Bio-RV, a Neonatal Rotavirus Vaccine Developed Through Bio Farma–MCRI Collaboration, Receives Marketing Authorization from the Indonesian Food and Drug Authority, BPOM

Bandung, September 3, 2026 – PT Bio Farma (Persero), together with Murdoch Children's Research Institute (MCRI), has marked an important milestone in efforts to strengthen the protection of children against rotavirus disease following the issuance of marketing authorization for Bio-RV, a neonatal rotavirus vaccine, by the Indonesian Food and Drug Authority (BPOM).

Bio Farma officially received marketing authorization for Bio-RV on September 2, 2026. This regulatory milestone follows an extensive journey encompassing research, process development, preclinical and clinical studies, technology transfer, regulatory submission, and manufacturing preparation involving various national and international institutions.

The marketing authorization confirms that Bio-RV has undergone BPOM's evaluation of its safety, efficacy, and quality in accordance with applicable regulatory standards and requirements. For Bio Farma and MCRI, this achievement shows how collaboration among research institutions, academia, industry, and global partners can translate into biotechnology innovation with the potential to deliver tangible public health benefits.

Bio-RV is a naturally attenuated live rotavirus vaccine administered orally. The vaccine is intended to prevent gastroenteritis, or acute diarrhea, caused by rotavirus infection. It is administered in a three-dose schedule: the first dose at 0–5 days of age, the second at 8–10 weeks, and the third at 12–14 weeks. These characteristics allow vaccination to begin during the neonatal period,

establishing protection against rotavirus disease from the earliest stage of an infant's life, at a time when families are in contact with their local health services

Bio-RV is particularly relevant as rotavirus remains one of the leading causes of severe diarrhea among infants and young children. Citing data from the Indonesia Rotavirus Surveillance Network for 2001–2017, the Indonesian Ministry of Health reported that rotavirus accounted for approximately 41–58 percent of diarrhoeal cases among children under five requiring hospitalization. Recurrent diarrhea may also impair nutrient absorption and increase the risk of growth disorders in children.

Bio Farma President Director Shadiq Akasya said that obtaining marketing authorization for Bio-RV reflects the company's commitment to delivering vaccine innovations that address public health needs while strengthening Indonesia's national capabilities in vaccine development.

"Bio-RV is not simply about introducing a new vaccine. Behind this achievement lies an extensive journey of scientific advancement, process development, preclinical and clinical studies, technology transfer, regulatory submission, and manufacturing preparation. This entire process has been made possible through collaboration among researchers, academia, industry, and global partners," Shadiq said.

According to Shadiq, Bio-RV's neonatal dosing schedule provides an opportunity to establish protection against rotavirus from the earliest stage of life.

"What we aim to deliver is protection for Indonesian children as early as possible, while ensuring that Indonesia has the capacity to independently safeguard the continuity of vaccine supply. This forms part of Bio Farma's contribution to strengthening national health resilience and sovereignty," he added.

Bio-RV originated from the RV3-BB vaccine candidate, based on a neonatal rotavirus strain developed by MCRI. The collaboration then progressed through clinical research and further development to prepare for Bio-RV production in Indonesia.

Human rotavirus was first identified in 1973 by MCRI Professor Ruth Bishop and Professor Ian Holmes from the University of Melbourne. Soon after, MCRI's Professors Bishop and Barnes established a collaboration with UGM's Professor Yati Soenarto, who was the first to confirm that rotavirus was the most common cause of diarrheal death and hospitalization in children in Indonesia. In 1982, Professor Bishop identified RV3, an unusual rotavirus strain that infected newborn babies without causing disease and appeared to protect them from subsequent severe rotavirus diarrhea.

Building on this discovery, MCRI Professor Julie Bines led the development of RV3-BB as a live oral neonatal vaccine, taking it from a promising naturally occurring strain through clinical development in Australia, New Zealand and Indonesia. This work provided the foundation for Bio Farma's Bio-RV vaccine. The close 50-year collaboration between the teams at UGM and

MCRI has been pivotal to the clinical development of MCRI's original RV3-BB vaccine and Bio Farma's Bio-RV. The MCRI RV3-BB vaccine development was made possible through grants from the Gates Foundation and the Australian National Health and Medical Research Council. MCRI also acknowledges the Australian Government's enduring support for global health through the Department of Foreign Affairs and Trade.

Several partners have also supported the collaboration between Bio Farma and MCRI, including Universitas Gadjah Mada (UGM), Universitas Airlangga through the Airlangga Integrated Research Clinic (AIRC), and PATH at various stages of development.

This collaboration has not only delivered a new vaccine but also strengthened Bio Farma's capabilities to build Indonesia's vaccine innovation ecosystem through cooperation among global research institutions, national academic institutions, and industry. Developing domestic capabilities across the Bio-RV development and manufacturing processes is expected to strengthen vaccine availability, reduce reliance on imported products, and support the sustainability of Indonesia's National Immunization Program.

As part of the Danantara Indonesia ecosystem, Bio Farma remains committed to transforming national strategic assets and capabilities into tangible benefits for society while upholding good corporate governance, professionalism, and integrity. The development of Bio-RV represents a concrete contribution to improving quality of life through health innovation while strengthening Indonesia's capabilities and competitiveness in the vaccine and life sciences industries.

This initiative aligns with Danantara's purpose, "Transforming National Assets into Prosperity with Integrity," particularly through efforts to improve quality of life and build a stronger Indonesia supported by robust national healthcare industry capabilities.

This achievement also reflects Bio Farma's spirit of "Advancing Hope, Shaping the Future," by turning hope into reality through health protection, science, innovation, and collaboration, while helping shape the future of healthcare in Indonesia and around the world.

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