

GlyTherix Establishes its Initial US Development and Manufacturing Capabilities with 3D Imaging LLC

Sydney (Australia) – September 10, 2024. GlyTherix Ltd (GlyTherix), an Australian targeted radiotherapy company specializing in developing antibody radiopharmaceuticals for solid tumors, is pleased to announce the execution of a Master Service Agreement with 3D Imaging LLC (3DI), a Contract Development and Manufacturing Organization (CDMO), for the manufacture of GlyTherix's targeted radiotherapy antibody products for its US clinical trials.

Under the terms of the agreement, 3DI will manufacture and deliver finished clinical unit doses of GlyTherix's imaging and therapeutic products (⁸⁹Zr-Miltuximab[®] and ¹⁷⁷Lu-Miltuximab[®]) from 3DI's central facility in Little Rock, Arkansas, USA located close to the Global FedEx hub. 3DI will also supply its own cyclotron-produced GMP Zirconium-89 oxalate product for the manufacture of ⁸⁹Zr-Miltuximab[®]. The agreement is structured to support GlyTherix's US manufacturing needs and incorporates potential future product distribution requirements in the Asia-Pacific region.

Dr. Brad Walsh, GlyTherix Chief Executive Officer said, "We are very excited to continue strengthening GlyTherix's development, supply and manufacturing efforts, distinguishing ourselves from the current generation of radiopharmaceuticals that have many logistical limitations due to very short half-lives. Globally, there is a growing clinical interest in novel targeted radiopharmaceuticals. Through our preclinical and clinical studies in Australia, GlyTherix is establishing itself as a leader in the advanced manufacturing of diagnostic and therapeutic nuclear medicines to improve treatment outcomes for adults with cancer. This agreement represents another step in our US manufacturing and development strategy as we build a network of suppliers capable of producing our products from early-stage trials through to commercial supply."

Marc Berridge, 3D Imaging President added, "The mission of 3DI is to contribute to global healthcare by applying our radiochemistry and manufacturing expertise to the development and production of quality radiopharmaceuticals. Our goal is to support the major innovative companies as they bring their breakthrough products to market. We are thrilled to be working with Glytherix to follow their successes in Australia and support a speedy rollout of their Miltuximab[®] products for US clinical trials and distribution."

GlyTherix will use both the imaging and therapeutic Miltuximab[®] products targeting tumors expressing Glypican-1 in its planned Australian Phase Ib therapeutic dose escalation trial scheduled to commence early 2025. Glypican-1 is an attractive tumor target that occurs in several aggressive and invasive cancers including prostate, pancreatic, bladder, lung, glioblastoma and ovarian cancer.

About 3D Imaging LLC

3D Imaging LLC is a CDMO specializing in radiopharmaceutical development and supplying cyclotron produced radionuclides such as Zr-89, Cu-64, F-18 and I-124. Founded in 2001, 3DI reorganized in Little Rock, AR in 2007 and opened its current custom built cGMP facility with over 13,000 sq ft of office and laboratory space in 2018. Their facility now operates a Siemens Eclipse 11 MeV dual beam cyclotron and an Advanced Cyclotron Systems TR-19 14-19 MeV dual beam cyclotron, as well as associated hot

cells dedicated to positron emitting radionuclides and custom radiopharmaceutical production. They support a wide range of pharmaceutical companies in their research, development, and clinical trials.

<https://www.3dimagingllc.com/>

About GlyTherix

GlyTherix Ltd is an Australian targeted radiotherapy company specializing in developing antibody radiopharmaceuticals for solid tumors. Miltuximab[®] specifically targets Glypican-1, a protein found in solid tumors such as prostate, bladder, pancreatic, glioblastoma, esophageal and ovarian cancers, and is not present in healthy tissue. The company has a strong proprietary and Intellectual Property position covering both Miltuximab[®] and the antigen Glypican-1. This provides robust and long-term protection for the commercialization of important new treatments to people with little hope.

GlyTherix has completed a 'First-in-Human' trial of 12 patients using Miltuximab[®] with no drug-related adverse. Miltuximab[®] will be used in a Phase Ib trial as an antibody theranostic. GlyTherix is currently raising funds in a Series B raise and is interested in partnerships or collaborations with larger biotech and pharmaceutical partners.

For more information regarding this release please contact:

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