Dimerix

For Immediate Release

DMX-200 MANUFACTURING UPDATE

MELBOURNE, Australia, 27 May 2019: Dimerix Limited (ASX: DXB), a clinical-stage biopharmaceutical company, provides an update on the Company's activity relating to the commercial scale manufacturing of DMX-200.

- Commercial manufacturing capabilities secured with an FDA registered manufacturer, and demonstration batch manufacture completed
- Analytical methods developed and validated
- Commercial scale batch manufacture planned in FY2020

The development of Dimerix manufacturing capabilities has significantly progressed throughout the last quarter. The establishment of the commercial manufacturing process and the development of validated analytical methods for pharmaceutical grade DMX-200 is an essential component of the product development program and will support global marketing authorisations (including US FDA), commercialisation and partnering activities.

What is DMX-200?

DMX-200 is a compound known as propagermanium that inhibits the activity of a cellular receptor of inflammation: CCR2 (C-C Chemokine Receptor Type 2). DMX-200 is being developed by Dimerix for the treatment of Diabetic Kidney Disease and for Focal Segmental Glomerulosclerosis.

DMX-200 is not a generic
It has never been FDA approved

DMX-200 (propagermanium) has never been approved by a regulatory authority for clinical use in the US, Europe or Australia. DMX-200 is not available as a generic drug and is not available by prescription outside of Japan.

The US FDA regulates the manufacturing and quality of pharmaceuticals. The main regulatory standard for ensuring pharmaceutical quality is the Good Manufacturing Practice (GMP) regulation for human pharmaceuticals. Patients expect that each batch of medicines they take will meet quality standards so that they will be safe and effective.

DMX-200 has never been approved in the US for any indication. As such, it is considered a New Chemical Entity (NCE) by the FDA and will require a full new drug application (NDA) known as a 505(b)(1) application. The NDA must include a large amount of information about the drug being evaluated including the ingredients, how it is manufactured, pre-clinical study results, clinical trial results in humans, what the drug does in the body, and how it will be packaged. Commercial scale manufacture and product packaging are often components of the product development process

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that can hold up marketing authorisation, since stability testing of the final product must be completed in real time.

By developing robust manufacturing processes and conducting commercial scale batch manufacture at this stage of development, and placing this on stability testing in real-time using FDA validated methods, Dimerix can ensure that the appropriate stability and shelf-life of the product is known at the time of submitting the NDA, thus helping to avoid delays in the marketing authorisation process. The manufacturing package is also likely to add significant value to any potential partner licencing transaction.

It is anticipated that DMX-200 would be the only pharmaceutical grade (GMP compliant), FDA approved medicine available to the patient, and at the approved dose. Dimerix has appointed an FDA approved, US based manufacturer for DMX-200 supply and has spent time carefully developing a pharmaceutical-grade method of manufacturing where impurities are strictly measured and controlled. Dimerix exclusively owns the intellectual property and know-how associated with the manufacturing processes and methodology for DMX-200 and has completed manufacture of a demonstration batch.

Why not purchase DMX-200 from an alternative source?

Propagermanium is sometimes available as a nutritional and dietary supplement in Japan and in other countries, including the United States (US). However, there are no supplements that are manufactured to pharmaceutical grade (i.e. according to GMP) or tested to the appropriate regulatory quality standard. In fact, due to the uncertainty around the quality of the manufacturing process and the risk of poorly manufactured propagermanium containing toxic impurities, the FDA has placed a restriction on importing any germanium containing products into the US.

The US healthcare system is complex. At a high level, the patient has the majority of their pharmaceutical product costs paid for by their insurer (typically provided by the employer). The insurance company will not pay for, nor can a doctor prescribe, a medicine that is not FDA approved. As such, the patient cannot get a prescription or have their costs covered for a non-approved medicine such as a nutritional supplement. This will continue to be the case in the event that DXM-200 receives regulatory approval from the FDA, with the FDA guidance specifically stating that "*just because an ingredient is contained in an FDA-approved drug product does not mean it is safe in the dosages or amounts used in non-prescription products*".

For further information, please visit our website at www.dimerix.com or contact:
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About Dimerix

Dimerix (ASX: DXB) is a clinical-stage biopharmaceutical company developing innovative new therapies in areas with unmet medical needs for global markets. Dimerix is currently developing its proprietary product DMX-200 for both Diabetic Kidney Disease and Focal Segmental Glomerulosclerosis (FSGS). DMX-200 was identified using Dimerix' proprietary assay, Receptor Heteromer Investigation Technology (Receptor-HIT), which is a scalable and globally applicable technology platform enabling the understanding of receptor interactions to rapidly screen and identify new drug opportunities.

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