

## **Report of the Medicines Patent Pool Expert Advisory Group on the Proposed Licence Agreement with Medigen Vaccine Biologics Corporation on Covid-19 vaccine**

### **Introduction**

The Expert Advisory Group (EAG) of the Medicines Patent Pool (MPP) submits the following report to the Governance Board of the Medicines Patent Pool on the proposed licence agreement (the Agreement) between MPP, as the implementing partner of the Covid-19 Technology Access Pool (C-TAP), and Medigen Vaccine Biologics Corporation (Medigen) for a COVID-19 vaccine.

This report reflects the outcome of a consultation by correspondence between 07 and 12 of July 2023 of EAG members: Luis Gil Abinader, Zeba Aziz, Jennifer Cohn, Carlos Maria Correa, Manuel Gonçalves, Mariatou Tala Jallow, Deepa Joshi, Martha Gyansa-Lutterodt, Jordan Jarvis, Gugu Mahlangu, Deus Mubangizi and Fatima Suleman, as well as Nathan Ford and Francois Venter of the Scientific Advisory Panel (SAP) and Maka Gogia and Javier Bellocq from the Communities Advisory Panel (CAP).

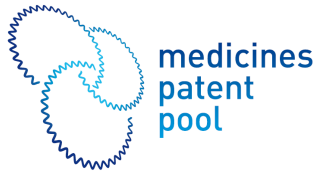
### **Background, Overview of the Proposed Agreement**

In May 2020, the World Health Organization (WHO) launched the Covid-19 Technology Access Pool (C-TAP) to facilitate timely, equitable, and affordable access to Covid-19 health products via sharing of intellectual property, data, and know-how for the subsequent scale-up of production. MPP is an implementing partner of C-TAP, responsible for handling negotiations of licences and subsequent licence management while C-TAP retains responsibility for fielding and screening submissions of interest. The EAG understands that WHO has conducted a technical assessment of the patents, patent applications and the scope of the technology transfer, and has concluded that those outlined here would be suitable for inclusion into C-TAP. Furthermore, the EAG notes that the C-TAP advisory group has reviewed the terms of the licence and provided a positive opinion thereafter. The results of that review were shared by WHO with MPP in a report. The EAG has reviewed that report which recommends that MPP proceed with the proposed Agreement and agrees with its recommendation.

The EAG understands that Medigen has developed a COVID-19 vaccine based on the COVID 19 Spike protein sequence owned by the National Institutes of Health. This COVID-19 vaccine is formulated with: 1. the Dynavax CPG 1018 adjuvant that Medigen procures from Dynavax, and: 2. A10H3 which Medigen procures from Croda Health Care. It is produced in the CHO cell system from Thermo Fisher in cGMP facilities approved by the TFDA. Further it is formulated in 0.5mL liquid, to be injected intramuscularly and can be stored at 2- 8°C for at least 12 months.

The EAG understands that this COVID-19 vaccine has undergone various clinical studies, including phase 1 and phase 2 clinical trials; the results of which enabled it to be filed for Emergency Use Authorization (EUA) and to obtain a EUA licence in Taipei in July 2021. Studies have shown that it has a promising safety profile and favourable immunogenicity results in comparison to COVID-19 vaccines from AstraZeneca, Moderna and Pfizer. Medigen is currently conducting several additional studies, including a Phase III placebo-controlled field efficacy study.

Key aspects of the proposed licence are as follows:



- **Aim of the Licence:** To facilitate the manufacture and commercialisation of Covid-19 vaccine around the world.
- **Products:** Any product that is covered by the patent rights, material, and know-how from Medigen.
- **Know-how:** Medigen to provide all necessary know-how and materials to the licensees, specified in the license.
- **Field of use:** COVID-19 vaccine.
- **Territory:** Worldwide.
- **Scope of the grant:** Non-exclusive right to grant sublicences to develop the patent rights, material, and know-how into Products, and to commercialise Products.
- **Royalties:** Royalty rates apply on the net sales of the Products where there is a patent right granted and in force in the country of manufacture or sale as follows:
  - a royalty of 0.5% for low-income economies;
  - a royalty of 1% for lower-middle income economies;
  - a royalty of 3% for upper middle-income economies; and
  - a royalty of 5% for high-income economies.
- **Fees:** Technology fees apply to sublicensees, which includes one-time fees for entering into the sublicense; the licensed technology; basic support and training; the preparation of materials; the first launch of the Product; and also a running technology fee.
- **Term:** Continuing until the later of (i) the date the last patent right has lapsed, expired, or been invalidated or (ii) the expiry date of the last to expire sublicense agreement entered into pursuant to proposed licence.

The form of the sublicense agreement is included in the proposed Agreement. Medigen and MPP will discuss and agree upon the identities of interested and suitable sublicensees.

### **Assessment of the Proposed Agreement**

The EAG finds the proposed Agreement is aligned with MPP's statutory requirements and therefore recommends that the Medicines Patent Pool Governance Board request the Executive Director to sign the proposed Agreement between Medigen and MPP, as the implementing partner of C-TAP.

A handwritten signature in black ink, appearing to read "P. Beyer".

Peter Beyer  
Chair, Expert Advisory Group  
Date: 13 July 2023