



NEWS RELEASE

# Highly Accomplished Executives Join BioVie's Board of Directors

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Hariri, Gorlin, and Rogich to Contribute Their Tremendous Industry Insights and Stature

SANTA MONICA, Calif., June 16, 2020 (GLOBE NEWSWIRE) -- BioVie, Inc. (OTCQB: BIVI) ("BioVie" or "Company"), a clinical-stage company developing innovative drug therapies for liver disease, is pleased to announce the appointments of Dr. Robert Hariri, Mr. Steve Gorlin, and Mr. Sig Rogich to its Board of Directors. Terren Peizer, BioVie's Chairman and Chief Executive Officer commented, "We are humbled to have these industry titans join our company. Robert has leveraged his deep expertise in biology to pioneer and found leading-edge life science companies. Steve has been founder and initial investor in many successful biopharma companies. Sig has served multiple US presidents over the years and has been dedicated to improving Alzheimer's disease patient care. The new directors join current member and industry leader Cuong Do, who was formerly Chief Strategy Officer at Merck & Co. and currently President of Samsung Global Strategy Group. The combination of unique talents and capabilities of these distinguished gentlemen will greatly benefit BioVie as we advance the Company.

Mr. Steve Gorlin has founded many biotechnology and pharmaceutical companies over the past forty-five years, including Hycor Biomedical, Inc. (acquired by Agilent), Theragenics Corporation, Medicis Pharmaceutical Corporation (sold to Valeant for approximately \$2.6 billion), EntreMed, Inc., MRI Interventions (MRIC), DARA BioSciences, Inc., MiMedx, Medivation, Inc., sold to Pfizer for \$14 billion and Conkwest which became NantKwest. Mr. Gorlin served for many years on the Business Advisory Council to the Johns Hopkins School of Medicine and on The Johns Hopkins BioMedical Engineering Advisory Board. He also served on the Board of the Andrews Institute. He is currently a member of the Research Institute Advisory Committee (RIAC) of Massachusetts General Hospital. He started The Touch Foundation, a nonprofit organization for the blind and was a principal financial contributor to the founding of Camp Kudzu for diabetic children.

Robert J. Hariri, MD, PhD, is the chairman, founder, and chief executive officer of Celularity, Inc., a leading human cellular therapeutics company. Dr. Hariri was the founder and CEO of Anthrogenesis Corporation, and after its

acquisition by Celgene Corporation, served as CEO of Celgene Cellular Therapeutics. Dr. Hariri also co-founded the genomic-based health intelligence company, Human Longevity, Inc. He has served on numerous public boards including Cryoport. Dr. Hariri pioneered the use of stem cells to treat a range of life-threatening human diseases and continues to make transformative contributions in the fields of immuno-oncology and cell therapeutics. He is widely acknowledged for his discovery of pluripotent stem cells derived from the human placenta, and assisting with the discovery of the physiological activities of tumor necrosis factor (TNF). He holds over 170 issued and pending patents and has authored over 150 published chapters, articles, and abstracts. Over the years he has garnered numerous awards for contributions to the fields of biomedicine and aviation.

Mr. Sigmund “Sig” Rogich is President of The Rogich Communications Group and serves on the Board of Keep Memory Alive, a philanthropic organization which raises awareness about brain disorders and Alzheimer's disease. Keep Memory Alive funds clinical trials through Cleveland Clinic’s Lou Ruvo Center for Brain Health to advance new treatments for patients with Alzheimer’s, Huntington’s and Parkinson’s disease, as well as frontotemporal dementia and multiple sclerosis. Mr. Rogic was formerly the US Ambassador to Iceland. He has served as a senior consultant to candidates for the highest office, including Presidents Ronald Reagan and George H.W. Bush. Mr. Rogich serves on the Board of Directors for many charitable causes.

#### About BioVie and BIV201

BioVie Inc. is developing BIV201 (continuous infusion terlipressin) an Orphan Drug candidate for the treatment of ascites due to advanced liver cirrhosis. First-to-market Orphan therapies typically receive 7 years of market exclusivity in the US for the designated use(s). It is being investigated as a potential new therapy for patients suffering from ascites, and future development opportunities include hepatorenal syndrome (HRS) and other life-threatening complications of advanced liver cirrhosis. The initial disease target for BIV201 therapy is ascites, which is a serious complication of advanced liver cirrhosis. The Company has completed a Phase 2 clinical trial protocol that is summarized on [www.clinicaltrials.gov](http://www.clinicaltrials.gov), trial identifier NCT04112199. The FDA has never approved any drug specifically for treating ascites, and the Company is not aware of any competing drugs in late-stage development for ascites. The active agent in BIV201, terlipressin, is approved for use in about 40 countries for the treatment of related complications of advanced liver cirrhosis but is not available in the US or Japan. BIV201 has also received Orphan Drug designation for the treatment of hepatorenal syndrome (HRS) and has FDA Fast Track status.

