healing power of a patient's own stromal cells. Information on GID's SVF-2 device, biologic cellular implants, POC therapy, osteoarthritis clinical program and pipeline can be found at: https://www.HealingIntelligently.com.

[1]*Arthritis.org. Arthritis by the Numbers. 2018; v2; 4100.17.10445: https://www.arthritis.org/Documents/Sections/About-Arthritis/arthritis-facts-stats-figures.pdf*

[2]*Bedard NA, Dowdle SB, Anthony CA, et al. The AAHKS Clinical Research Award: What Are the Costs of Knee Osteoarthritis in the Year Prior to Total Knee Arthroplasty? The Journal of arthroplasty. 2017;32(9s):S8-S10.e11*

[3]*Kotlarz H, Gunnarsson CL, Fang H, Rizzo JA. Insurer and out-of-pocket costs of osteoarthritis in the US: evidence from national survey data. Arthritis Rheum. 2009;60(12):3546-3553*

Media contact: Kellee Johnson, kjohnson@ballastgroup.com or 312-751-3959