NeuClone Discloses Two Biosimilars Referencing Opdivo® and Keytruda®

SYDNEY, AUSTRALIA, September 1, 2020 – NeuClone Pharmaceuticals Ltd (NeuClone), a clinical-stage biopharmaceutical company developing high-quality biosimilar products, today disclosed two additional biosimilars in active development. The products are biosimilar candidates referencing Opdivo® (nivolumab) and Keytruda® (pembrolizumab).

These biosimilars reference two antibody products that block the PD-1 immune checkpoint inhibitor pathway and their use has dramatically improved the prognosis of patients across multiple oncology settings. Combined global sales of the two reference products in 2019 were US$19.2 billion and are forecast to reach over US$32 billion in 2024.[1]

> "These two medicines have helped reshape previous standard-of-care approaches for many cancer patients" stated Dr Noelle Sunstrom, CEO and Founder of NeuClone. "Providing affordable biosimilar alternatives is crucial to allow many more patients around the world access to these life changing treatments."

The biosimilar candidates are in the advanced stages of pre-clinical development and are being co-developed by NeuClone and its strategic manufacturing partner, Serum Institute of India (Serum Institute).

> "Serum Institute is committed to co-developing a broad range of biosimilars with NeuClone to expand global market access of these valuable medicines to under-served cancer patients" stated Mr Adar Poonawalla, CEO of Serum Institute.

The disclosure of these biosimilars demonstrates NeuClone's unique ability to develop multiple biosimilars simultaneously through its proven NeuMAX® platform. In addition to these two products, NeuClone and Serum Institute are developing eight other biosimilars, including clinical-stage candidates referencing Stelara® (ustekinumab) and Herceptin® (trastuzumab).

About NeuClone
NeuClone is a clinical-stage biopharmaceutical company focused exclusively on developing a portfolio of biosimilar monoclonal antibodies. Eight biosimilar products have been disclosed in NeuClone's portfolio, including clinical stage biosimilars referencing Stelara® (ustekinumab) and Herceptin® (trastuzumab), as well as several preclinical biosimilars referencing Perjeta® (pertuzumab) and Prolia®/XGEVA® (denosumab). NeuClone develops biosimilar products using its proprietary NeuMAX® platform that facilitates low-cost manufacture of biologics, while enabling the highest product quality. NeuClone is led by a highly experienced team with state of-the-art integrated facilities based in Sydney, Australia. For more information, please visit www.neuclone.com.

About the NeuClone and Serum Institute Partnership
NeuClone and Serum Institute have partnered to develop ten biosimilars for global registration in accordance with the most stringent regulatory standards. Serum Institute is well known in the vaccine industry as the world's largest vaccine manufacturer by number of doses produced and sold globally (over 1.5 billion annually). NeuClone and Serum Institute have a strategic and commercial vision to replicate Serum Institute's vaccine success with biosimilars – making them available at sufficient volume, quality and price to deliver globally. Under the arrangement, NeuClone is responsible for initial biosimilar development, analytical characterisation and biosimilarity confirmation. Serum Institute is responsible for scale-up and clinical and commercial manufacture. In September 2019, Serum Institute inaugurated their Rs 3,000 crore (US$410 million) biologics facility located in Manjri, India. The two million

square foot facility will include commercial scale biosimilar manufacture and is designed for global regulatory compliance including US and European agencies.

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References

[1] EvaluatePharma. Cancer Immunotherapy Drug Classes to Watch in 2020 and Beyond. 2020. Available at: https://www.evaluate.com/cancer-immunotherapy-drug-classes-watch-2020-and-beyond