For Immediate Release

Luina Bio announces new Bio-manufacturing GMP and development facility expansion

1st September 2020

Highlights

- **Small scale GMP manufacturing suites open in Q3 2020**
- **500L tech transfer and process development site aim for open Q4 2020**
- **This precedes the next phase with Luina planning to commission a 10,000m^2 late phase clinical and commercial production facility targeting late 2021**
- **New facilities capture more of the global value chain supporting technically advanced microbiome projects**
- **New expanded capacity for bacterial and yeast recombinant projects including vaccine manufacturing including COVID-19 candidates**

Brisbane, Queensland – Luina Bio, one of Australia's most experienced biopharmaceutical contract development and manufacturing (CDMO) organisations, is pleased to announce several expansion plans to meet the increasing demand in the microbiome and recombinant biopharma markets.

The first stage of the expansion will see Luina open additional small scale (30L) GMP manufacturing suite in late 2020, broadening he company's service offering for new clinical projects that need small scale GMP facilities. This facility will be available to customers in Q3 2020 and has already generated interest from Luina Bio clients.

This will be followed by the opening of four additional development laboratories in late 2020, allowing Luina to take customer projects from the earliest development stage to a volume of 500L. This opening formally introduces the Company's systems approach to facility design and utilisation, known as the Luina Flexible Manufacturing Platform (Luina FMP™). The Luina FMP™ environment is designed to deliver the speed and technical excellence necessary to handle the development of technically advanced microbiome & recombinant protein projects. It capitalises on years of experience Luina Bio has growing bacteria initially thought to be unable to be grown at useful quantities for customers.

Les Tillack, CEO of Luina Bio commented: “This new small-scale suite will allow us to respond to those customers that need a smaller active dose for their initial clinical development, while also giving them access to Luina’s proprietary FMP™ facility flexibility. Luina FMP™ was developed from over three decades of contract manufacturing experience, knowledge and expertise culminating in a unique manufacturing approach that advantages Luina Bio’s customers.”

New large-scale GMP Facility

Currently in planning, the next stage will see Luina develop a 10,000m^2 late phase clinical and commercial production facility for commissioning in late 2021.

The new facility will have up to five production lines in parallel, ensuring that multiple-strain live biotherapeutics projects have compressed production times. Luina’s largest reactor (2,000L) will allow it to deliver live biotherapeutics volumes compatible with the commercial needs of those companies that have single-strain projects.

The facility will also boast new technologies to decrease the downstream processing time of live biotherapeutics and bacterial recombinant biotherapy projects dramatically.

“We aim to deliver the world’s most technologically advanced live biotherapeutics manufacturing plant so that our customers can be safe in the knowledge that their projects will be delivered on specification and on budget. This quality-centric approach will start at the earliest possible development stage and continue throughout the life of the project,” said Mr Tillack.

Over 200 companies and projects are exploring the potential of live biotherapeutic based medicines in a vast array of conditions. Luina Bio is at the forefront of this effort and intends to continue leading the global value chain in developing manufacturing solutions for our customers. It further expands Luina’s capability for expanded capacity for bacterial and yeast recombinant projects including vaccine manufacturing, particularly in light of COVID-19 vaccine manufacturing demand.

Mr Tillack further commented, “Luina Bio already possesses the intricate cGMP capabilities needed to manufacture a COVID-19 vaccine and has the potential to cut down the time associated with this type of infrastructure and advanced processes development by a number of years helping Australia’s preparedness for COVID and other potential pandemic challenges.

Luina Bio’s location allows it to use Australia’s high-quality scientific workforce for this expansion. Luina continues to work with the Queensland government grant programs enabling new process engineering, systems capability and jobs. The company will also be

recruiting additional technical and scientific staff further supporting and growing the biotechnology industry in Queensland potentially up to a further 300 staff.

About Luina Bio

Luina Bio is one of Australia's most experienced biopharmaceutical contract manufacturing organisations, offering a comprehensive set of services including cGMP manufacture in TGA/APVMA licensed facilities of recombinant proteins, vaccines, and synthetic molecules for human and veterinary uses. The company's facilities have been in operation for over twenty years. For more information, please visit www.luinabio.com.au.

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