#### **STATEMENT**

## Biovac to partner with ImmunityBio for second generation COVID-19 vaccine manufacture

Biovac has announced a local manufacturing partnership with US-based immunotherapy company, ImmunityBio. The collaboration aims to develop capability in South Africa for the full value-chain manufacturing of vaccines. The first stage of this will be to locally manufacture ImmunityBio's second generation COVID-19 vaccine, which is aimed at being more broadly protective against the virus and its emerging variants.

ImmunityBio's COVID-19 vaccine candidate is currently undergoing clinical trials in South Africa and United States. Unlike the first generation of COVID-19 vaccines, which are antibody-based, the hAd5 T-cell SARS-CoV-2 vaccine kills the infected cell, preventing virus replication. This could offer broader protection against multiple variants of COVID-19, like the 501Y.V2 variant found in South Africa.

The technology transfer with ImmunityBio, will build Biovac's capability for Active Pharmaceutical Ingredient (API) manufacturing. This will allow Biovac to expand on their existing capacity, which currently allows for formulation and filling of inactivated and bacterial conjugate vaccines.

Initially targeted at manufacturing ImmunityBio's COVID-19 vaccine, the partnership ensures a sustainable and equitable approach to vaccine manufacturing and will form a solid foundation for an independent local response to future pandemics.

## **ENDS**

### **Comments from spokespersons:**

### On ImmunityBio's collaboration with Biovac:

**Patrick Soon-Shiong, M.D., Chairman ImmunityBio** stated "In addition to working with local researchers in the clinical development I am equally pleased to commence work with Biovac which is the only specialist vaccine company in South Africa and that has proven that vaccines can be produced in Africa at a high standard as demonstrated by their prior collaborations on paediatric vaccines with global multinational vaccine companies. This gives us the confidence that South African manufacturing capability is at an equally high standard to its global counterparts and has the potential to respond more fully to future pandemics. Biovac's Private Public Partnership model also demonstrates that private sector can partner with government in the quest for a common health response."

On the clinical development of the ImmunityBio COVID-19 vaccine in South Africa:

University of Cape Town (UCT) researchers have commenced a Phase I clinical trial of a hAd5 T-cell SARS-CoV-2 vaccine developed ImmunityBio, after approval from the South Africa Health Products Regulatory Authority (SAHPRA). The trial is being conducted at the Wellcome Centre for Infectious Diseases Research in Africa (CIDRI-Africa) Khayelitsha Clinical Research Site. While high-income countries are already rolling out safe and effective vaccines, there are a number of reasons why this Phase 1 trial is urgently needed and critically important in South Africa.

**Patrick Soon-Shiong, M.D., Chairman ImmunityBio** stated, "We are excited about the potential of our COVID-19 vaccine candidate and the issues it could solve globally. Unlike antibody-based vaccines, T-cell-based vaccines kill the infected cell, preventing virus replication, and could provide long-term memory to recipients. Pursuing a vaccine that does not rely solely on targeting the S protein where the mutations are occurring is of critical importance as multiple variants of the SARS-CoV-2 virus have appeared globally, with concentrated outbreaks being detected in South Africa. In addition, we will be testing through clinical trials if our vaccine could be administered via the sublingual or oral routes."

## On building local vaccine manufacturing capacity for future pandemics:

**Dr Morena Makhoana, CEO of Biovac** stated "the collaboration with ImmunityBio is a significant step not only for Biovac but for South Africa as a whole. Biovac has developed capability over many years of investment in formulation and filling of inactivated and bacterial conjugate vaccines adopting a reverse integration strategy. The "missing" capability that Biovac and the country has is in the capability of Active Pharmaceutical Ingredient / Drug Substance manufacturing of viral vaccines. This collaboration with ImmunityBio is a strategic step in our quest for fully fledged vaccine manufacturing capability in Africa. Biovac has also recently collaborated with Wits Universities' AntiViral Gene therapy Unity (ATGRU) where Biovac's staff are being trained to handle viral vaccines. These collaborations are a significant steppingstone to addressing the gap in Africa of self-reliance and pandemic response capability."

# **COMPANY BIOS:**

## **About Biovac:**

Biovac was established in 2003 to revive local human vaccine production in Southern Africa. Alongside the development of modern facilities, the company has secured high profile technology transfers from international pharmaceutical companies Pfizer and Sanofi Pasteur. The company currently sources and supplies a comprehensive range of paediatric vaccines required for the Department of Health's

Expanded Programme of Immunisation. Supplying over 15-million doses of vaccines per year, across South Africa and into neighbouring countries. For more information, please visit: <a href="https://www.biovac.co.za">www.biovac.co.za</a>

## **About ImmunityBio:**

ImmunityBio is a leading late-clinical-stage immunotherapy company developing next-generation therapies that drive immunogenic mechanisms for defeating cancers and infectious diseases. The company's immunotherapy platform activates both the innate (natural killer cell and macrophage) and adaptive (T cell) immune systems to create long-term "immunological memory."

ImmunityBio has an unparalleled immunotherapy pipeline with more than 40 clinical trials (company sponsored or investigator initiated)—of which 25 are at Phase II and III stage of development—across 19 indications in solid and liquid cancers and infectious diseases. Currently 17 first-in human immunotherapy agents are in clinical testing and, to date, over 1,800 patients have been studied with our antibody cytokine fusion proteins, albumin chemo immunomodulators, Adeno and yeast vaccines and our off-the-shelf natural killer cell products. Anktiva™ (ImmunityBio's lead cytokine infusion protein) is a novel interleukin-15 (IL-15) superagonist complex and has received Breakthrough Therapy and Fast Track Designations from the U.S. Food and Drug Administration (FDA) for BCG-unresponsive CIS non-muscle invasive bladder cancer (NMIBC).

The company's platforms are based on the foundation of four separate modalities: Antibody cytokine fusion proteins, synthetic immunomodulators, second-generation human adenovirus (hAd5) and yeast vaccine technologies, and state-of-the-art, off-the-shelf natural killer cells, including autologous and allogenic cytokine-enhanced memory NK cells.

ImmunityBio is a leading producer of cryopreserved and clinical dose forms of off-the-shelf natural killer (NK) cell therapies. The company has established GMP manufacturing capacity at scale with cutting-edge cell manufacturing expertise and ready-to-scale facilities, as well as extensive and seasoned R&D, clinical trial, and regulatory operations and development teams. For more information, please visit: <a href="https://www.immunitybio.com">www.immunitybio.com</a>