



## **Beroni Group Included in List of Commercial Manufacturers and Laboratories Who Have Notified US FDA of Validated Serology Tests for COVID-19**

NEW YORK and SYDNEY, Australia, April 3, 2020 (GLOBE NEWSWIRE) - Beroni Group (OTCQX: BNIGF; NSX: BTG) (“Beroni” or the “Company”), an international diversified biopharmaceutical enterprise focused on the research, development, innovation and commercialization of therapies and products for treatment of global diseases, is pleased to announce it has been added to the list of Commercial Manufacturers and Laboratories which have notified the U.S. Food and Drug Administration (FDA) that they have validated serology tests as set forth in Section IV.D of the FDA’s Policy for Diagnostic Tests for Coronavirus Disease – 2019 (“the Policy”).

Under this Policy, the FDA does not intend to object to the development and distribution by commercial manufacturers, or development and use by laboratories, of serology tests to identify antibodies to SARS-CoV-2, where the test has been validated, notification is provided to FDA, and information along the lines of the following is included in the test reports:

- This test is currently being reviewed by the FDA
- Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals
- Results from the antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status
- Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E

Beroni’s SARS-CoV-2 IgG/IgM antibody detection kit based on colloidal gold is a rapid single-use immunochromatographic test intended for the qualitative detection of IgG and IgM protein from the SARS-CoV-2 virus in capillary “fingerstick” whole blood, plasma, and serum samples. The point-of-care test kit is intended for professional use and delivers clinical results within 10 minutes.

Jacky Zhang, Chairman and CEO of Beroni Group, said, “With the rapid increase in the number of coronavirus cases globally, the availability of fast and effective test kits is of utmost urgency. We want to make our test kit available in the U.S. and other markets as soon as possible to combat the exponential growth of the coronavirus infections.”

Beroni will continue to consult with the FDA about qualifying the test kit under FDA's Emergency Use Authorization. The Company has already obtained the CE mark approval for the test kit and will be distributing the product in the European Union market.

Beroni will immediately commence discussion with potential distributors to distribute the test kit product to the U.S. and other markets. All interested parties are welcome to contact the company at [enquiry@beronigroup.com](mailto:enquiry@beronigroup.com).

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### **About Beroni Group Limited**

Beroni Group is an international biopharmaceutical enterprise dedicated to the innovation and commercialization of drugs and therapies to combat various global diseases such as cancer and infectious diseases. Its diversified portfolio is comprised of a US FDA approved virus diagnostic kit, an e-commerce platform for the sale of pharmaceutical products and a development pipeline targeting oncology and cell therapies. Beroni has operations in Australia, United States, China and Japan. To learn more about Beroni, please visit [www.beronigroup.com](http://www.beronigroup.com).

### **Forward-Looking Statements Disclaimer**

This press release contains forward-looking statements or forward-looking information, within the meaning of applicable United States and Australian securities laws with respect to the Company. By their nature, forward-looking statements are subject to a variety of factors that could cause actual results to differ materially from the results suggested by the forward-looking statements. Accordingly, readers should not place undue reliance on the forward-looking statements. Generally forward-looking statements can be identified by the use of terminology such as "anticipate", "will", "expect", "may", "continue", "could", "estimate", "forecast", "plan", "intend", "believe", "potential" and similar expressions.

Forward-looking information contained in this press release is based on Company management's opinions, estimates and assumptions in light of its experience and perception of historical trends, current conditions and expected future developments, as well as other factors that management currently believes are appropriate and reasonable in the circumstances. Forward-looking statements involve significant risks, uncertainties and assumptions, and there can be no assurance that such statements, or its underlying risks, uncertainties and assumptions will prove to be accurate. Factors that could cause actual results or events to differ materially include, without limitation, risks related to laws, rules and regulation applicable to the Company as well as the industry in which it operates (including in respect of taxes and other levies), economic or market conditions on both a national and global level, currency fluctuations, risks inherent to other entities at a similar stage of development and industry in which the

Company currently is, competition from the Company's competitors, unsatisfactory development or marketing of the Company and/or its products or services, regulatory action or litigation (including product liability claims), and failure to enter into agreements or arrangements with other parties on fair or reasonable terms. Forward-looking information is made only as of the date on which it is provided and, except as may be required by applicable laws, the Company disclaims any intent or obligation to update such forward-looking information whether as a result of new information, future events or otherwise.

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