IDT Australia Limited
ABN 66 006 522 970
45 Wadhurst Drive
Boronia, Victoria 3155, Australia
T +61 3 9801 8888
W www.idtaus.com.au

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ASX ANNOUNCEMENT
13 October 2021

IDT EXECUTES CONTRACT MANUFACTURING AGREEMENT WITH MONASH UNIVERSITY

IDT TO MANUFACTURE MONASH INSTITUTE OF PHARMACEUTICAL SCIENCES' mRNA COVID-19 RECEPTOR BINDING DOMAIN cGMP DRUG PRODUCT FOR MIPS' CLINICAL TRIAL

- *IDT has entered into a Master Services Agreement and Services Order with Monash Institute of Pharmaceutical Sciences (MIPS). The Agreement is for IDT to provide cGMP manufacturing services to produce drug product for MIPS' mRNA COVID-19 receptor binding domain vaccine clinical trial.*
- *The Australian Government Department of Health (Health) has consented to IDT's use of its sterile manufacturing facilities pursuant to the Sterile Readiness Agreement.*
- *MIPS' mRNA COVID-19 receptor binding domain vaccine will be Australia's first locally developed COVID-19 mRNA vaccine candidate to advance to a clinical trial.*

IDT Australia Limited (ASX: IDT) provides the following market update.

The Company has today entered into a Master Service Agreement and accompanying Services Order (collectively an Agreement) with Monash University, pursuant to which IDT will provide cGMP contract manufacturing services to produce drug product for Monash Institute of Pharmaceutical Sciences' (MIPS') mRNA COVID-19 receptor binding domain vaccine clinical trial.

As previously announced, IDT undertook sterile readiness activities as provided for in the Sterile Readiness Agreement finalised between IDT and The Australian Government Department of Health (Health) (see ASX announcements made on 19 March 2021, 23 August 2021 and 15 September 2021). These sterile readiness activities culminated in the Therapeutic Goods Administration's grant of a sterile manufacturing licence extension (see ASX announcement 28 September 2021). The Sterile Readiness Agreement between IDT and Health provides for an exclusivity period during which Health has the exclusive option to negotiate to use IDT's sterile manufacturing facility. The exclusively period continues for 4 months from completion of IDT's sterile readiness works. IDT has sought and received consent from Health for IDT to utilise its sterile manufacturing facility, during the exclusivity period, for the MIPS mRNA COVID-19 vaccine manufacturing activities.

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Key terms of the Monash Agreement are as follows:

Scope: This Agreement formalises the discussions and activities between MIPS and IDT with respect to MIPS' COVID-19 receptor binding domain vaccine clinical product; and IDT providing cGMP manufacturing services encompassing the following activities: technical transfer, vendor assurance, specialised equipment installation and commissioning, documentation, analytical method development, lipid nanoparticle formulation, media fill, engineering trial(s), cGMP batch manufacture and stability trials.

Other Key Provisions: Monash to supply to IDT the bulk raw materials (including: up to 200mg of mRNA drug substance encoding part of the SARS-CoV-2 spike protein, excipients, lipids and polymers). Monash to lend IDT certain items of specialised equipment, which shall be returned to Monash following the completion of the project. Acceptance testing shall be a shared responsibility between Monash and IDT. All intellectual property rights in any background IP remain with the party that contributed the background IP. All intellectual property rights in the services IP vest with Monash.

Term and Termination: Agreement commencement date: 12 October 2021, Agreement expiry date: 30 April 2022. Monash may extend the Agreement by notice in writing, for such period as is specified in that notice. Monash may terminate the Agreement with 30 days' written notice. Either party may terminate the Agreement with written notice to the other party fourteen days following the other party's failure to remedy a breach of the Agreement.

Fees: IDT's fees under the Agreement are based on achieving certain project milestones in relation to the cGMP manufacturing activities. Total fees (excluding GST) are AUD 1,999,999 and will be invoiced for work performed on a monthly basis.

The MIPS COVID-19 receptor binding domain vaccine project is funded by mRNA Victoria and the Commonwealth Government's Medical Research Future Fund; and it is hoped that the initial clinical trial will commence in the fourth quarter of this calendar year. The receptor binding domain mRNA vaccine candidate has been developed by MIPS in conjunction with The Peter Doherty Institute for Infection and Immunity and is Australia's first locally developed COVID-19 mRNA vaccine candidate to progress to clinical trial. If successful, the Company believes that it will be the first Australian manufactured cGMP mRNA finished product.

Monash University President and Vice-Chancellor Professor Margaret Gardner AC said Monash is home to Australia's largest network of RNA and mRNA researchers.

"We are building an RNA ecosystem that will lead to the rapid development of life-saving vaccines and therapeutic treatments for communities across the country," Professor Gardner said. "To enable Australia to avoid ongoing issues around vaccine supply chains from other countries, we need our own mRNA production connected to research and development, and late-stage clinical trials capability.

About IDT

IDT (ASX:IDT) is an Australian pharmaceutical manufacturing company based in Boronia, Victoria, Australia. The Company has extensive experience in the development and production of high potency and high containment pharmaceutical products for local and international clients. IDT's facilities are cGMP compliant and are regularly audited by the US FDA and Australian TGA. With an experienced team of specialists within world-class facilities, IDT provides a full-scale service for new drug development and scale-up, commercial active drug manufacture as well as a variety of oral and injectable finished drug dose forms.

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This partnership agreement with IDT and the ongoing support from the Victorian and Commonwealth Governments is a significant step in Australia moving towards establishing unlimited capability."

“We are very appreciative of the Australian Government’s support in getting IDT’s sterile manufacturing facility ready to take on a project of this nature; and for allowing IDT to utilise the facility for this work.” said IDT Australia Limited’s CEO Dr David Sparling. “We are also very appreciative of the Victorian Government’s support for this project. Being Australia’s first locally developed mRNA COVID-19 vaccine, all of the team here at IDT are excited to be a part of the MIPS project. It is a great opportunity for IDT to develop and showcase our cGMP manufacturing capabilities in mRNA product manufacture.”

Ends…./

IDT
Authorised by the Board of Directors of IDT Australia Limited. For further information please contact:

Dr David Sparling
Chief Executive Officer - IDT Australia Limited
+61 3 9801 8888

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