



ASX ANNOUNCEMENT

3 September 2014

Cynata Initiates European Regulatory Process

Cynata Therapeutics Ltd (ASX: CYP) announced today that it has formally initiated a Scientific Advice procedure with the European Medicines Agency (EMA). This important interaction represents the first step in formal engagement with the EMA, the body responsible for issuing therapeutic product approvals in the EU. It follows the Company's exhaustive review of the regulatory landscape earlier this year and a positive briefing meeting with the EMA's Innovation Task Force, facilitating clarification of the Company's product development plans for its proprietary Cymerus® stem cell technology.

The EMA regulatory process enables advice to be provided to a company on the appropriate tests and studies in the development of a medicine. This is designed to facilitate the development and availability of high-quality, effective and acceptably safe medicines, for the benefit of patients.

"This is an important event with the European regulator, being the opening formal regulatory interaction in the Company's progress toward approval of an application to commence the first clinical study of our Cymerus® stem cell (mesenchymal stem cell, or MSC) product", said Dr Kilian Kelly, Cynata's Vice President, Product Development. "Whilst a final decision has not yet been made by the Company on the site(s) of the Phase 1 study it is prudent to begin regulatory dialogue now to confirm our approach."

The Company expects to deploy the advice received from this engagement in its ongoing planning and product development activities.

Media contacts: Dr Ross Macdonald, CEO: Tel: 0412 119343; email ross.macdonald@cynata.com
Dr Stewart Washer, Executive Chairman: Tel: 0418 288212; email stewart.washer@cynata.com

About Cynata Therapeutics (ASX: CYP)

Cynata Therapeutics Ltd (ASX: CYP) is an Australian stem cell and regenerative medicine company that is developing a therapeutic stem cell platform technology, Cymerus™, originating from the University of Wisconsin-Madison, a world leader in stem cell research. The proprietary Cymerus™ technology seeks to address a critical shortcoming in existing methods of production of mesenchymal stem cells (MSCs) for therapeutic use, which is the ability to achieve economic manufacture at commercial scale. Cymerus™ does so through the production of a particular type of MSC precursor, called a mesenchymoangioblast (MCA). The Cymerus™ MCA platform provides a source of MSCs that is independent of donor limitations and provides a potential "off-the-shelf" stem cell platform for therapeutic product use, with a pharmaceutical business model and economies of scale. This has the potential to create a new standard in the emergent arena of stem cell therapeutics and provides both a unique differentiator and an important competitive position.