MARKET-LED PROPOSAL EVALUATION SUMMARY – MAY 2023

PROPOSAL NAME: MLP20022 Lifeblood Microbiome

PROPONENT: Australian Red Cross Lifeblood

PROPOSAL STATUS: Completed - successfully met criteria and terms accepted

PROJECT VALUE: $2,500,000

PROPOSAL DESCRIPTION

Australian Red Cross Lifeblood's (Lifeblood) microbiome facility on Wellington Street, Perth is the first Therapeutic Goods Administration (TGA) licensed manufacturer of faecal microbiota for transplant (FMT) in Australia. A clinical trial is being undertaken at Fiona Stanley Hospital (FSH) using FMT to treat patients with recurrent *Clostridioides difficile* infection (rCDI). More than 250 Western Australians suffer from rCDI each year, with an average of 20 hospital inpatient days. FMT is not readily available in the public health system in WA or Australia.

This proposal supports the expansion of the current clinical trial to a service that can address the emerging unmet need for FMT, with the aim of expanding the service across the State and nationally. The TGA has extended the license of the Lifeblood Perth Processing Centre to include the collection, processing, testing, storage and distribution of FMT products.

The Lifeblood Microbiome proposal was unique due to the proponent being the only TGA licensed manufacturer of FMT in Australia at the time. Further, the proponent is a not-for-profit organisation with extensive experience in collection, testing, processing, storing and distribution of blood, plasma and biological products in Australia, and at the time, was deemed to be the only company able to deliver the proposal in its entirety.

This proposal comprises three phases:

- registration of the FMT product on the Australian Register of Therapeutic Goods.
- development of an encapsulated FMT product.
- automation and scaling of production, inclusive of product development for an enema compatible product, manufacturing innovations partnership and a clinical trial pilot with FSH.

FMT is a highly effective and evidence-based treatment recommended by both Australian and international expert guidelines for the treatment of rCDI. International literature indicates reduced average length of patient stay and therefore net cost savings for patients, when using FMT compared to antibiotic alternatives. The FSH clinical trial supports savings of up to $15.7k[1] per episode on total hospital costs, to treat patients with rCDI – allowing a potential reallocation of approximately $4m within the WA Health system.

The objectives of the proposal are as follows:

1. to make FMT accessible for the routine treatment of rCDI, improving health outcomes for patients in Western Australia

[1] Cost savings were based on modelling conducted at a certain point for the clinical trial at FSH.

2. to advance the treatment method for FMT by developing safer delivery methods (encapsulation)
3. to improve equity of access to FMT for patients in Western Australia and nationally, for treatment and clinical trials for new indications
4. to prioritise development of innovative and automated health solutions for Western Australia.

BENEFITS

- Improved health outcomes for people suffering from rCDI. 70-90 percent cure rate with reduced use of antibiotic therapies.
- Reduction in health care costs – 41 percent net reduction in total hospital costs for the treatment of patients with rCDI equating to approximately $4 million per annum when applied to the treatment of 257 patients.[2]
- Improved safety and access to FMT through production in a facility accredited by the TGA to Good Manufacturing Practice (GMP) standards.
- Increased access to FMT for patients with rCDI and other conditions benefitting from the treatment.
- Creation of innovative partnerships with WA-based universities.

QUALITATIVE ASSESSMENT

The proposal has strong strategic alignment with the following Government priorities:

- Improvements in delivery of health services is a government priority, particularly in reducing demand on traditional hospital services.
- The State health priority of reducing demand on hospital services and prevention of patient re-admissions.
- 2019 Sustainable Health Review and its recommendations.

The following additional points were noted in the assessment of the proposal:

- The proponent has extensive clinical, manufacturing, logistic, collection and testing capabilities to support the operation of a microbiome facility in Perth.
- Increased equity of access for patients with rCDI, providing significantly improved health outcomes.
- Promotes collaboration between clinicians, researchers, and consumers to drive innovations in improved patient care.
- Potential to drive innovation in the use of FMT in treatment of other conditions, including inflammatory bowel disease, cancer, and depression.

QUANTITATIVE ASSESSMENT

Item	Cost / Benefit (AUD)
Benefits	
Net reduction in hospital expenses (per annum)	$4,023,078[2]
Costs	
Government contribution (once-off)	$2,500,000[3]

[2] Based on the results from the FSH clinical trial and the treatment of 257 patients per annum. The facility will take several years to ramp up to operate at full capacity.
[3] No ongoing commitment from the State Government.