BioVie recently invented a patent-pending BIV201 prefilled syringe for use in the upcoming Phase 2 trial subject to conducting certain additional standard analytical testing expected to take approximately two weeks. Room temperature stability of the prefilled syringe has been confirmed at 6 months, with the potential for 12 months or up to two years of stability (yet to be confirmed). Room temperature storage presents a key product differentiation versus terlipressin products in countries where the drug is approved. To the best of the Company's knowledge, all other terlipressin products sold globally must be stored under refrigeration and there is no prefilled syringe format

of terlipressin available for treating patients in these countries. Terlipressin, which is not available in the US or Japan, is often sold as a lyophilized powder for reconstitution in hospital pharmacies in Europe and Asia. The traditional powder format is satisfactory for hospital use, but creates a logistical challenge when administering terlipressin via ambulatory infusion pump in patients located outside the hospital setting. To solve this challenge, the Company developed a patent-pending liquid formulation for delivery via prefilled syringe. This novel drug delivery system is expected to simplify at-home patient treatment and improve patient compliance by enabling easy injection of the liquid concentrate into the IV bag connected to the infusion pump. It avoids the manual mixing of minute (2 – 4 mg) quantities of terlipressin powder in saline solution, thereby reducing the possibility of dosing errors during reconstitution, and is expected to improve drug solution sterility. The Company has begun applying for global patent protection for our novel BIV201 prefilled syringe, which could eventually provide up to 20 years of patent coverage in each country for which the Company seeks patent protection, including the US, according to the patent laws of that country. For more information about BioVie, please visit our website: [www.biovieinc.com](http://www.biovieinc.com) .

#### About Liver Cirrhosis, Ascites, and Hepatorenal Syndrome

Chronic liver cirrhosis and its complications are the eighth-leading cause of death in the US ( Runyon 2013). Cirrhosis results primarily from hepatitis, alcoholism, and nonalcoholic steatohepatitis (NASH) linked to fatty liver disease and obesity. Ascites is the most common serious complication of advanced liver cirrhosis. Patients with cirrhosis and ascites account for an estimated 116,000 US hospital discharges annually with frequent early readmissions. Those requiring paracentesis (physical removal of ascites fluid with a large-bore needle) experience an average hospital stay lasting 8 days and generate approximately \$5 billion annually in medical costs in the US ( HCUP Nationwide Readmissions Database 2016). Certain drugs approved for other uses may provide initial relief, but patients develop so-called refractory ascites, failing to respond to them as the ascites worsens. For refractory ascites the mean one-year survival rate is only 50% (Bureau et al. 2017). Patients with refractory ascites often progress to hepatorenal syndrome (HRS) which is the onset of kidney failure and requires emergency hospitalization. About one-half of these patients typically succumb within only 2 to 4 weeks and no drug therapies have been FDA approved specifically to treat HRS.

#### Forward-Looking Statements

This press release contains forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 that involve risks, uncertainties and assumptions that could cause BioVie's actual results and experience to differ materially from anticipated results and expectations expressed in these forward-looking statements. BioVie has in some cases identified forward-looking statements by using words such as "anticipates," "believes," "hopes," "estimates," "looks," "expects," "plans," "intends," "goal," "potential," "may," "suggest," and similar expressions. Among other factors that could cause actual results to differ materially from those expressed in forward-looking statements are BioVie's need for, and the availability of, substantial capital in the future to fund its operations and research and development; and the risks that BioVie's compounds may

experience delays or difficulties in commencing or successfully completing pre-clinical testing or clinical studies, or may not be granted regulatory approval to be sold and marketed in the United States or elsewhere. BioVie cannot guarantee the effectiveness of its Orphan Drug designations or any patents that BioVie may be issued. A more complete description of these risk factors is included in BioVie's filings with the Securities and Exchange Commission. In addition to the risks described above and in BioVie's filings with the SEC, other unknown or unpredictable factors also could affect BioVie's results. No forward-looking statements can be guaranteed, and actual results may differ materially from such statements. Given these uncertainties, you should not place undue reliance on any forward-looking statements. BioVie undertakes no obligation to release publicly the results of any revisions to any such forward-looking statements that may be made to reflect events or circumstances after the date of this press release or to reflect the occurrence of unanticipated events, except as required by applicable law or regulation.

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